Development of a Footcare Education Intervention Delivered by Community Health Workers to Type 2 Diabetes Patients

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Abstract

Background: Diabetes-related complications can be severe and costly, particularly diabetic foot problems, which can arise or be exacerbated by patients' lack of awareness of proper footcare. Indonesia has the fifth highest diabetes incidence globally and is expected to have a diabetic population of 28.6 million by 2045. It is predicted there will be an inevitable rise in the occurrence of diabetic foot ulcers (DFUs) that can be anticipated and forestalled with proactive measures. One potential approach is to involve community health workers (CHWs) who can increase community awareness about diabetes prevention and promotion. Although there is evidence demonstrating the effectiveness of CHWs delivering footcare interventions (FCIs) as part of Diabetes Self-Management Education (DSME) programmes in high-resource countries, there is limited evidence on delivering such interventions in low-resource countries. Furthermore, there is a lack of detailed information on the core components of FCI delivered by CHWs from previous review.

Aims and objectives: This study aims to develop an FCI for diabetes patients delivered by CHWs, referred to as FIne-CHWs ("Footcare Intervention Delivered by CHWs").

Method: An exploratory sequential mixed-methods approach was employed to develop the FIne-CHWs following the new Medical Research Council (MRC) framework for developing and evaluating complex interventions. An initial scoping review to identify the core components of foot care intervention within the context of a DSME programme delivered by CHWs did not provide detailed information about FCI. A mapping review was then conducted to gather more evidence on FCI delivered by healthcare professionals (HCPs) for patients with low-risk DFUs (LR-DFUs), to

address the paucity of data. Following the scoping and mapping review, semi-structured interviews were conducted to gather the opinions of key stakeholders' patients, their family members, CHWs, and HCPs regarding the acceptability and practicality of FIne-CHWs in the Indonesian context.

Data from previous steps were integrated and triangulated to develop the core components of the FIne-CHW. These core components of FIne-CHWs were then subjected to a three-round Delphi consensus. This consensus process involved gathering agreement or disagreement among a panel of diabetes experts across Indonesia to refine the intervention. All these steps in data collection sought to establish and justify the core component of the intervention, aligning with the initial phase of the new MRC Framework, before deciding to proceed with a feasibility study of the FIne-CHWs.

Findings: This study identified the core components of FIne-CHWs from the scoping and mapping review. Thematic analysis of interview data generated several key themes: community experience of foot prevention, enhanced healthcare uptake by extending CHW's role, community embeddedness, CHW resources (recruitment and selecting CHWs), and community training approach.

All participants in the interviews supported the acceptability of the FIne-CHWs, but they raised concerns about its practicality within the community. Using the triangulation approach to synthesise the data collected in previous steps, 42 statements were identified representing the core components of the FIne-CHWs. After two rounds of the Delphi exercise, a consensus agreement was reached on 41 out of 42 statements of the core components of FIne-CHWs, with a consensus disagreement regarding the specific types of patients who can be referred to the FIne-CHWs programme. Free-

text responses of the Delphi survey were analysed using thematic analysis. One overarching theme emerged: CHWs are only “volunteers” (reflecting a lack of policy for connectivity and integration of CHW programme into healthcare service delivery); this then was discussed in three themes, namely CHWs deliver footcare education for all people with diabetes (role CHW clarity); flexibility of community FCI (community-based intervention); and remuneration and incentives. This study also identified that the position of CHWs within the Indonesian healthcare system could impact the implementation of the FIne-CHWs programme alongside remuneration and CHW resources and recruitment.

Implications: This study determined the core components of FIne-CHWs. Even though all the key stakeholders interviewed affirmed the acceptability and practicality of FIne-CHWs, as reflected in the expert panel consensus agreement on most statements on the core components of the intervention, there are certain barriers related to healthcare policies concerning the role of CHWs within the Indonesian healthcare system that need to be resolved prior to expanding the FIne-CHWs programme. These challenges must be addressed to effectively implement CHWs in the community for promoting and preventing DFUs. Nevertheless, this study serves as a fundamental building block for future investigations into foot care intervention delivered by CHWs.

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I am immensely grateful and indebted to Allah, SWT, who possesses profound knowledge of the secret of all hearts. Through His blessings, I have embarked on this PhD journey.

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Lastly, I acknowledge that this study is the initial step in developing interventions. I know several steps must be taken to implement this intervention in Indonesia. Nevertheless, I sincerely hope that this study will significantly empower communities to assist underserved populations in combating diabetes-related foot ulcers.

Publications and Dissemination

1. Poster presentation at the School of Health Science Research Festival held at Jubilee Conference Centre University of Nottingham at 21st June 2022. Acceptability and Practicality Footcare Intervention delivered by Community Health Workers (CHWs).
2. Poster Presentation at AH PGR Conference, Monica Partridge Building, University of Nottingham, on 24th January 2023.Foot care Intervention delivered by Community Health Workers (CHWs) – A Delphi Study.
3. Oral Presentation at the 8th Padjajaran International Nursing Conference 2022, Indonesia on 15 September 2022. Foot Care Intervention delivered by Community Health Workers (CHWs) – Scoping review.

COVID-19 Pandemic Declaration

This study began in July 2021 during Indonesia's second wave of the COVID-19 pandemic; by July 27th, over three million confirmed cases and 2069 deaths were recorded. The healthcare system struggled with an average of 49,435 new daily cases and 1,000 deaths, marking its highest daily death toll.

Java, Indonesia's most populous island, faced healthcare challenges, with communities stepping in due to healthcare system collapse. A policy enforced stricter measures: remote work for non-essential workers, online learning, limited market operations until 8 p.m. at 50% capacity, and closure of malls, sports facilities, etc. Restaurants only offered online orders and deliveries from July 3rd to 20th, 2021.

This study centred on primary health centres in Bandung, West Java, impacting data collection. Remote semi-structured interviews were chosen due to time constraints and distancing requirements, aligning with data-gathering needs.

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List of Abbreviations

A1C	Average blood glucose test
ADA	American Diabetes Association
BMI	Body mass index
BOK	Health Operational Fund
BP	Blood pressure
BG	Blood glucose
CBO	Community-based organization
CG	Control group
CHW	Community health worker
CHWP	Community health worker-led programme
CI	Confidence interval
CoDE	Community Diabetes Education
DALYs	Disability-adjusted life-years
DFP	Diabetic foot problem
DFU	Diabetic foot ulcers
DM	Diabetes mellitus
DSME	Diabetes Self-Management Education
FBO	Faith-based organization
FCI	Footcare intervention
FIne-CHWs	Footcare Intervention Delivered by CHWs
HbA1c	Haemoglobin A1c
HCPs	Healthcare professionals
HPC	Health primary care
IDF	International Diabetes Federation
IG	Intervention group
ILO	International Labour Organization
IWGDF	International Working Group on the Diabetic Foot
JBI	Joanne Briggs Institute
LOPS	Loss of protective sensation
LR-DFU	Low-risk diabetic foot ulcer
M	Mean
MRC	Medical Research Council (UK)
NCD	Non-communicable disease
NGO	Non-governmental organization
NGT	Nominal Group Technique
NICE	National Institute for Health and Care Excellence

NIHR	National Institute of Health Research
NR	Not reported
PAD	Peripheral artery disease
PCC	Population, concept, and context (mnemonic)
QoL	Quality of life
RCT	Randomized controlled trial
RNAO	Registered Nurses' Association of Ontario
RTA	Reflexive thematic analysis
SD	Standard deviation
SDGs	Sustainable Development Goals
SDSCA	Summary of Diabetes Self-Care Activities
T2DM	Type 2 diabetes mellitus
TA	Thematic analysis
TIDieR	Template for the Description and Replication of Interventions
UHC	Universal Health Coverage
USPTF	US Preventive Services Task Force
WA	WhatsApp
WHO	World Health Organization
YLDs	Years of life lived with disability
YLLs	Years of life lost

Glossary of Indonesian Organizations

BOK	Bantuan Operasional Kesehatan/ Health Operational Fund
INA-CBGs	Indonesia Case-Based Groups This is a bundled payment model which covers a specific disease classification episode of care in National Health Insurance
IPKKI	Ikatan Perawat Kesehatan Komunitas/ Association of Community Nurses Indonesia
InWOCNA	Indonesian Wound Ostomy Continence
ISP	Integrated Service Post/ Community Health Post (Posyandu-Posbindu)
ISP Working Group	Village Committee under MoHA
JKN	Jaminan Kesehatan National (National Health Insurance)
MoH	Ministry of Health (Indonesia)
MoHA	Ministry of Home Affairs (Indonesia)
MoH-RI	Ministry of Health Republic of Indonesia
NHI	National Health Insurance (Indonesia)
PEDI	Perkumpulan Educator Diabetes Indonesia/ Diabetes Educator Society
PERKENI	Persatuan Endokrinologi Indonesia/ The Endocrinologist Society
PERSADIA	Persatuan Diabetes Indonesia/ Indonesia Diabetes Association
P2PTM Kementerian Kesehatan	Pencegahan dan Pengendalian Penyakit Tidak Menular/ Division of Non-Communicable Disease, MoH
PKK/FWM	Pemberdayaan Kesejahteraan Keluarga/ Family Welfare Movement (FWM) Women organizational under MoHA.
Posyandu/ ISP-Maternal and Children	Pos Pelayanan Terpadu ISP -Community Post for Maternal and Children Health
Posbindu (PTM)/ ISP-NCDs	Pos Pembinaan Terpadu Penyakit Tidak Menular (PTM) (Community Post for NCD programme)/ ISP-NCD Integrated Service Post Non-Communicable Diseases
Prolanis/	Program Pengendalian Penyakit Kronis (National Health Insurance Program for Diabetes and Hypertension Patients)
Puskesmas/PHC	Pusat Kesehatan Masyarakat/ Primary Health Centre

Chapter 1

Introduction

This chapter elucidates the study's introduction, focusing on the incidence of diabetes mellitus and its associated foot complications. It explores the potential role of Community Health Workers (CHWs) as non-healthcare professionals to deliver new healthcare interventions in Indonesia while also presenting healthcare policies related to non-communicable disease (NCD) programmes. Finally, the chapter considers how to develop a new intervention, following the guidance of the UK's Medical Research Council (MRC) Framework.

1.1. Diabetes Mellitus (DM)

Diabetes is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The current World Health Organization (WHO, 2016) diagnostic criteria for diabetes is a maintained fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–hour plasma glucose ≥ 11.1mmol/l (200mg/dl). Etiopathogenetic diabetes is divided into two major categories: type 1 DM, caused by absolute deficiency of insulin secretion; and the majoritarian type 2 DM (T2DM), which is a result of a combination of resistance to insulin action and an inadequate compensatory insulin secretory response (WHO, 2016). T2DM is the most common type of diabetes and accounts for over 90% of all diabetes cases worldwide (International Diabetes Federation [IDF], 2021).

Diabetes is a chronic illness that is rapidly becoming more prevalent worldwide. According to estimates, approximately 537 million adults aged 20-79 years old are currently living with diabetes, which accounts for 10.5% of the population in this age

group. It is projected that the number of individuals with diabetes will rise to 643 million (11.3%) by 2030, and 783 million (12.2%) by 2045. Of these cases, an estimated 240 million people are living with undiagnosed diabetes worldwide, which means almost half of the adults with diabetes are unaware of their condition. Undiagnosed diabetes is exceptionally high in low- and middle-income countries, where nearly 90% of undiagnosed cases are concentrated (IDF, 2021).

In Indonesia, there were 19.5 million individuals aged 20-79 years diagnosed with diabetes in 2021, making it the country with the fifth highest incidence of diabetes globally. Incidence of diabetes is expected to increase to 28.6 million by 2045 (IDF, 2021). An estimated 70% of T2DM cases in Indonesia are undiagnosed, and among those who were treated, 67.9% failed to achieve the target of glycated haemoglobin (HbA1c) of less than 7% (Soewondo, Ferrario and Tahapar, 2013; Yunir *et al.*, 2021).

Diabetes was Indonesia's third leading cause of disability-adjusted life-years (DALYs) in 2016, after ischemic heart disease and cerebrovascular disease. DALYs were calculated by summing years of life lost (YLLs) and years of life lived with disability (YLDs). YLDs were calculated by taking into account disease severity, exclusivity, and comorbidity while YLLs were computed by multiplying the number of deaths in each age group by a reference life expectancy from analyses of all-cause mortality (Mboi *et al.*, 2018). According to the national Riskesdas survey, conducted every 5-6 years by the Indonesian Ministry of Health (MoH), the incidence of DM diagnosed by a medical practitioner among individuals aged ≥ 15 years in Indonesia has increased to 2% in 2018, from 1.5% in 2013. However, the prevalence of DM, as determined by blood glucose level tests, increased slightly from 6.9 % in 2013 to 8.5

% in 2018. Additionally, only 25% of people with diabetes are estimated to be aware of their condition (MoH-RI, 2020).

1.2. Diabetic Foot Problem (DFP) as a Diabetes Complication

The chronic hyperglycaemia of diabetes is related to long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels, and peripheral neuropathy. Peripheral neuropathy is associated with risk of diabetic foot ulcers (DFUs), amputations, and charcot joints (American Diabetes Association [ADA], 2010). Diabetic foot complications are a common problem in diabetes disease management. Approximately every 30 seconds a lower limb or part of a lower limb is lost to amputation somewhere in the world as a consequence of diabetes (IDF, 2019).

The pathophysiology of DFUs is the result of combining several attributing factors that have different roles contributing to ulcers, including peripheral neuropathy, vascular disease (arterial circulation), and inflammatory cytokines, which are also linked to susceptibility to infection (Alavi *et al.*, 2014). Neuropathy represents a significant risk factor for ulceration, given its detrimental effect on the perception of injury due to loss of protective sensation. Neuropathy-induced foot deformities or restricted joint mobility can result in abnormal foot pressure and the consequent development of calluses over pressure points.

Distal sensorimotor peripheral neuropathy is common in approximately 50% of older individuals with T2DM. It manifests as dysfunction in small-fibre nerves, leading to the loss of pain and temperature perception. Consequently, patients experience a literal loss of the protective mechanism of pain, making them more susceptible to tissue

damage. Additionally, large-fibre dysfunction contributes to instability, increasing the likelihood of trips and falls. This poses a risk for recurrent minor injuries that may go unnoticed, potentially leading to the development of progressive destruction of bone and soft tissues at weightbearing joints (charcot neuroarthropathy).

Moreover, motor neuropathy plays a role in the wasting of small muscles in the foot and can disrupt the balance between flexor and extensor functions. Autonomic neuropathy is another aspect of this condition, which involves dysfunction in the peripheral sympathetic nervous system, resulting in decreased sweating and dryness of the foot skin. This increases the risk of callus formation, particularly in the absence of peripheral artery disease. Furthermore, due to the release of vasoconstriction, individuals with autonomic neuropathy may experience warm feet even without peripheral arterial disease. The presence of plantar callus in the neuropathic foot significantly raises the risk of developing ulcers (Boulton *et al.*, 2018) (Figure 1).

However, the neuropathic foot does not spontaneously ulcerate; instead, the formation of ulcers is dependent on a combination of neuropathy and other contributing factors, such as excessive ambulation, ill-fitting footwear, walking without shoes or in stockings, as well as the formation of calluses over regions of increased pressure (Alavi *et al.*, 2014)

Further progress in increasing the local pressure combined with undetected repetitive injury leads to local tissue injury, inflammation, tissue death (necrosis), and finally ulceration. Micro-and- macrovascular disease causing ischemia is a contributing factor in 90% of diabetic patients undergoing major amputation. Leukocyte function, immune functions, and decreasing host resistance are affected by the chronic

condition, with more susceptibility to superficial increased bacterial burden in the wound base and deep or surrounding skin infection (Alavi *et al.*, 2014).

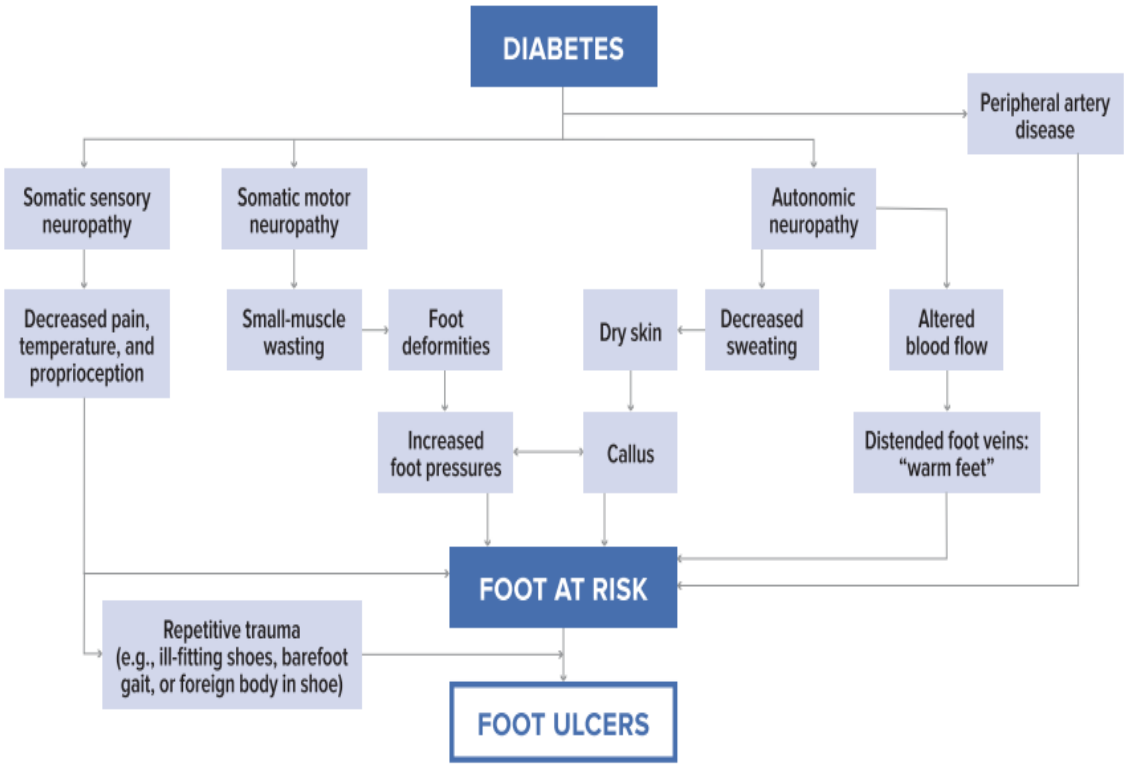

Figure 1: Pathways to diabetic foot ulceration

Source: Boulton *et al.* (2018)

A cross-sectional study conducted at an Indonesian National Referral Hospital between 2010 and 2015 investigated the non-vascular contributing factors to DFU severity. According to the study findings, most DFU patients (84.6%) had leucocytosis, a marker of infection which was significantly related to the size of the DFU. It is important to note that infection can cause impaired wound healing, sepsis, necrosis, and gangrene, all of which can lead to amputation. Furthermore, the study discovered that most patients had poor glycaemic control, with a mean HbA1c level of 9.6% (Yunir *et al.*, 2021).

1.2.1. Global Impact of DFPs

DFPs are among the most serious, feared, and costly complications of diabetes. Throughout their lifetime, up to one-third of the half a billion diabetic patients worldwide will develop a DFU (Armstrong *et al.*, 2020). A majority of DFUs will ultimately result in an infection, of which cases approximately 17% will necessitate amputation (Armstrong *et al.*, 2020). Diabetic patients are at a 15- to 40-fold increased risk of a lower limb amputation than non-diabetic patients (Suh and Hong, 2015). Armstrong *et al.* (2020) reported high mortality rates from US studies since 2007 for charcot (29%), DFU (30.5%), and minor and major amputations (46.2% and 56.6%, respectively).

Many DFUs do not heal or become recurrent, making this complication challenging to treat (Matricciani and Jones, 2015). Diabetic patients diagnosed with foot ulcers have recurrence rates for the incidence of new ulcers of around 50-70% over 3-5 years (Registered Nurses' Association of Ontario [RNAO], 2007). This can lead to physical disability (Dorresteijn, Kriegsman and Valk, 2010) depression, and reduced quality of life (QoL) (Dorresteijn and Valk, 2012; Matricciani and Jones, 2015). The consequences of DFUs also mean that many patients are not able to lead a full social life, becoming socially isolated, which leads to poor psychological well-being, aside from reducing physical activity and thus leading to further secondary health issues (Khunkaew, Fernandez and Sim, 2019). Only 33% of DFUs heal through standardized care, and 20-25% of all hospital admission days for patients with DM are related to foot complications (Suh and Hong, 2015).

People with DFPs use significantly more health services than diabetic patients without foot problems, entailing an economic burden (Perrin, Swerissen and Payne, 2009;

Dorresteijn and Valk, 2012). The economic burden of diabetic foot diseases is mainly related to patients requiring frequent hospitalization for treatment and surgery, with prolonged hospital stay duration (National Diabetes Working Group, 2011). Diabetes treatment costs outweigh those for cancer treatment in the US, costing USD 237 billion in 2017, compared to USD 80 billion for cancer in 2015. Lower extremities can account for up to one-third of the direct costs of diabetes treatment (Armstrong *et al.*, 2020).

1.2.2. DFP Incidence in Indonesia

In line with the growing global diabetes prevalence, Indonesia has a growing incidence of risk of DFUs, and the prevalence of undiagnosed DM in Indonesia is continually growing. Despite low diagnosis, chronic T2DM complications such as DFU are commonly observed in Indonesian diabetic patients (Yunir *et al.*, 2021, 2022). DFUs were found to have a relatively high prevalence among T2DM patients, and must never be neglected due to the high associated mortality rate (Hariftyani, Novida and Edward, 2021). The main complications for diabetic patients in Indonesia are neuropathic (13-78%), microvascular (16-53%) and DFU (7.3-24%) complications (Soewondo, Ferrario and Tahapar, 2013). A study in Makassar in Eastern Indonesia showed a prevalence of neuropathy and angiopathy risk and associated factors for DFUs among T2DM patients of 55.4%. These findings are within the global prevalence of risk of 40-70% (Yusuf *et al.*, 2016).

Data on the number of patients with DFU in Indonesia are unavailable due to the absence of nationally representative health indicator data since 2001, this can be attributed to the impact of decentralization regulations which have resulted in weak integration of health information systems across multiple data sources (Soewondo,

Ferrario and Tahapar, 2013). A review of literature on the prevalence and associated risk factors of DFU in Indonesia found scant studies to support evidence on the outcomes and control of diabetes; additionally, data on annual checking and glucose monitoring was only available for patients attending clinics (Soewondo, Ferrario and Tahapar, 2013).

According to medical record data from Dr Cipto Mangunkusumo National General Hospital, a national referral hospital in Indonesia, 33.9% of all diabetic patients hospitalized in 2007 were caused by DFU and gangrene, of which 14.3% died, and 34.7% had major complications or minor amputation. Furthermore, 58.2% of amputations were repeated; one-third of diabetic patients were hospitalized due to DFU, and these patients were associated with longer hospital stay and higher cost (Yunir *et al.*, 2021). Among Indonesian T2DM patients, DFU complications incur the second-highest medical costs (approximately USD 522.86), after cardiovascular disease (approximately USD 774.37) in terms of direct medical costs per six-month treatment period (Andayani, Ibrahim and Asdie, 2010). This could be because the majority of cases admitted to the hospital are advanced, emphasising the importance of early diagnosis and prompt treatment (to improve patient health and prospects, as well as to minimize health system costs) (Yunir *et al.*, 2021). The mitigation of complications associated with T2DM not only holds potential benefits for the patient, but also has the capacity to lead to a reduction in aggregate healthcare expenditures (Andayani, Ibrahim and Asdie, 2010).

1.2.3. Prevention of DFPs

There are five key elements that underpin prevention of foot problems: identification of the at-risk foot; regular inspection and examination of the at-risk foot; education of

patient, family and healthcare providers; routine wearing of appropriate footwear; and treatment of pre-ulcerative signs (Schaper *et al.*, 2017).

Those at high risk of DFPs can be identified with simplified screening, and it is thought early recognition of DFP would prevent amputations and improve QoL (Perrin, Swerissen and Payne, 2009; Dorresteijn, Kriegsman and Valk, 2010; Dorresteijn and Valk, 2012; Alavi *et al.*, 2014; Matricciani and Jones, 2015; Suh and Hong, 2015). Several studies have shown that amputation rates could be reduced by between 40% and 85% through the detection of high-risk patients and a subsequent interprofessional approach focused on preventive measures. Screening may also detect foot ulcers and other lesions that the patient is not aware of, including blisters, calluses, fissures, tinea pedis, and ingrown toenails (Alavi *et al.*, 2014).

The risk categories shown in Table 1 were adapted from the four-tiered diabetic foot risk classification system recommended by the International Working Group on the Diabetic Foot (IWGDF) (Boulton *et al.*, 2018).

Table 1: Modified ADA Diabetic Foot Risk Classification

Priority	Indications	Timeline	Suggested Follow-up
URGENT (active pathology)	▸ Open wound or ulcerative area, with or without signs of infection ▸ New neuropathic pain or pain at rest ▸ Signs of active Charcot deformity (red, hot, swollen midfoot or ankle) ▸ Vascular compromise (sudden absent DP/PT pulses or gangrene)	Immediate referral/ consultation	As determined by specialist
HIGH (ADA risk category 3: the diabetic foot in remission)	▸ Presence of diabetes with a previous history of ulcer or lower-extremity amputation ▸ Chronic venous insufficiency (skin color change or temperature difference)	Immediate or "next available" outpatient referral	Every 1–2 months
MODERATE (ADA risk category 2)	▸ PAD ± LOPS ▸ DP/PT pulses diminished ▸ Presence of swelling or edema	Referral within 1–3 weeks (if not already receiving regular care)	Every 2–3 months
LOW (ADA risk category 1)	▸ LOPS ± longstanding, nonchanging deformity ▸ Patient requires prescriptive or accommodative footwear	Referral within 1 month	Every 4–6 months
VERY LOW (ADA risk category 0)	▸ No LOPS or PAD ▸ Patient seeks education on topics such as routine foot care, athletic training, appropriate footwear, or injury prevention	Referral within 1–3 months	At least annually for all people with diabetes

DP, dorsalis pedis; LOPS, loss of protective sensation; PT, posterior tibial. Modified from Diabetes Care 2008;31:1679–1685 (ref. 6), with permission from the American Diabetes Association, ©2008.

Source: Boulton *et al.* (2018)

Someone without loss of protective sensation (LOPS) and without peripheral artery disease (PAD) is classified as IWGDF risk 0, which indicates a very low risk for ulceration. Such patients only require annual screening. All other categories are considered "at risk", and require more frequent foot screening, regular inspection, and foot examination than patients who are not at risk (Boulton *et al.*, 2018) (see Table 2).

Table 2: IWGDF risk category versus preventive screening frequency

Category	Characteristics	Frequency
0	No peripheral neuropathy	Once a year
1	Peripheral neuropathy	Once every 6 months
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity	Once every 3–6 months
3	Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation	Once every 1–3 months

Source: Schaper *et al.* (2017)

On the other hand, the ADA (2018) recommends that patients with very low ADA risk category 0, with no issue with LOPS or PAD, engage with education on topics such as routine footcare, athletic training, appropriate footwear, or injury prevention while patients with low-risk of foot ulcers (ADA risk category 1); LOPS ± longstanding, nonchanging deformity emphasize prescriptive or accommodative footwear (Boulton *et al.*, 2018).

In addition, the risk stratification outlined by the National Institute for Health and Care Excellence (NICE, 2020) was employed to ascertain the probability of an individual developing diabetic foot complications, slightly different from ADA (2008) and IWGDF (2015); NICE categorizes patient into four category risk of DFUs:

1. Low risk: No risk factors present except for callus alone.
2. Moderate risk: Deformity, neuropathy, or non-critical limb ischaemia.
3. High risk: Previous ulceration or amputation, on renal replacement therapy, neuropathy and non-critical limb ischaemia together, or a combination of neuropathy with callus and/or deformity or non-critical limb ischaemia with callus and/or deformity.
4. Active DFP: Ulceration, spreading infection, critical limb ischaemia, gangrene, suspicion of an acute charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain.

According to the NICE (2020) guidelines, preventing DFPs involves managing the risk level of each individual. Patients with a low risk of developing DFUs should undergo annual foot assessments and receive reminders on the importance of proper footcare. However, patients categorized as moderate or high-risk are referred to foot protection services. An annual foot examination should be conducted to identify those

at risk to detect any signs of peripheral neuropathy or peripheral artery disease. For patients with peripheral neuropathy, screening should be done for a history of foot problems, deformities, pre-ulcerative signs, poor foot hygiene, and inappropriate footwear. After the examination, each patient is placed in a risk category to guide future preventative measures.

Overall, for patients classified as very low and low risk for DFUs, prevention is the preferred measure. This involves identifying the risk of DFUs as well as patient education on footcare, including the appropriate footwear and injury prevention, to avoid further foot complications.

It is acknowledged that a significant proportion of high-risk foot complications are preventable (Diabetic Foot Australia, 2016). Patient education on appropriate self-care has the potential to play a crucial role in preventing foot complications (Mcinnes *et al.*, 2011; Matricciani and Jones, 2015) as DFUs are associated with poor socioeconomic conditions, lack of proper diabetic footcare education, and incorrect footwear (Jeffcoate, 2011). Early detection and treatment are one strategy for reducing the diabetes burden (RNAO, 2007; IDF, 2017). In Indonesia, the majority of cases admitted to the hospital are advanced, emphasising the importance of early diagnosis and prompt treatment (Yunir *et al.*, 2021).

Combining the two aspects of foot screening and foot self-care is pivotal to prevent DFU occurrence, and to minimize the negative impacts and prognoses of existent ulceration when detected. Diabetic foot screening involves assessing for the previous history of foot complications, deformity, pedal pulses, foot lesions and neuropathy. Moreover, it is also crucial that diabetic individuals perform regular foot self-management. Foot self-management involves daily foot inspection, hygiene and

moisturizing of feet, regular trimming and filing of nails, appropriate footwear both in and outdoors, exercise, and seeking professional care as needed (RNAO, 2007; National Diabetes Working Group, 2011; Stevens, Bruneau and Moralejo, 2017). The asymptomatic nature of the disease can mean the importance of routine foot examinations, and the identification of the high-risk foot is underestimated in both inpatient and outpatient settings (Suh and Hong, 2015). Data in Indonesia showed that performance of daily foot inspection was less prevalent among DFU risk factor prevention measures (Yusuf *et al.*, 2016).

It is important to acknowledge that most patients with foot complications are categorized as being at low risk (Mcinnes *et al.*, 2011), defined as no risk factors being present except callus (NICE, 2020). Many low-risk patients do not regularly seek or attend healthcare specialist appointments, whereby footcare education is mostly targeted at patients with pre-existing complications, higher HbA1c levels, and those who have had diabetes for several years (Mcinnes *et al.*, 2011). Patients at high risk for foot complications tend to be more aware and practice better self-care than those at low risk, so encouraging low-risk diabetic patients to take basic footcare is essential to prevent development of foot ulcers (Matricciani and Jones, 2015). Studies have proved that self-footcare or basic footcare is effective to improve footcare knowledge, self-efficacy and behaviour (Fan *et al.*, 2014), and have shown positive effects on reducing the occurrence of minor foot problems for T2DM patient with low-risk DFUs (LR-DFUs) (Fan *et al.*, 2013, 2014)

As mentioned earlier, essential footcare practices involve washing and drying between the toes, moisturizing the feet, and regularly checking for abnormalities, while these basic footcare practices are straightforward and can empower patients to actively

manage their diabetes, simply providing written materials without individual support from HCPs may not be enough to motivate low-risk patients to incorporate self-footcare into their routine effectively. This can pose challenges in the patients' transition from acquiring knowledge to changing their behaviours (Mcinnes *et al.*, 2011).

1.3. Community Health Workers (CHWs)

Inter-professional healthcare teams (i.e., physicians, nurses, and footcare specialists) are required to provide detailed and early patient assessment and education (Suh and Hong, 2015). However, the shortage of such trained HCPs, especially in limited resource settings, is a core part of the general human resource crisis in healthcare systems globally (Lehmann and Sanders, 2007). In Indonesia it is a formidable challenge for healthcare systems to overcome diabetes, and the limited numbers and quality of trained professionals who can manage diabetes care is a significant deficiency, combined with the high costs of treatment, these factors provide significant barriers to accessing care for DFU prevention (Soewondo, Ferrario and Tahapar, 2013). To address this issue, a new strategy is required.

One approach is to use community members to provide certain essential health services to their communities by delegating tasks to the "lowest" category of healthcare personnel, which can become successful in health promotion (Lehmann and Sanders, 2007). In addition, it is needed to prioritize primary prevention and develop effective strategies to achieve remission of DFUs (Armstrong *et al.*, 2020).

Care standards recommend that diabetic patients receive self-management support from lay health coaches, navigators, and CHWs, to help reduce health disparities

(American Diabetes Association (ADA), 2017). The 1978 Declaration of Alma-Ata marked a global-level recognition of the potential for CHWs to serve as a foundation for primary healthcare, which acknowledged that CHWs can play an important role in extending essential health services to underserved areas. The World Health Assembly (2019) highlighted the key role that CHW-led programmes (CHWPs) will need to play in order to achieve Universal Health Coverage (UHC) and the health-related Sustainable Development Goals (SDGs) (Perry, 2021). CHWs are defined by the International Labour Organization (ILO, 2012) as per ISCO 3253:

> "Community health workers provide health education and referrals and follow-up, case managements, basic preventive healthcare and home visiting service to specific communities. They provide support and assistance to individuals and families in navigating the health and social services system" (ILO, 2012, page 192)

CHWs have a large number of different titles, with 36 different terms applied in various countries. In Indonesia they are known as "kader" (Lehmann and Sanders, 2007; MoH-RI, 2012). CHWs must be members of the communities where they live, selected by them, offering support to the health system but not necessarily being a part of its organization, and requiring shorter training than professional healthcare workers (Lehmann and Sanders, 2007). Figure 2 illustrates the elements and relationships within the peripheral health system, including the public, private, and household sectors, and span non-governmental organizations (NGOs), community-based organizations (CBOs), and faith-based organizations (FBOs).

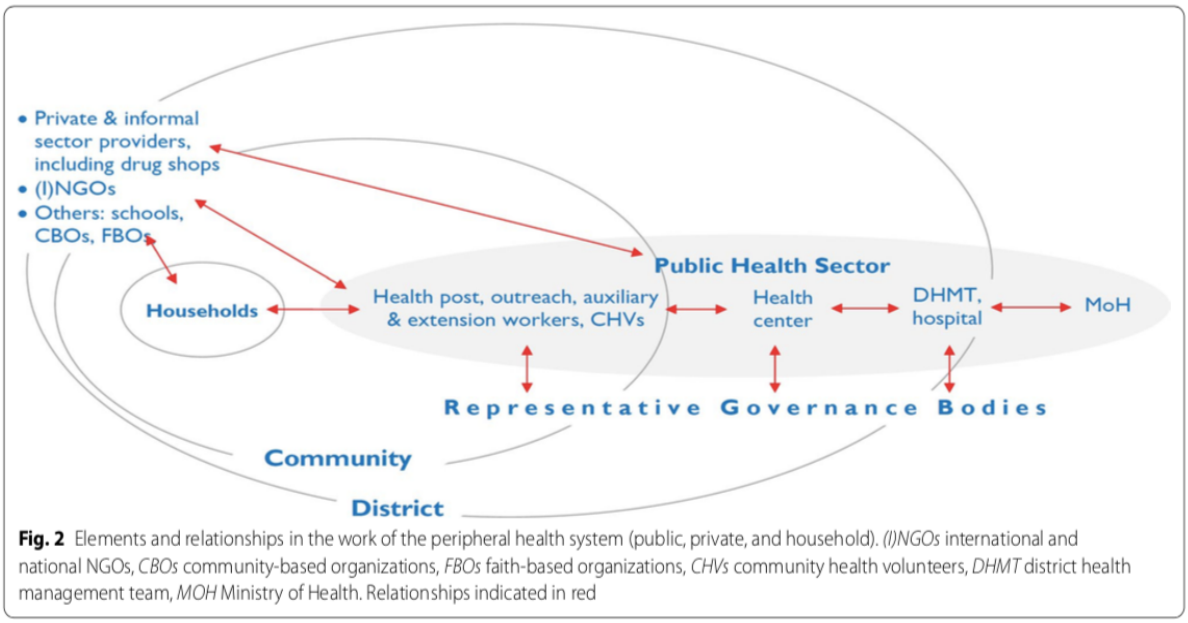

Fig. 2 Elements and relationships in the work of the peripheral health system (public, private, and household). *(I)NGOs* international and national NGOs, *CBOs* community-based organizations, *FBOs* faith-based organizations, *CHVs* community health volunteers, *DHMT* district health management team, *MOH* Ministry of Health. Relationships indicated in red

Figure 2: CHW within the health sector

Source: Hodgins *et al.* (2021)

The healthcare system at the peripheral level overlaps with the complex community systems. Community members can also be important in supporting and helping those providing health services, including CHWs. The lower tier of the primary healthcare system consists of fixed structures below the health centre level, such as community clinics and health posts (Hodgins *et al.*, 2021). In Indonesia, there are several community health posts managed by CHWs, such as community health posts for children and maternal (Posyandu) and for managing NCDs (Posbindu PTM). HCPs based at higher-level facilities supervise some CHWPs (Figure 4).

CHWs' roles are characterized by altruism, volunteerism, community norms, and reciprocity, as CHWs are a social benefit which cannot be readily discounted by economic analyses, which is the strength of CHWPs (Lehmann and Sanders, 2007). The CHW model perhaps can be part of a solution to counter disparities in healthcare

access (Spencer *et al.*, 2011), and increase community awareness on the promotion and prevention of NCDs, including diabetes care (Perry and Hodgins, 2021). Many studies reported that CHWs could make a valuable contribution to communities by facilitating uncomplicated accessibility and availability to their clients (Lehmann and Sanders, 2007; Silverman *et al.*, 2018). In addition, the availability of reminders and recall systems for diabetes control and complication risk assessment is needed to ensure the success of the diabetes programme (RNAO, 2007). In this context, CHWs have the potential to act as a reminder system, giving continuous reinforcement to the community concerning footcare education.

1.4. Indonesian Healthcare System

1.4.1. Overview

Indonesia is the largest archipelago in the world, comprising an estimated 17,504 islands. While it is politically stable (Mahendradhata *et al.*, 2017), its economy was severely affected by global COVID-19 lockdowns, and Indonesia was reclassified from upper-middle income to lower-middle income status as of July 2021 (The World Bank, 2022). The country ranks fourth globally in population, with over 280 million inhabitants, speaking 724 distinct languages and dialects. The distribution of the population in Indonesia is uneven, with more than 50% of the population residing on Java, which creates governance, communication, transportation, and accessibility challenges to basic healthcare services. To overcome these challenges, the Indonesian Government implemented Law 22 of 1999, which initiated the process of decentralization. The healthcare system in Indonesia is a combination of public and private providers and financing, administered in accordance with the decentralized

government system, with the central, provincial, and district governments holding distinct responsibilities (Mahendradhata *et al.*, 2017).

By 2016, around 65% of the people in Indonesia were covered by National Health Insurance (NHI), known as Jaminan Kesehatan Nasional (JKN) (Hidayat *et al.*, 2022). The healthcare payment system in Indonesia is a combination of different approaches. Primary care operates on a capitated (fixed payment per patient) and non-capitated payment system. On the other hand, secondary and tertiary care involve two payment models. The first is a bundled payment model called Indonesia case-based groups (INA-CBGs), which covers a specific disease classification episode of care. This model includes professional fees, bed and board, diagnostics and laboratories, medicines and supplies, and operating room fees. The tariff for INA-CBGs varies based on the facility class, hospital ownership, level of care, and region. The facility classes range from A (highest) to D (lowest). The second payment model is an unbundled fee-for-service model known as non-case-based groups (non-CBGs) (Hidayat *et al.*, 2022).

The shift in disease patterns in Indonesia, known as the epidemiological transition, has resulted in a dual challenge of health issues. This includes the growing prevalence of NCDs like diabetes, cerebrovascular disease, and ischaemic heart disease. Diabetes has experienced a significant recent surge, placing additional strain on the healthcare system (Mboi *et al.*, 2018). NHI covers diabetes care, and under the INA-CBGs, a fixed price is provided for a seven-day supply of glucose-lowering drugs for certain chronic diseases, such as diabetes, as part of back-referral programme. For patients receiving specialist care, the remaining 23 days of medication are reimbursed under the non-CBGs. This 23-day supply can be obtained from the hospital or accredited

retail pharmacies. Patients who can manage T2DM effectively are transitioned to primary care and receive a 30-day supply of medications from accredited pharmacies. After three months, they may be referred back to a specialist if needed (Hidayat *et al.*, 2022).

The Indonesian Government has implemented various measures to promote and prevent NCDs, including Presidential Decree No. 1 (2017), which aims to encourage healthy lifestyles by emphasizing physical activity, maintaining a nutritious diet, and early detection of health problems (Mboi *et al.*, 2018). Additionally, since 2010, it has initiated a chronic disease management programme (Programme Pengendalian Penyakit Kronis [Prolanis]), targeted for diabetic patients and hypertension patients. With the commencement of UHC in 2014, Prolanis has since been implemented to all patients under the NHI. This chronic disease management programme is a multi-faceted intervention that involve both, pharmacologic and non-pharmacologic strategies (e.g. patient education, physical activity, monitoring, and reminder systems). Patients with chronic diseases are able to register to this programme and receive the following services:

1. Medical consultation/health education.
2. Regular health status monitoring.
3. Home visits.
4. SMS reminders.
5. Club activities.
6. Monthly routine drugs.

The programme is facilitated by Primary Health Centres (PHCs), in collaboration with the NHI, which encompasses primary care clinics and private doctors (Akbar,

Gondodiputro and Raksanagara, 2020). The expenses incurred by Prolanis include the costs of health status monitoring through screening for diabetes and hypertension, health education, and activity clubs. Monthly medical counselling is provided by general physicians at PHC. Physical Activity clubs entail group physical activities conducted regularly by the PHC for Prolanis participants (Khoe *et al.*, 2020).

1.4.2. Integrated Health Service Post and CHWs in Indonesia

In Indonesia, community integrated service posts (ISPs), known as Posyandu-Posbindu, provide various services. ISP-maternal and children is known as Pos Pelayanan Terpadu (Posyandu), a programme established with support from the national women's Family Welfare Movement (FWM) (Pemberdayaan Kesejahteraan Keluarga (PKK) since the 1970s. Volunteers CHWs called kader (as explained previously in section 1.3) are trained to conduct health and nutrition promotion activities in each village. The Posyandu programme has been flourishing as a community-driven initiative for over 35 years, since being formally recognized by the MoH in the mid-1980s (Oendari and Rohde, 2021).

Later services expanded by developing specialist ISPs for NCDs (ISP-NCDs) are known as community health posts for promotive and preventive NCDs (Pos Binaan Terpadu Penyakit Tidak Menular [Posbindu-PTM]) in many administrative blocks. Routine and periodic services are developed and delivered for and by community. ISP-NCDs aim to increase community awareness in preventing and detecting of risk of NCDs, which involve targeted groups of healthy and at-risk people, and people diagnosed with NCD (aged over 15 years old) (MoH-RI, 2012). Prevention activities include health promotion, screening, and monitoring of the risk factors, seeking to

identify NCD cases as early as possible, and providing immediate treatment (MoH-RI, 2012; Alfiyah and Pujiyanto, 2019).

The MoH developed the guidelines for the activities performed in the ISP-NCD (Posbindu PTM). The policies that support these activities include the Minister of Health Regulations no. 71/2015 (on the Management of Non-Communicable Diseases), no. 5/2017 (on the Action Plan for Managing Non-Communicable Diseases), and no. 43/2016 (on the Minimal Standards for Healthcare). The regulations state that the community must be involved and empowered in the management and prevention of NCDs through ISP-NCDs (Alfiyah and Pujiyanto, 2019). These activities in ISP-NCDs are run on the agreement between community member and report to the PHC or Pusat Kesehatan Masyarakat (Puskesmas). The ISP-NCDs are accessible and easy to operate in neighbourhood areas, and are more economical, because their activities are *for* and *by* served communities (Rahajeng and Kusumawardhani, 2010). Three stakeholders who are closely related in carrying out the NCDs programme are the Health Office, PHC, and sub-districts (MoH-RI, 2012; Alfiyah and Pujiyanto, 2019).

ISP-NCDs are implemented by CHWs who are specifically trained, fostered, or facilitated to monitor NCDs risk factors (MoH-RI, 2012). The community plays a vital role in selecting CHWs, which is part of the responsibilities of the FWM (Oendari and Rohde, 2021). The selection criteria include being able to read and write, having a sociable and voluntary spirit, being knowledgeable about the customs and habits of the community, being willing to commit the required time, residing in the village, being friendly and sympathetic, and being accepted by the community. Although being female is not a requirement, the majority of volunteers or recommended CHWs are

women; male CHWs are rare, but do exist sporadically (Oendari and Rohde, 2021). CHWs who manage ISP-NCDs are required to have 12 years of education (MoH-RI, 2012). However, the new guidance for CHWs reported no educational attainment required to be CHWs (MoH-RI, 2019).

The average length of service for a CHW is three to five years, but some have served for over ten years until retirement. As CHWs drop out, new ones are selected by FWM to fill vacancies and begin working, even if they have not received formal training. In some cases, a departing CHW may even be responsible for finding and training their replacement (Oendari and Rohde, 2021). It is not uncommon for a retired CHW's daughter, who was previously served at the Posyandu, to take over the role, and be inspired by their mother's dedication, also harnessing community trust and familiarity with certain known CHW families and locations (Wicaksono, 2017; Oendari and Rohde, 2021).

CHWs in Indonesia might be considered typically generalists responsible for various primary healthcare services such as maternal and child health, immunizations, and environmental health (Oendari and Rohde, 2021). However, they also undertake specific technical programmes, such as supervising medication adherence for tuberculosis patients, which are known as specialized CHWs as per the definition of Hodgins, Crigler and Perry (2013). Generalist CHWs receive focused training on a specific task and then additional training on another skill after two to three months. This results in a diverse group of CHWs with expertise in nutrition, family planning, NCDs, mental health, and other areas (Oendari and Rohde, 2021).

In Indonesia, CHWs belong to category 2, as classified in Perry's (2021) typology of CHWs worldwide. They are volunteers with defined regular responsibilities, typically

requiring weekly activities, and receive periodic short-term training sessions that last several days. These CHWs are usually residents within their communities and receive financial incentives for their regular duties, though they may dedicate fewer hours, like approximately 5 hours per week, to community service (Perry, 2021), CHWs typically dedicate about 10-20 hours per month to their work (Oendari and Rohde, 2021).

Alfiyah and Pujiyanto (2019) documented the implementation of the ISP-NCDs (Posbindu PTM) programme in an urban region of West Java, Indonesia. Their findings are likely indicative of how the ISP-NCDs (Posbindu PTM) operates in rural areas of Java as well. CHWs arrange monthly outreach events for organizing the ISP-NCDs (Posbindu PTM). The evaluation of ISP-NCDs in Bogor, West Java, revealed that the way it was conducted in the community was ineffective. The socialization of ISP-NCDs occurred on the day before the event. It was communicated to the community by CHWs through various channels such as WhatsApp (WA) groups, mosques, and door-to-door visits in the morning just before the event. Moreover, the activity occurred during working hours from 8 am to 12 pm, making it difficult for working individuals and school-age populations to attend. Consequently, people aged between 15 to 44 years rarely utilized ISP-NCDs services (Alfiyah and Pujiyanto, 2019).

A well-functioning ISP involves at least five CHWs who conduct monthly sessions (MoH-RI, 2012). The CHWs utilize five desks representing different stages when visitors come to Posbindu PTM. At each desk, the CHWs record the visitor's personal data and health information on an individual card provided by Posbindu PTM.

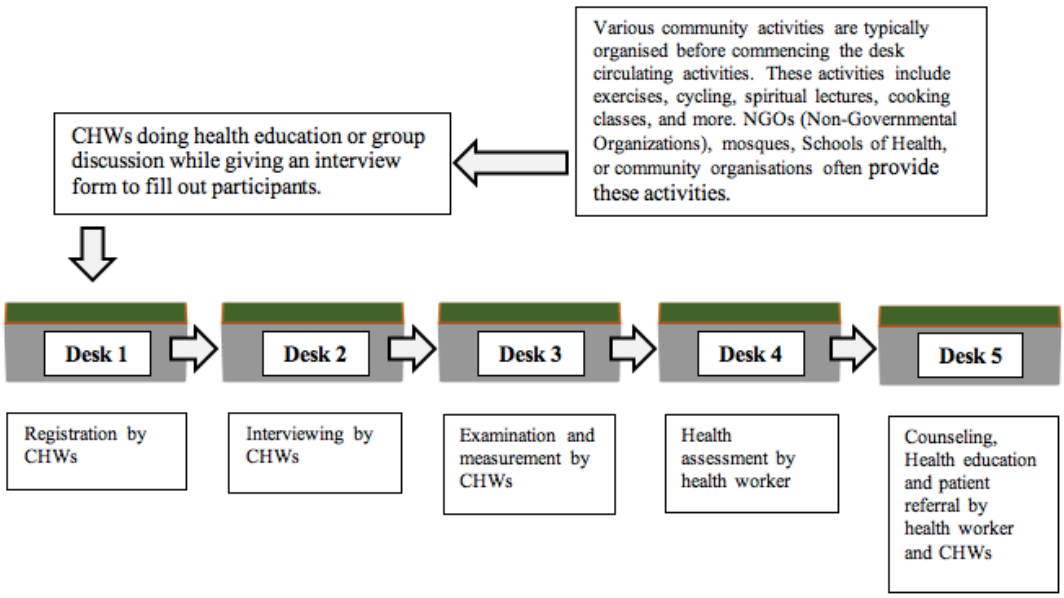

Figure 3: The ISP- NCD (Posbindu PTM) flow diagram

Source: MoH (2012)

The initial desk at the ISP-NCD is designated for registration. Here, the CHWs collect the participant's name and age and perform measurements. However, not all examination results specified in the guidelines are recorded on the participant's card or ledger. Only height, weight, blood pressure (BP), blood glucose (BG), and cholesterol levels are documented. This incomplete data in the participant notes, and the absence of a monitoring sheet pose challenges in monitoring changes in the visitors' health status every month.

The second desk is allocated for interviewing participants regarding their health history, signs, and symptoms of illnesses. However, sometimes the CHWs fail to inquire about risk factors, and a HCP takes over this responsibility during BP measurements. Additionally, the participant's body mass index (BMI), a critical health status indicator, is not consistently calculated by the CHWs.

The third desk is to measure body weight, height, abdominal circumference, and BP. However, occasionally, the CHWs conduct these examinations during the initial registration step at the first desk.

At the fourth desk, glucose blood tests, cholesterol, and triglyceride levels are measured. Glucose testing is mandatory every three months for diabetic patients and annually for those at risk. The ISP-NCDs does not routinely examine participants' BG and cholesterol levels, except for their BP. Participants with risk factors are referred to PHC for further examinations. The limited funds available to each ISP-NCDs restrict their ability to conduct routine blood examinations, leading to referrals to PHCs (Puskesmas), where examination strips are available.

The fifth desk is dedicated to counselling, health education, and providing recommendations for patient referrals. HCP identify risk factors and conduct follow-up procedures. CHWs occasionally provide health counselling because some issues regarding the advanced age impact CHWs' abilities to deliver healthcare education to ISP visitors (Alfiyah and Pujiyanto, 2019).

The ISP-NCDs (Posbindu PTM) programme has been identified as having the potential to control and prevent NCDs, including the reduction of DM prevalence. This programme has demonstrated significant benefits by increasing health knowledge and awareness of individuals' health conditions (Yandrizal *et al.*, 2016). However, the sustainability of the ISP-NCDs programme is an issue that needs to be addressed, as it requires technical facilities, partnerships, and social support. Structural policy support and coordination forums are necessary to implement the programme at the district level to stimulate NCDs prevention programmes (Rahajeng and Kusumawardhani, 2010).

ISP-NCDs (Posbindu PTM) can be divided into two groups based on the types of early detection, monitoring, and follow-up activities it carries out (MoH-RI, 2012).

a. Primary (basic) ISP-NCDs aim to detect early risk factors through interviews and physical measurements, including family history of NCDs, risky behaviour, the potential for injury and domestic violence, weight, height, abdominal circumference, BMI, body fat analysis, BP, pulmonary function test, and breast self-examination counselling.
b. Prime ISP-NCDs offers basic services of primary ISP-NCDs, as well as BG, total cholesterol, and triglyceride checks, clinical breast examination and acetic acid Visual Inspection (IVA) test for cervical cancer survey, respiratory and alcohol test, and urine amphetamine test for drivers. The services are provided by trained HCPs, including doctors, midwives, nurses, laboratory analysts, and others in villages, sub-districts, districts, community groups, organizations, and institutions. The Prime ISP-NCDs can be integrated with the Village Health Post in community groups and institutions where HCPs are available according to their competence.

The CHWs' responsibilities encompass conducting monthly ISP (Posyandu-Posbindu) sessions, performing follow-up visits in the community, attending village committee (ISP working group) meetings, and updating ISP targets and utilization data. Depending on the village, CHWs also update ISP session utilization and outcomes statistics, conduct follow-up visits to absent participants and those requiring further health education, and attend village committee meetings (Figure 4) (Oendari and Rohde, 2021).

The management and financial support of ISP-NCD are organized through an agreement with the community and reported to the PHC (Puskesmas). The funding for activities comes from the local budget and the Bantuan Operasional Kesehatan (BOK) or Health Operational Fund. Local budget funds are utilized for ISP-NCDs (Posbindu) revitalization, while BOK funds are allocated for procuring BG and cholesterol testing strips. Due to limited funds, CHWs must exercise caution in their expenditure (Alfiyah and Pujiyanto, 2019).

CHWs offer their services voluntarily without any financial compensation, although they may receive reimbursements for transportation expenses, they may receive informal compensation, such as free medical treatment from PHC. Volunteering as kader is highly esteemed in the community, due to the cultural value placed on helping one's neighbours (Oendari and Rohde, 2021).

The CHWs receive technical supervision as needed from health professional, but their primary accountability lies with the village committee (ISP working group) under the Ministry of Home Affairs (MoHA) (Figure 5) that selected and supports them in their work. CHWs operate under the MoH for health programmes but are financed and accountable to a village committee under the MoHA (Oendari and Rohde, 2021).

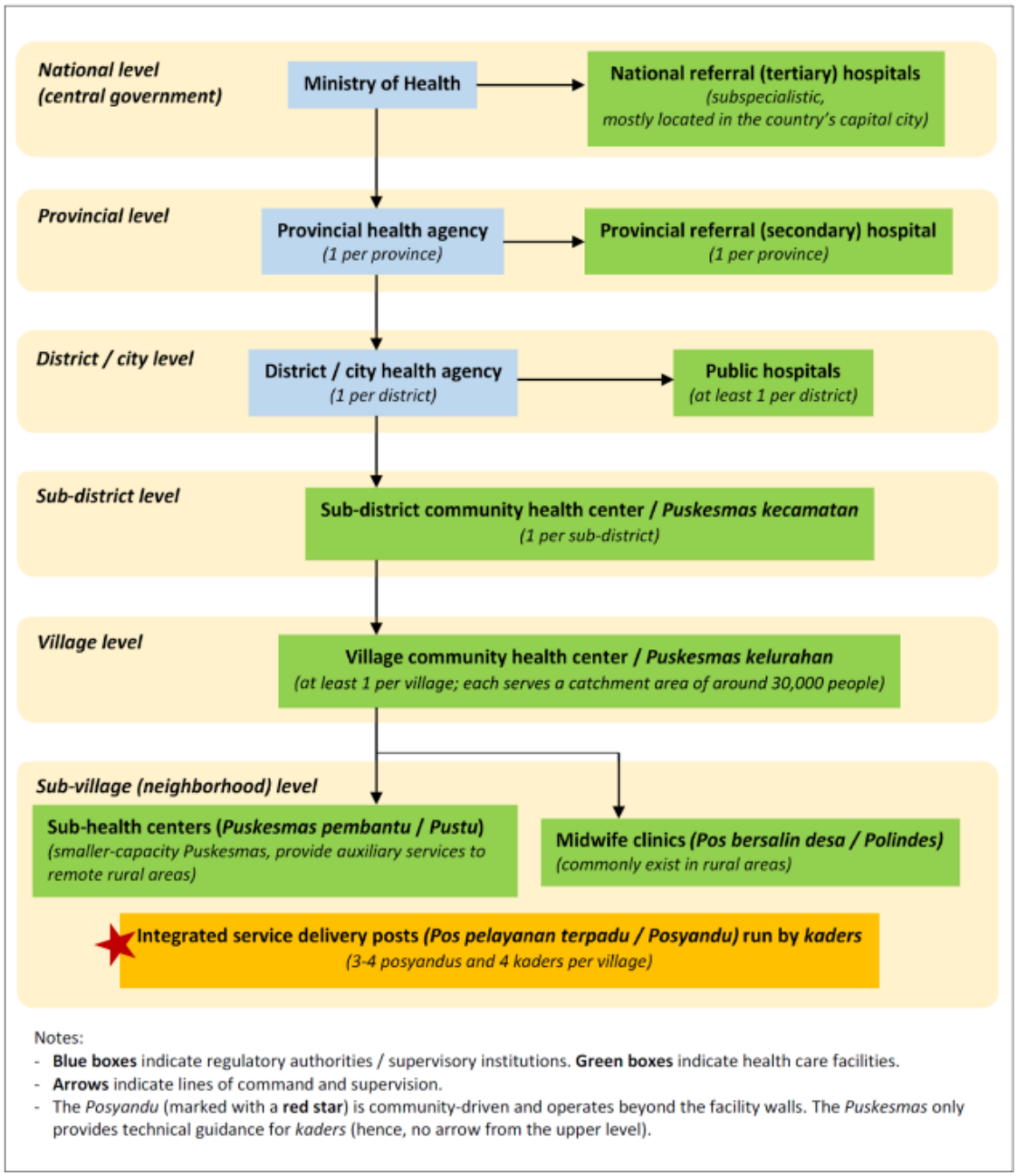

Figure 4: CHWs in Indonesian healthcare

Source: Oendari and Rohde (2021)

The position of the ISP (Posbindu PTM or Posyandu) in Indonesia Health system was described by (Surjaningrum, Minas, *et al.*, 2018) (illustrated in Figure 5), An ISP involves intersectoral cooperation between the MoH and the MoHA at the village level through a body called 'ISP working group' (village committee). This working group

coordinates with the Women's Agency (FWM) of the MoHA to run an ISP monthly activity whose operationalization is managed by a PHC. The MoHA establishes 'national working groups of ISPs' to guide the operationalization of ISPs. Working groups are found at all levels of government: national, province, district, sub-district, and village levels. Even though the ISPs are run by the community, PHC centres are responsible for ensuring ISPs are in their coverage area. PHC centres must supervise community posts and have their HCP present when ISPs holds monthly activities, represented mainly by midwives and nurses (Surjaningrum, Minas, *et al.*, 2018). In this context CHWs are not part of the formal facility-based health system but link to this system (ISPs) (Figure 4) (Lewin, Lehmann and Perry, 2021).

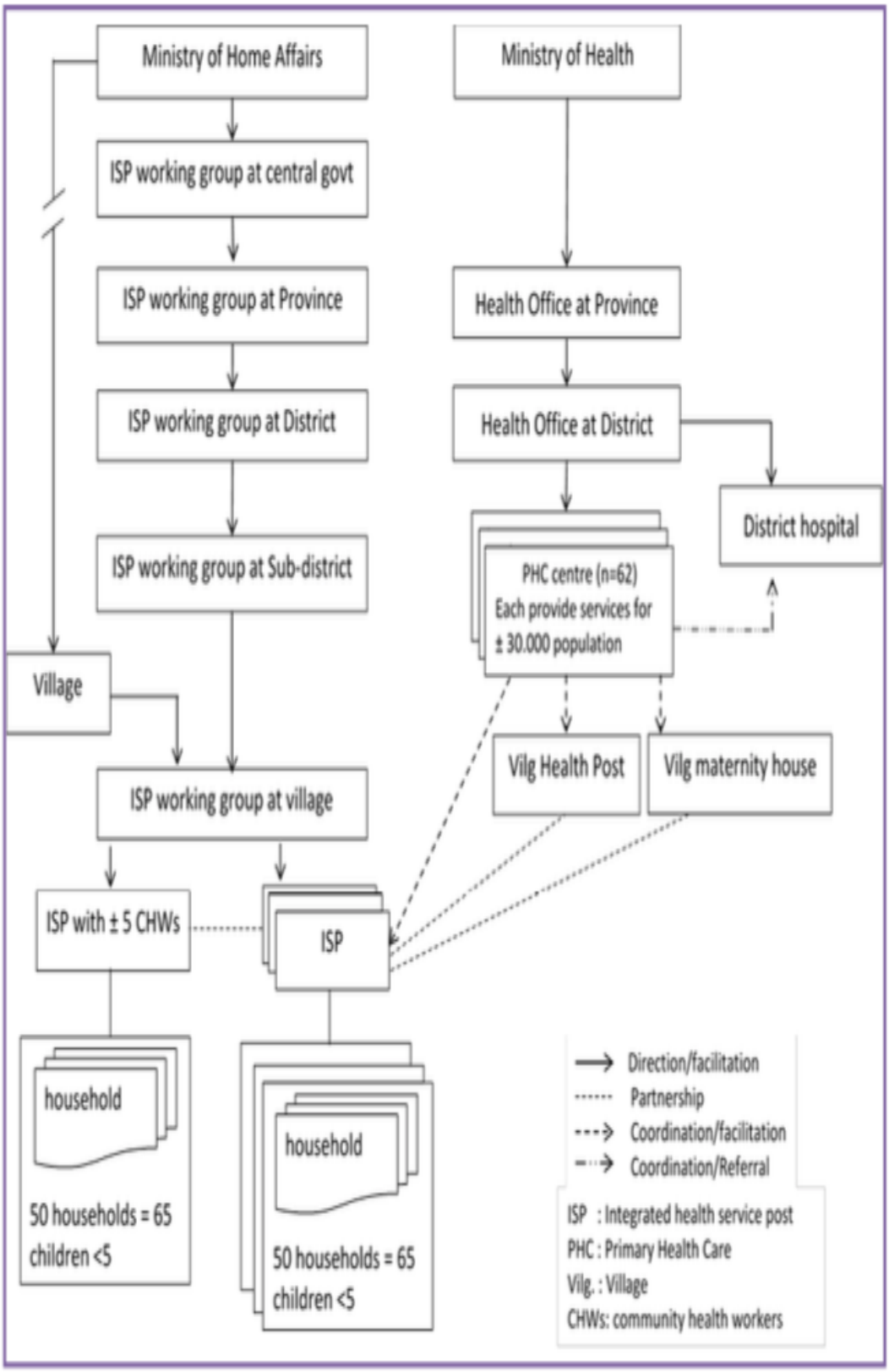

Figure 5: Intersectoral cooperation between MoH and MoHA at village level

Source: Surjaningrum *et al.* (2018)

A promising solution that has been proposed is to empower CHWs to tackle NCDs like diabetes mellitus at the community level. To achieve this, the Indonesian Government has implemented the ISP-NCDs programme, encouraging community involvement and improving healthcare utilization to combat diabetes and its complications

1.5. Developing a Footcare Intervention (FCI) in Indonesia

1.5.1. Challenges

The scarcity of HCPs poses a challenge in managing DFPs (Soewondo, Ferrario and Tahapar, 2013). One potential approach to decrease the occurrence of DFUs entails involving CHWs as educators for individuals with diabetes in the local community. Nevertheless, the development of FCI delivered by CHWs requires attention. This intervention is complex due to its incorporation of various contextual factors and the involvement of multiple community stakeholders, including patients, their families, HCPs, and CHWs. Additionally, it is essential to take into account the healthcare policies and cultural aspects of the intervention's implementation. These interconnected elements influence the intervention, rendering it intricate in nature. Therefore, the new MRC Framework is used to develop new FCI delivered by CHWs (Skivington *et al.*, 2021)

1.5.2. The UK Medical Research Council (MRC) Framework

Complex interventions refer to interventions that consist of multiple interconnected components (Craig *et al.*, 2019). These components can act independently or dependently on each other. They typically involve behaviours, parameters related to those behaviours (such as frequency and timing), and methods of organizing and

delivering those behaviours (such as the type of practitioner, setting, and location) (MRC, 2000). Complex interventions are commonly employed in healthcare and social care services, public health practices, and other domains of social and economic policies that have implications for health. These interventions are implemented and evaluated at various levels, from individual to societal. Examples of complex interventions include the introduction of a new surgical procedure, restructuring a healthcare programme, and modifying welfare policies (Skivington *et al.*, 2021).

The UK MRC's initial framework of 2000 was updated in 2006. This guidance aimed to assist researchers and research funders in developing and evaluating complex interventions (Craig *et al.*, 2019). The latest MRC Framework was introduced in 2020 by the National Institute of Health Research (NIHR) and the MRC Methodology Research Programme. The previous framework and guidance focused primarily on determining the effectiveness of interventions. In contrast, the new MRC Framework considers factors such as the feasibility of implementation, cost-effectiveness, transferability, and scalability of interventions in real-world conditions. This shift represents a broader set of criteria and concerns regarding complex interventions beyond their effectiveness (Skivington *et al.*, 2021).

The framework outlines four phases for developing complex interventions: intervention development or identification, feasibility assessment, evaluation, and implementation (Figure 6). The choice of which stage to begin a research programme depends on the primary uncertainties surrounding the specific intervention. Each phase incorporates a set of consistent core elements across all phases. These elements include considering the context, developing and refining the programme theory, involving

stakeholders, identifying key uncertainties, refining the intervention, and weighing economic considerations (Skivington *et al.*, 2021).

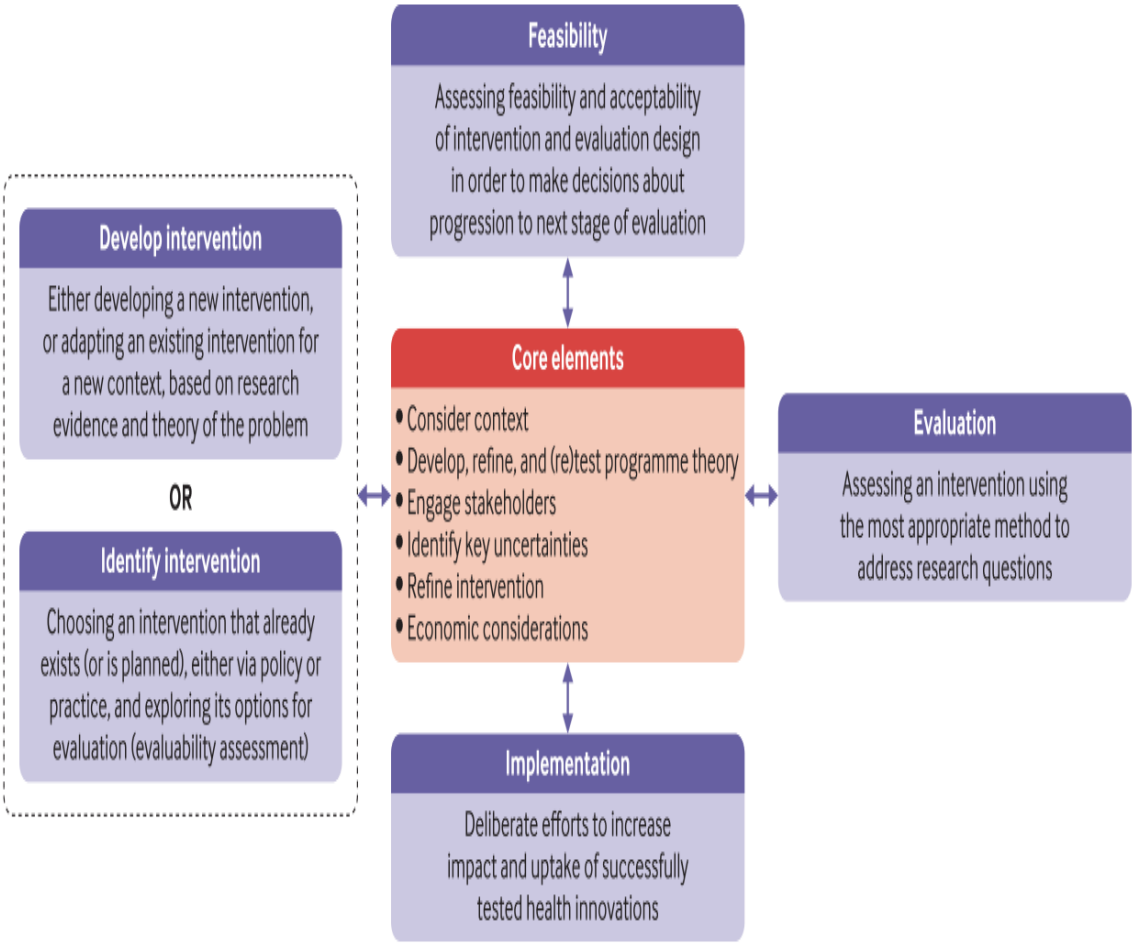

Figure 6: Framework for developing and evaluating complex intervention

Source: Skivington *et al.* (2021)

The sequential framework is valuable as it outlines the specific goals that must be achieved at each stage before progressing to the subsequent step. However, it is essential to note that this framework should not be rigidly followed as a fixed checklist. Instead, it should be viewed as guidance to be applied according to its relevance at each research stage (Craig *et al.*, 2019).

The new MRC Framework embraces a pluralistic approach and outlines four perspectives that can guide designing and conducting research on complex interventions. These perspectives include efficacy, effectiveness, theory-based, and systems approaches (Skivington *et al.*, 2021), as explained below.

Efficacy: This perspective focuses on determining the extent to which the intervention achieves its intended outcomes within controlled experimental or ideal conditions.

Effectiveness: This perspective examines the extent to which the intervention achieves its intended outcomes within real-world settings, considering the complexities and challenges of practical implementation.

Theory-based: This perspective aims to understand what interventions work under specific circumstances and how they bring about change. It emphasizes examining the mechanisms and interactions between interventions and the contextual factors, which can lead to the refinement of existing theories.

Systems: This perspective investigates how interventions interact and adapt within complex systems. It views the intervention as a disruptive force within the more extensive system.

Identifying barriers or rate-limiting steps in intervention pathways is essential, as complex interventions can fail due to unforeseen obstacles. Such barriers can be cognitive, behavioural, organizational, sociocultural, or financial, and may occur early in the intervention process or during steps not previously considered or deemed necessary (Campbell *et al.*, 2007). It is recommended to systematically develop interventions by utilizing the best evidence and relevant theories. The process involves testing interventions through a phased approach, beginning with pilot studies targeting

critical design uncertainties. Exploratory and definitive evaluations follow this, and subsequent findings should be widely disseminated. Further research should then be conducted to support and monitor the implementation process (Craig *et al.*, 2008).

As the initial step in intervention development, it is necessary to analyse current evidence to define the health problem and its determinants and understand the contextual factors associated with the situation (O'Cathain *et al.*, 2019). Qualitative research is crucial for comprehending the reasons behind certain phenomena and testing assumptions related to the intervention. This helps identify whether incorrect beliefs and assumptions may influence the selection of an intervention or hypothesis and determines the active components of a complex intervention while excluding irrelevant elements. Various methods, such as individual in-depth interviews, can be employed for qualitative research. However, it is not limited to qualitative evidence alone; quantitative surveys of practitioners can also be used to identify beliefs, behaviours, or organizational factors that influence the plausibility of an intervention (Craig *et al.*, 2019).

Developing an footcare intervention in Indonesia follows the new MRC Framework for developing and evaluating a complex intervention. The success of the intervention can vary depending on the specific context in which it is implemented. Context encompasses various factors, including physical, spatial, organizational, social, cultural, political, and economic aspects of healthcare, the health system, and public health settings (Skivington *et al.*, 2021). Additionally, the intervention involved community stakeholders such as patients, family members, HCPs, and CHWs to deliver healthcare services. Understanding the dynamic interaction between the

intervention and its context is facilitated by viewing systems as complex and adaptive, characterized by properties like emergence and feedback (Skivington, 2021).

It is crucial to understand the issue at hand to determine whether it is worthwhile to develop a new intervention. Factors such as potential costs outweighing the benefits, limited reach leading to increased health inequalities, or the unsuitability of the current context for implementation should be considered. It also important to assess the available resources. Inadequate time spent on intervention development can result in an ineffective or costly intervention that fails to be implemented in practice, thus wasting research efforts. On the other hand, excessive time dedicated to development can also waste resources, leading to an outdated intervention that is no longer feasible or relevant due to significant changes in the context or shifting priorities. Implementing a comprehensive review involves multiple revisions and cycles, which can be time-consuming and require flexibility. As more evidence is gathered, the review process may evolve and require iterative development of protocols over time (Noyes *et al.*, 2019).

Evaluating complex interventions presents challenges due to the difficulty in identifying and separately assessing the effects of different components within the intervention. This can hinder the generalizability of findings. To address this issue, it is suggested that instead of defining the elements of the intervention as standard, the focus should be on standardizing the functions while allowing flexibility in the specific form applied. For instance, in a health promotion intervention, the delivery of specific educational materials may be a component, but the content can vary to suit the target group's needs. Thus, a comprehensive evaluation of complex interventions requires

considering not only the defined components but also the broader contextual factors that can impact the intervention's effectiveness (Blackwood, 2006).

Once the development process is complete, external entities such as policymakers, programme planner, or service providers may express interest in implementing or evaluating the intervention. To facilitate this, it is crucial to provide a comprehensive intervention description using appropriate reporting guidelines like the Template for the Description and Replication of Interventions (TIDieR) (O'Cathain *et al.*, 2019). Additionally, creating a manual or document that outlines the training and content of the intervention can be helpful. It is also beneficial to publish both unsuccessful and successful interventions, as it can reduce research waste. When dealing with a highly complex problem with a history of failed interventions, it is crucial to allocate sufficient time for meticulous development (O'Cathain *et al.*, 2019).

CHWs show the potential to provide promotive and preventive care for diabetes-related foot issues within the community. However, further evidence is required to establish the effectiveness of interventions delivered by CHWs. Therefore, it is necessary to thoroughly examine existing evidence from around the world before developing a new intervention tailored to the context of Indonesia.

Chapter 2

Scoping Review

Prior to developing an footcare intervention for Indonesia, it was necessary to seek current evidence on the nature and effectiveness of CHW-delivered FCIs. This chapter presents a scoping review of FCIs delivered by CHWs to provide relevant evidence for developing new FCIs. This chapter also justifies the research and develops research aims and objectives.

2.1. Rationale for Scoping Review

The importance of evidence synthesis has grown significantly in guiding choices for both policy and practical decision-making. Its application extends beyond assessing effectiveness and includes tailored methods for various research inquiries (Campbell *et al.*, 2023). A good theoretical understanding identifies requirements, and the weaknesses to be avoided in the intervention being designed (Craig *et al.*, 2019). By reviewing published research evidence, one can identify existing interventions, understand the evidence base for each intervention component and determine if the proposed intervention may not work as intended (O'Cathain *et al.*, 2019).

This study attempts to expand the role of CHWs in promoting and preventing DFPs in Indonesia. This is crucial due to the projected increase in the number of individuals experiencing complications related to diabetes, particularly DFU (IDF, 2021), and a significant proportion of patients seeking care at the national referral hospital in Indonesia who have already progressed to advanced stages of DFUs. This highlights the importance of early detection and timely treatment (Yunir *et al.*, 2021). Foot self-management programmes can either be independent initiatives or integrated into

broader diabetes education or management programmes (Stevens, Bruneau and Moralejo, 2017).

The variation in CHW interventions in diabetes self-management, in general, has been reviewed by many studies and their findings have significantly improved physical health outcomes, diabetes knowledge, self-care behaviours, and emotional well-being while reducing distress (Trump and Mendenhall, 2017). However, specific interventions concerning the role of CHWs in footcare education are scarce. A preliminary search for existing evidences on this topic was conducted, and no studies were identified that explored specific interventions by CHWs in footcare. Therefore, it was necessary to gain current evidence on CHWs delivered footcare intervention before developing complex intervention (Craig *et al.*, 2019; O'Cathain *et al.*, 2019; Skivington *et al.*, 2021). This was undertaken using a scientific approach to select and review literature particularly in terms of maintaining objectivity (Grant and Booth, 2009). It is essential to scope the literature so that the reviewers can develop specific research questions (Flemming *et al.*, 2019).

This study utilized the scoping review method to review the current evidence and identify knowledge gaps in CHWs deliver FCI. Additionally, the method was employed to investigate the research conducted (Munn, Peters *et al.*, 2018), to synthesize evidence and assess the extent of the literature on this particular topic, because this can help determine whether a systematic literature review is needed (Tricco *et al.*, 2016; Munn, Peters *et al.*, 2018). A scoping review follows many of the same methodological steps as a systematic review. However, quality assessment is atypical for a scoping review as the focus is on the findings of the study itself (Grant and Booth, 2009). According to Cooper (2016), unlike systematic reviews, scoping

reviews emphasise the identification of findings rather than the initial requirement of study quality for inclusion and the synthesis of data whereby scoping reviews is typically more qualitative in nature. This review followed the Joanne Briggs Institute (JBI) guidance for scoping reviews (Peters *et al.*, 2020).

2.2. Aims and Objectives of Scoping Review

The aim of the scoping review was to establish the evidence base of DFU interventions delivered by CHWs, as a first step to developing an DFU intervention suitable for the Indonesian context. The objectives of the scoping review were to:

1. Identify and examine the nature of FCIs delivered by CHWs.
2. Identify the core components of FCIs delivered by CHWs.

2.3. Inclusion Criteria

2.3.1. Types of Participants

This scoping review only included literature on adult participants diagnosed with T2DM, as diabetic foot disorders are more common in adults, and self-management needs may differ for children (Stevens, Bruneau and Moralejo, 2017).

2.3.2. Concept

This review included CHW-delivered intervention. CHWs were either the sole focus of the intervention under study or other nomenclature referring to the CHW role (Lehmann and Sanders, 2007). CHWs have fully featured as footcare educators in FCI. Exclusion criteria eliminated studies that included CHWs among multiple professional types (e.g., “informal caregivers” and “peer leaders”) or those with team-based interventions when patients were educated by HCPs.

2.3.3. Context

The context of this review were FCIs for diabetic patients or footcare in diabetes self-management studies where footcare was included in educational programs (e.g., diabetes in general) and where eligible FCI data was available, eligible CHWs fully featured as footcare educators in diabetes self-management studies (e.g., diabetes in general).

2.3.4. Types of Sources

Any study design written in English was eligible; the studies that did not have data concerning footcare or if their full-text versions were unavailable through the University of Nottingham (UoN) Library service were excluded from this scoping review.

2.4. Search Strategy

Using Medical Subjects Headings and text words, including DM, CHWs and footcare, the following search terms were used:

> ("Community health workers" Or CHWs OR "Lay Health workers" OR LHWs OR "Volunteer health workers" OR VHWs OR "Community health distributors" OR "Community health surveyors" OR "Community health assistants" OR "Community health promoters" OR "Promotoras de Salud" OR "Kader") AND Diabetes Mellitus (Mesh) OR Diabetes AND ("Foot care education" OR "Foot care" OR "Diabetic foot care" OR "Foot education" OR "Diabetes foot care" OR "Foot care knowledge" OR "Foot self-care" OR Foot)

I conducted three scoping reviews using the exact keywords in 2019, 2021 and 2022, respectively, and found similar articles from the first and second scoping reviews. A recent scoping review added two articles that differed from the previous two search data sets. The following electronic databases were searched for articles from the first indicated date through to December 2022: CINAHL, EMBASE, Cochrane, Scopus, Web Science, Theses ProQuest, PubMed, google scholar and other sources. A total of ten articles which reported nine studies were identified that met the described inclusion criteria from the initially detected 1644 (see Figure 7).

2.5. Data Extraction

Data were extracted using a form aligned with the review's objective. Tables 3 and 4 categorize issues and critical information regarding diabetes foot intervention delivered by CHWs. Study data were extracted by my colleague Desy Nuryunarsih, a PhD researcher and I, and then we both screened all the titles and abstracts identified based on inclusion/exclusion criteria. Any disparities or variations in the table were resolved through discussion between the reviewers until a mutual agreement was achieved. Additionally, the two supervisors analysed and interpreted the data.

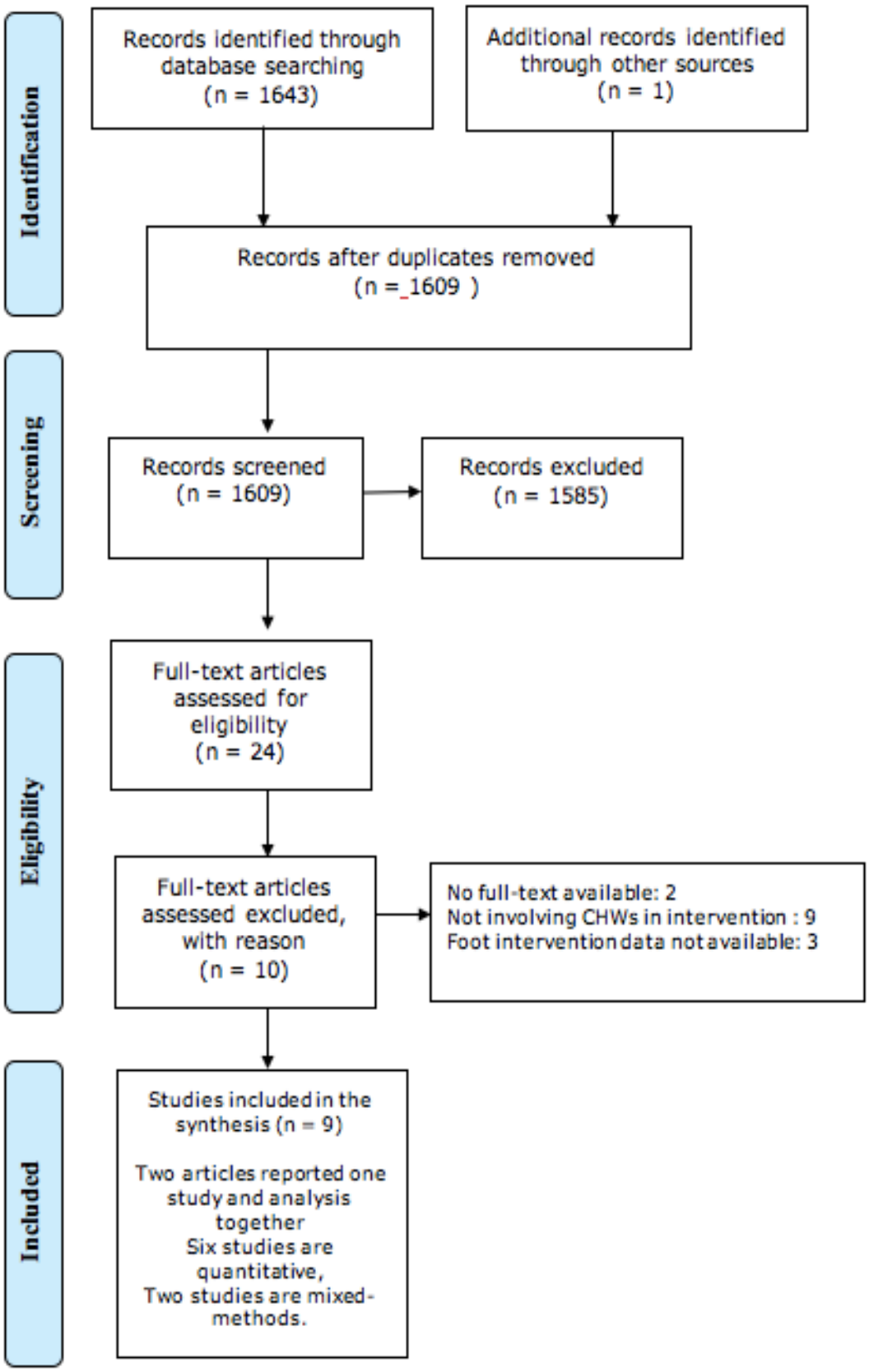

Figure 7: PRISMA flow diagram

Table 3: Description of included studies DSME delivered by CHWs (FCI as part of DSME)

Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
Vaughan *et al.* (2017)	US Low-income Hispanics	RCT	62	42.5	The objectives of the study were: (1) to assess whether it is feasible to integrate CHWs as part of the leadership team and (2) to examine early evidence of the effectiveness of this integration in improving clinical outcomes and adhering to 8 ADA and USPTF guidelines.	Health educator Stress management	Baseline, 3-month, and 6-month A1C and lipid levels during the group visits (1) At month 6, the authors collected data on 8 standards of care per ADA and USPTF: (weight loss, (2) retinal screening, (3) comprehensive foot exam (i.e., assessment of foot pulses, sensation, skin exam), (4) BP, (5) urine microalbumin, and (6-8) cancer screening (breast, cervical, colorectal)	The CHWs provided complete foot exam	Comprehensive foot exam (i.e., assessment of foot pulses, sensation, skin exam) IG (%) 57.1 CG (%) 0.0	(P < .001)
Schoenberg *et al.* (2016)	US Kentucky	RCT	41 IG n=20 CG n=21	58	The pilot study aimed to improve T2DM outcomes in rural areas by measuring cost, retention, and satisfaction as primary outcomes.	Health educator Care coordinator (Patient Navigator-Appointment adherence)	HbA1c, BP, lipids, and BMI Self-management activities (blood glucose monitoring, diet, PA, footcare, medication taking, and medical appointment adherence).	NR	Footcare was the best-managed domain of diabetes management, with participant checking their feet an average of 5.32 (SD	P = 0.38

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Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
							(3) (self-efficacy and patient activation). Spirituality/religiosity data		=2.10) days per week 5.70 (SD=1,76) and 4.95 (SD=2.92) for IG and CG respectively	
Hughes *et al.* (2016)	US, Chicago Hispanic and non-Hispanic Black population	Pre post-test single group design. Case report	325	57	A diabetes intervention programme in Chicago aimed to reduce HbA1c levels in adults with T2DM in the North and South Lawndale areas. The programme also sought to identify successful participant traits.	Health educator Home visits Patient care and health management (create patient goal) Care coordinator Offered referral	HBA1C, Biological/clinical, behavioural and psychosocial, diabetes self-care activities	NR	Footcare improvement in categorized diabetes self-care activities, comparison of diabetic participant characteristics for footcare at baseline and follow-up: baseline (5.3%), follow-up (6.2%), change difference 0.9% CI (0.5-1.2)	P=<0.02
Rothschild *et al.* (2014)	US Mexican-Americans in	RCT	144	53.7	This study assessed whether CHWs could improve glycaemic control among	Health Educator Home visits Patient care and health	Short-term physiological outcomes (mean HbA1c levels and	NR	Summary of Diabetes Self Care Activities, d/wk	NR

Table 3: Description of included studies DSME delivered by CHWs (FCI as part of DSME)

Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
	metropolitan Chicago				Mexican-Americans with diabetes.	management (create a Patient goal)	percentage with controlled BP) Self-management behaviours, such as daily self-monitoring of blood glucose, medication taking, and adherence to diet and PA recommendations		Footcare: Mean ± SD (5.1 ± 2.7) IG: Mean ± SD (4.8 ± 3.0) CG: Mean ± SD (5.5 ± 2.4)	
Islam *et al.* (2013)	US Bangladeshi migrants in New York City	Pre post-test single group design (mixed method, quantitative and qualitative)	26	53	The aim was to assess the effects and viability of a trial CHWP for enhancing diabetes management among Bangladeshi-American individuals with T2DM residing in New York City.	Health educator Home visits Care coordinator (appointment adherence)	Clinical, behavioural, and satisfaction measures Qualitative measures	NR	Frequency of checking feet and irritation increased from 27% to 77% daily between baseline and 12-months	P = 0.026
Spencer *et al.* (2011)	US African-Americans and Latinos	RCT Randomized IG and CG design	183 Allocation: IG (n=84), CG (n=99) 6-month follow-up	52	Culturally-tailored intervention by CHWs for low-income African-Americans and Latinos with diabetes. Aimed to improve HbA1c,	Health educator home visits, Patient care and health management (create a patient goal)	Physiological measures, self-management knowledge, diabetes self- management, measured diabetes-specific psychological	NR	The IG had significantly improved adherence to inspecting the inside of their shoes every day at the 6-month	P < 0.01

Table 3: Description of included studies DSME delivered by CHWs (FCI as part of DSME)

Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
			IG Active (n-59) CG Active (n=77)		BP, and lipid levels, diabetes knowledge, self-management behaviour, and diabetes-related distress compared to standard care.	Care coordinator (appointment adherence)	distress and diabetes self-efficacy scale		follow-up (49-77%; P < .01) and significantly improved compared with the CG	
Pacheco *et al.* (2015)	Philippines Rural population	RCT Prospective, education-intervention trial	155 Recruited from villages. Randomized in DMSE IG (n=80), and standard care CG (n=70)	57	This study evaluates how effective DSME is in a rural agricultural town.	Health educator	Anthropometric, biochemical, health behaviours, and medication	NR	At baseline, the performance of foot examination was initially done by a fewer number of participants in the IG compared with the CG (24.10 versus 41.43%, P = 0.0220). After 3 months, IG performed more frequent foot examinations (76.56 versus 57.63%, P = 0.0250).	3rd month follow-up P = 0.0250 6th month follow-up P = 0.2310

Table 3: Description of included studies DSME delivered by CHWs (FCI as part of DSME)

Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
									After 6 months, there was no more difference in the proportion of participants in the two groups who perform foot examination (75.81 versus 85.11%, P = 0.2310)	
Castillo *et al.* (2010)	Southeast Chicago, US Hispanics/ Latinos T2DM	Pre post-test single group design. Quantitative and qualitative	47	58	To conduct a diabetes education programme delivered by CHWs in community settings and to evaluate its effectiveness in improving glycaemic control and self-management skills in Hispanics/Latinos with T2DM.	Health educator Patient care and health management (Health coaching) Home visits	Diabetes knowledge, Self-care behaviours, self-efficacy, depression, A1C, weight, and BP	NR	3-month post test results Check feet P-value = .005 Check inside of shoes P-value = < 0.000	P < 0.000

Table 3: Description of included studies DSME delivered by CHWs (FCI as part of DSME)

Author/ year	Country/ study setting	Study design	Sample size	Participant mean age in years	Aims and objectives	CHW role	Outcome finding	Type of footcare education	Significant changes in footcare education	Associated statistical significance (p; respective)/ effect size (if reported)
Prezio *et al.* (2014) and Culica *et al.* (2007)	US Mexican-American	RCT	180 CG n=90 IG n=90	47	A programme led by CHWs aims to evaluate its effectiveness in managing and educating uninsured Mexican-Americans with diabetes while determining cost-effectiveness and complications improvements.	Health educator Patient care and health management (Health coaching)	Anthropometric, biochemical, health behaviours	The CHW performed a full foot examination, including visual inspection, assessment of pedal pulses and using monofilament	Intervention participants would experience significantly fewer foot ulcers at 5 years 10 years and 20 years At 20 years, there would be significantly fewer foot amputations among IG Foot exam in prior 12 months Within-group IG P < 0.001 CG P < 0.001	Significantly fewer DFUs at 5 years (p=0,0014), 10 years (p=0.001), and 20 years (p=0.001).

A1C: average blood glucose test, ADA: American Diabetes Association, BMI: Body mass index, CI: Confidence interval, CG: Control group, IG: Intervention group, NR: Not reported, RCT: Randomized Controlled Trial, SD: Standard deviation, USPTF: US Preventive Services Task Force.

Source: Author

2.6. Results on CHW Effectiveness in Preventing Diabetes Ulcer

2.6.1. Sample Characteristics

Studies in this review were published between 2010 and 2017 (Table 4). The sample sizes ranged from 41 to 325 participants (Mean (M) = 129). Study samples overall comprised 68.6 % female patients, participants had a mean age of 53.1 years old. Most of the studies reported targeted minority populations in the US, except one study conducted in underserved communities in urban settings in Philippines (Paz-Pacheco *et al.*, 2017). All studies conducted in US aimed to address healthcare disparities in specific populations such as the Hispanic/Latino community (Castillo *et al.*, 2010; Spencer *et al.*, 2011; Hughes *et al.*, 2016; Vaughan *et al.*, 2017), Mexican-American (Prezio *et al.*, 2014; Rothschild *et al.*, 2014) Bangladeshi immigrant (Islam *et al.*, 2013), and a shortage of healthcare providers (Paz-Pacheco *et al.*, 2017; Schoenberg, Ciciurkaite and Greenwood, 2017). Two articles reported a study of the Diabetes Education Programme for the same participants (uninsured Mexican-Americans) (Culica, Walton and Prezio, 2007; Prezio *et al.*, 2014); these studies were examined and analysed together as one study. Therefore, this scoping review examined nine studies.

2.6.2. Nature of FCI Delivered by CHW.

The focus of interventions were similar to those systematically reviewed by Trump *et al.* (2017) for general CHWs role in diabetes care. The role of CHWs in patient education in diabetes management can be categorized into four types of service:

- Patient education – all included studies had similar findings in terms of the role of CHWs as health educators, having been trained in diabetes and its complications

and lifestyle strategies for managing glycaemic control, such as nutrition, physical activity, blood glucose monitoring, and medication management.

- Patient care and health management – all included studies explored this, particularly Hughes *et al.* (2016) and Spencer *et al.* (2011), this type of service included developing self-management skills, creating goals and action plans, identifying potential barriers, and problem-solving.
- Care coordination (Castillo *et al.*, 2010; Spencer *et al.*, 2011; Hughes *et al.*, 2016; Schoenberg, Ciciurkaite and Greenwood, 2017) in this role, CHWs reinforced instructions from participants' primary care providers, and facilitated appointments and referral scheduling.
- Stress management (Islam *et al.*, 2013; Rothschild *et al.*, 2014; Vaughan *et al.*, 2017). The study involving Bangladeshi immigrants included a segment focusing on stress management, this section covered the impact of stress on both physical and emotional well-being which involved family support in coping with stress. Additionally, it was customized to incorporate herbal and home remedies for alleviating stress (Islam *et al.*, 2013). Furthermore, CHWs were involved in addressing psychological obstacles related to diabetes, such as anxiety and depression (Vaughan *et al.*, 2017).

All of the studies described the effectiveness of the patient's education programme delivered by CHWs on diabetes in general (which included footcare education) through a variable number of education sessions ranged 4 to 36 meetings. The content of the educational programme delivered consisted of Diabetes Self-Management Education (DSME), involving an overview of knowledge of diabetes, diet

management, physical activity, diabetes complications, social support, stress management, and how navigating the healthcare system.

2.6.3. Method of Evaluation

Six studies used RCTs to establish the effectiveness of the intervention compared with usual care (Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Schoenberg, Ciciurkaite and Greenwood, 2017; Paz-Pacheco *et al.*, 2017; Vaughan *et al.*, 2017). Other studies compared conditions at the baseline intervention (pre-test) with follow-up (post-test). Two studies (Castillo *et al.*, 2010; Islam *et al.*, 2013) used quantitative and qualitative methods by conducting interviews with the former participant after completing a one-group-repeated intervention.

The outcomes of DSME intervention were primarily evaluated through measurements of HbA1c levels and a combination of biological and clinical factors, as well as behavioural and psychosocial components. Footcare education was specifically assessed as part of the overall self-management activities, which included monitoring blood glucose levels, adhering to dietary guidelines, engaging in physical activity, practicing proper footcare, taking medications as prescribed, and consistently attending medical appointments.

Most of the studies did not provide a clear and detailed description of the type of FCI applied, specifically whether it consisted of foot screening or foot self-management. However, the Community Diabetes Education (CoDE) programme conducted by Culica, Walton, and Prezio (2007) and Prezio *et al.*, 2014 provided a comprehensive approach to footcare, whereby CHWs were trained to perform a complete foot examination, including visual inspection, pedal pulses assessment, and monofilament testing. The examination results were documented in the patient's chart and clinical

medical records, and any foot abnormalities were reported immediately to the physician. CHWs also provided education on appropriate footwear and daily home footcare. A similar approach was reported by Vaughan *et al.* (2017), whereby CHWs performed a comprehensive foot examination, including the assessment of foot pulses, sensation, and skin examination.

2.6.4. Outcome Variables

Outcome variables for specific interventions in footcare can be categorized into intermediate outcomes of self-care behaviour as part of diabetes self-care activities, measured by the frequency of the participants undertaking foot examinations. Most of the studies used explicit questions for measuring changing health behaviour adopted by using the Summary of Diabetes Self-Care Activities (SDSCA) to determine the frequency with which participants checked their feet (Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Schoenberg, Ciciurkaite and Greenwood, 2017). The SDSCA is a brief, self-reported questionnaire concerning diabetes self-management, including items assessing the following aspects of the diabetes regimen: general diet, specific diet, exercise, blood-glucose testing, footcare, and smoking; it consists of a core set of 11 items. Respondents reported on the frequency with which they performed various activities over the previous seven days (Toobert, Hampson and Glasgow, 2000)., which is unlikely to be sufficient to assess all patients' needs in preventing DFU.

Significant results for footcare education improving self-care behaviour ($p < 0.01$) were found in five studies (Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Paz-Pacheco *et al.*, 2017; Vaughan *et al.*, 2017). A study by Paz-Pacheco *et al.* (2017) in the Philippines found increased adherence to foot examination among the

DSME group at three-month follow-up (76.56 versus 57.63%, P = 0.025). However, the intervention did not have a lasting impact as after six months there was no difference in participant's adherence to foot examination between the two groups (75.81 versus 85.11%, P = 0.231). An RCT among 180 uninsured Mexican-Americans with T2DM conducted in 2006 utilized for secondary analyses described foot exams in the previous 12 months among the intervention group (P < 0.001) and control group (P < 0.001) (Culica, Walton and Prezio, 2007; Prezio *et al.*, 2014), similar to the findings of Rothschild *et al.* (2014), who reported an increase in patients performing foot exam after the intervention.

2.6.5. CHWs' Experience of FCI

Two studies explored CHWs' experiences in implementing the programme, including barriers, facilitators, recruitment, and retention of participants in the diabetes programme. Two studies (Castillo *et al.*, 2010; Islam *et al.*, 2013) used quantitative and qualitative methods. The first study included a Bangladeshi immigrant population in New York City (Islam *et al.*, 2013); the CHWs provided a detailed log during a one-on-one by describing interaction with the participant, documenting clinical outcomes and barriers to accessing healthcare, and engaging in behaviours for improving diabetes management while proposing a follow-up plan.

It also asked project staff, CHWs, and coalition members to assess the programme's strengths and weaknesses. Notes from CHW interviews and meeting and retreat transcripts were coded using narrative analysis, yielding themes about the importance of community, including CHWs' community concordance and leadership roles, as a critical factor that increased participants' trust in CHWs; these led to overcoming

barriers and facilitating the acceptability and feasibility of the intervention (Islam *et al.*, 2013).

A study of Hispanic/Latino participants in the US employed focus group discussions to illuminate the effectiveness of the diabetes programme from participants. In contrast, CHWs' experience of delivering diabetes programmes was not captured and explored in this study because CHWs were not included in the focus group discussion (Castillo *et al.*, 2010). Common themes were found in the study in Hispanic/ Latinos communities related to an increase in awareness of the programme, diabetes knowledge, diabetes self-management behaviour and self-efficacy. Patients mentioned specific information in footcare education.

> "I did not use to check my feet before. And I did not know I had to check them, and I asked here, and they told me, and I kept asking, and now I do it almost daily" (Castillo *et al*., 2010, p. 592).

The overall acceptability, feasibility, and efficacy of the programme showed promise for diabetes education programmes managed by CHWs.

Table 4: Core components of DSME (footcare part of it) delivered by CHWs

Author Year	Country/ Study Setting	Place	Content of educational related to footcare	Provider	Method of delivery	Time and Duration
Vaughan *et al.* (2017)	US Low-income Hispanics	Community clinic	Diabetes overview; prevention of diabetes sequelae	GP (medical management) CHWs bilingual volunteers who live or work in the vicinity of the clinic Social support (CHW-led to address physical barriers to health; i.e., transportation, self-management skills) Mental health (CHW-led to address psychological barriers to diabetes; i.e., anxiety or depression)	Small groups (max. 10 participants), targeting: (1) medical management (i.e., individual appointment with the physician), (2) social support (CHW-led to address physical barriers to health; i.e., transportation, self-management skills), and mental health (CHW-led to address psychological barriers to diabetes; i.e., anxiety or depression)	The IG received 3-hour (Saturdays, 9 AM to 12 PM), monthly comprehensive diabetes group visits with CHWs integrated as part of the leadership team Follow-up after 6 months
Schoenberg *et al.* (2017)	Kentucky, US Appalachian population	Patient homes, project office, community locations	Part of the session in avoiding complication: feet, teeth, eyes, sick days, kidneys, BP	CHWs	Six participants for in-person, group-based self-management educational sessions	6-session program 1 weekly session Follow-up months 2-6, month 7
Pacheco *et al.* (2017)	Philippines Rural population	Village health centre	The module of footcare as part of an 8-module DSME	Lay health advisors	CHWs deliver education with visual aids followed by group discussions with six to 15 participants in each session	NR Follow-up at 3 and 6 months
Hughes *et al.* (2016)	Chicago, US Hispanic and non-Hispanic Black population	Patient homes	NR	CHWs	Home visits for T2DM patients, develop individual management strategies and refer to clinic-based support	1 session, duration NR Follow-up at 12 months

Table 4: Core components of DSME (footcare part of it) delivered by CHWs

Author Year	Country/ Study Setting	Place	Content of educational related to footcare	Provider	Method of delivery	Time and Duration
Rothschild *et al.* (2014)	US Mexican-Americans in metropolitan Chicago	Patient homes	Five general self-management skills: brainstorming and problem solving, using a journal or written record, modifying the home environment to support behavioural change, seeking social support from family or friends, and managing stress	CHWs were bilingual Mexican-Americans who lived in the target community and worked for a local non-profit agency; non diabetes. No post-secondary education	Intervention: received a bilingual newsletter called Diabetes Action. Thirty-six mailed newsletters covered the AADE 7 topics and the 5 general self-management skills, Providing control: participants received the same number of contacts as received by those in the intervention arm and comparable DSME	Home visits lasting an average of 99 minutes, not including the time involved in transportation, missed appointments, and follow-up telephone calls CHWs delivered behavioural self-management training during 36 home visits over 2 years
Islam *et al.* (2013)	New York, US Bangladeshi migrants in NYC	Community outpatients, patient homes	Part of 6 sessions on diabetes complications and "the importance of footcare for diabetes"	2 trained, bilingual Bangladeshi CHWs who are community leaders; 1 male, 1 female	CHW-facilitated group sessions on topics related to diabetes management with an average of 5 participants per session and home visits	6 monthly, CHW- facilitated 2.5-hour group sessions 3 visits months 3, 6, and 9 of about 60 to 90 minutes each Follow-up Follow-up 4, 5, 9, and 12 months

Table 4: Core components of DSME (footcare part of it) delivered by CHWs

Author Year	Country/ Study Setting	Place	Content of educational related to footcare	Provider	Method of delivery	Time and Duration
Spencer *et al.* (2011)	US African-Americans and Latinos	Community location	NR	Trained CHWs, known in this study as family health advocates	CHWs delivered DSME education and regular home visits and accompanied patients to clinic visits during the 6-month intervention period.	A 2.5-hour group in 7 sessions Follow-up at 6 months
Castillo *et al.* (2010)	Southeast Chicago, US Hispanics/ Latinos	Community self-care centre (nonclinical settings)	NR	CHW	Group and individual activities class sizes ranged from 10 to 15 participants, including family and friends	The sessions were scheduled every week for ten weeks and were led by a team of two CHWs (facilitator and assistant)
Culica *et al.* (2007); Prezio *et al.* (2014)	US Mexican-Americans	Community clinic; uninsured, faith-based urban clinic	NR	A specially trained, bilingual CHW	A long-term and low-cost one-to-one educational programme involving supportive family members to attend sessions	The educational intervention included three 60-minute initial visits and quarterly 30-60 minute assessments, totalling seven patient contact hours over 12 months

A1C: average blood glucose test, AADE: American Association of Diabetes Educator, ADA: American Diabetes Association, BMI: Body mass index, CG: Control group, DSME: Diabetes Self-Management Education, IG: Intervention group, NR: Not reported, RCT: Randomized Controlled Trial, SD: Standard deviation, USPTF: US Preventive Services Task Force.

Source: Author

2.6.6. Core Components of Intervention

The following information follows the TIDieR checklist guidelines (Hoffmann *et al.*, 2014). The overarching purpose of the TIDieR checklist is to prompt authors to describe interventions in sufficient detail to allow their replication. The checklist contains the minimum recommended items for describing an intervention. Authors should provide additional information where they consider it necessary for the replication of an intervention.

2.6.6.1. Location of Intervention

The interventions' location mainly occurred in community settings such as health centres, clinics, schools, and senior centres. Three studies combined community-based Interventions with home visits (Spencer *et al.*, 2011; Islam *et al.*, 2013; Schoenberg, Ciciurkaite and Greenwood, 2017), while two other studies exclusively offered home visits (Rothschild *et al.*, 2014; Hughes *et al.*, 2016).

2.6.6.2. Content of Education

All of the studies discussed the overview of diabetes, including myths and facts, risk factors and information about the disease (Culica, Walton and Prezio, 2007; Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Prezio *et al.*, 2014; Hughes *et al.*, 2016; Paz-Pacheco *et al.*, 2017; Schoenberg, Ciciurkaite and Greenwood, 2017), physical activities and exercise (Islam *et al.*, 2013; Paz-Pacheco *et al.*, 2017); seeking social support, and managing stress (Castillo *et al.*, 2010; Islam *et al.*, 2013; Rothschild *et al.*, 2014).

2.6.6.3. Intervention Provider

The term "intervention provider" pertains to the individuals responsible for delivering the intervention and carrying out associated tasks. When describing the intervention,

it is crucial to address critical details, including the required skills and expertise of the providers, any additional training they may have undergone, and the presence of incentives and reimbursement for their involvement (Hoffmann *et al.*, 2014). The interventions offered by CHWs in DSME primarily involved health and nutrition promotion activities, including FCIs. CHWs serve primarily as educators and are trained in diabetes management, with differences in the number of hours of training reported across studies. Most studies reported that CHWs served primarily as educators in DSME in general, including FCIs. Only one study reported that the CHW acted as part of the team diabetes managements, but they were solely responsible for providing DSME and physiological support for diabetic patients (Vaughan *et al.*, 2017).

CHWs were referred to as trained CHWs (Culica, Walton and Prezio, 2007; Spencer *et al.*, 2011; Prezio *et al.*, 2014) or bilingual CHWs (Culica, Walton and Prezio, 2007; Islam *et al.*, 2013; Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Vaughan *et al.*, 2017).

Two studies provided details regarding the education prerequisites for individuals serving as CHWs in two different contexts. In the rural areas of the Philippines, it was found that no specific educational background was necessary for CHWs to be appointed to deliver DSME (Paz-Pacheco *et al.*, 2017). However, in the US, where the CHWs were responsible for providing DSME interventions to the underserved Hispanic population, they were required to possess a high school equivalency certificate (Culica, Walton and Prezio, 2007; Prezio *et al.*, 2014).

CHWs were trained by HCPs as a member of the team's research project. The training duration ranges from 17 to 20 hours of workshop combined with one-on-one or two-day workshops without specifying the number of hours spent on training. The

education material covered diabetes knowledge, dietary assessment, meal planning, technical interviewing skills (Culica, Walton and Prezio, 2007), human subjects' protection, standard use of blood glucose metres, BP monitors, and analyser tool for A1C evaluation, and use of written instruments for data collection and reporting (Castillo *et al.*, 2010). Furthermore, one study explained how CHWs gained the patients trust by having certificates of their training to delivery of diabetes prevention education (Islam *et al.*, 2013).

2.6.6.4. Method of Delivery

This section of TIDieR guidance considers if the intervention will be implemented individually, targeting a single participant, or if it involves a group of participants, and provides information regarding the group size. Furthermore, the delivery method is described, clearly indicating whether the intervention is conducted through face-to-face interactions or employed distance-based approaches (such as telephone, surface mail, email, internet, DVD, or mass media campaigns) or if it utilized a combination of various modes (Hoffmann *et al.*, 2014).

In the scoping review, the delivery method of included studies was primarily through face-to-face sessions, typically in small groups (with 5-15 members), with multiple intervention sessions ranging from 4 to 36 meetings. Three studies (Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Hughes *et al.*, 2016), utilized individual educational interventions, while Castillo *et al.* (2017) and Islam *et al.* (2013) reported the involvement of family and friends in group interventions.

2.6.6.5. Time and Duration

Information about the "when and how much" of an intervention varies depending on the specific type of intervention. In the case of interventions involving multiple

sessions, additional details are required, such as the scheduling of the sessions (Hoffmann *et al.*, 2014). All reviewed studies concerned interventions in which CHWs delivered DSME, which included teaching about footcare, with each intervention session lasting 60-150 minutes. Study participants also received one-on-one visits from the CHW at months 3, 6, and 9, ranging from 60 to 99 minutes in duration, to discuss diabetes management challenges and strategies with patients.

2.7. Summary

The CHWs had various roles in delivering education for diabetes self-management techniques, including as educators and care coordinators, covering patient care, health, and stress management. In general, the footcare education was included as part of the intervention. Most of the studies reported positive behaviour adherence of the frequency that participants checked their feet over the previous seven days by using the SDSCA. However, this measure is not sufficient to thoroughly assess the needs of all patients in preventing DFU. Furthermore, none of the papers reported a common outcome to evaluate footcare knowledge. The included studies covered many aspects of diabetes self-management which may not have predicted more specific outcomes in footcare education from CHW interventions.

Most studies used curriculum culturally and linguistically tailored as the intervention referred to disadvantaged groups, underserved medical services, or minority groups. Two studies also considered patient level literacy (Prezio *et al.*, 2014; Schoenberg, Ciciurkaite and Greenwood, 2017), and supported patient navigation by providing assistance in obtaining clinic visits (e.g., contacting providers' offices for

appointments, making reminder calls, and facilitating transportation and dependent care) (Schoenberg, Ciciurkaite and Greenwood, 2017).

The findings of several studies demonstrated the effectiveness of FCIs delivered by CHWs as part of diabetes care in general, particularly when engaging in culturally appropriate liaison with underserved communities, lacking access to appropriate healthcare services. The evidence of footcare education delivered by CHWs looked promising. The review provides preliminary information around place of intervention, method of delivery and how the intervention can be tailored in underserved community. However, procedure of intervention, time and duration alongside content of education needed further investigation in order to gain comprehensive information on the core components of an FCI delivered by CHWs. Furthermore, the findings suggested that footcare education delivered by CHWs can be considered a potentially effective intervention to prevent DFU.

2.8. Justification for the Study

Most of the identified studies were conducted in the US among ethnic minority populations facing barriers to healthcare access, highlighting the conditions of medically underserved communities and health disparities in this context, which can give insights, with careful adaption, for developing country contexts in seeking to develop and implement education interventions delivered by CHWs (i.e., such insights are pertinent to the case of Indonesia, which is the focus of this study).

Most studies used curriculum culturally and linguistically tailored. To start developing an intervention, it is essential to analyse existing evidence to identify the health issue

and its causes. Additionally, it's important to comprehend the contextual factors linked to the situation (O'Cathain, Murphy and Nicholl, 2007).

Acceptability, barriers, and drivers to understand the capacity and agency of CHW to deliver such programmes are poorly understood, and only two studies presented data on the acceptability of the education programmes offered. It is crucial to identify any barriers or obstacles that may limit the effectiveness of intervention pathways because complex interventions may fail if unexpected hurdles are not addressed (Campbell *et al.*, 2007).

No further explanation was given about practice guidelines on how CHW-delivered footcare for diabetic patients, since each study embedded footcare education material as part of a general DSME package. The type of FCI, in terms of foot screening or foot self-management, along with the precise nature and intensity of intervention, were not described substantially.

Furthermore, no available description was found of training for CHWs or characteristics of the CHWs delivering the intervention. Training is an essential element of all CHWPs (O'Brien *et al.*, 2009) and the issue of a lack of preparation and knowledge concerning particular health problems (e.g. diabetes) and patient needs is a commonly cited disadvantage of using CHWs (Sranacharoenpong and Hanning, 2011; Aponte, 2015; Policicchio and Dontje, 2018). Therefore, further research is needed to develop an FCI delivered by CHWs to combat incidence of DFUs though preventive measure for DM patients with LR-DFUs.

2.9. Research Project Design

There is high prevalence of T2DM in Indonesia with commensurately increased DFUs, and in the absence of effective diabetes footcare education leads to initially low-risk patients developing DFUs, fundamentally undermining their QoL and escalating healthcare costs for their treatment. It is acknowledged that essential footcare education delivered by CHWs as part of community programmes, might offer an effective strategy to counter DFPs in Indonesia. Additionally, it is worth considering the unique characteristics of CHWs in Indonesia, who possess different resources and training compared to their counterparts in high-resource countries. Unlike CHWs in those countries, who undergo specific training to fulfil educational roles and provide comprehensive diabetes prevention programmes (Spencer *et al.*, 2011), CHWs in Indonesia typically focus on delivering particular topics within community health programmes (Oendari and Rohde, 2021), as explained in the previous chapter.

This study was focused on the early stages of intervention development, mapped to the New MRC Framework (Figure 8). This study's focus was to develop the core components of a diabetic FCI delivered by CHWs (hereinafter referred to as FIne-CHWs) prior to feasibility testing of the intervention.

This study has developed FIne-CHWs as a new diabetic FCI delivered by CHWs and aims to be a solution for real-world practice in DFU prevention in Indonesia. This intervention required early and strong engagement with patients, practitioners and policymakers to adapt to the intervention context (Skivington *et al.*, 2021) or the local system, to guarantee the success of the intervention (Hodgins *et al.*, 2021) particularly in delivery of CHW-led models of diabetes prevention (Gore *et al.*, 2020). This took into account the emerging complexities of the intervention components and their

interactions with the context in which the intervention will be implemented. The FIne-CHWs was developed for implementation in the Indonesian context, which has considerably lower healthcare resources (Soewondo, Ferrario and Tahapar, 2013) compared to high-resource countries where diabetic FCIs have been implemented (Culica, Walton and Prezio, 2007; Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Hughes *et al.*, 2016; Schoenberg, Ciciurkaite and Greenwood, 2017; Vaughan *et al.*, 2017)

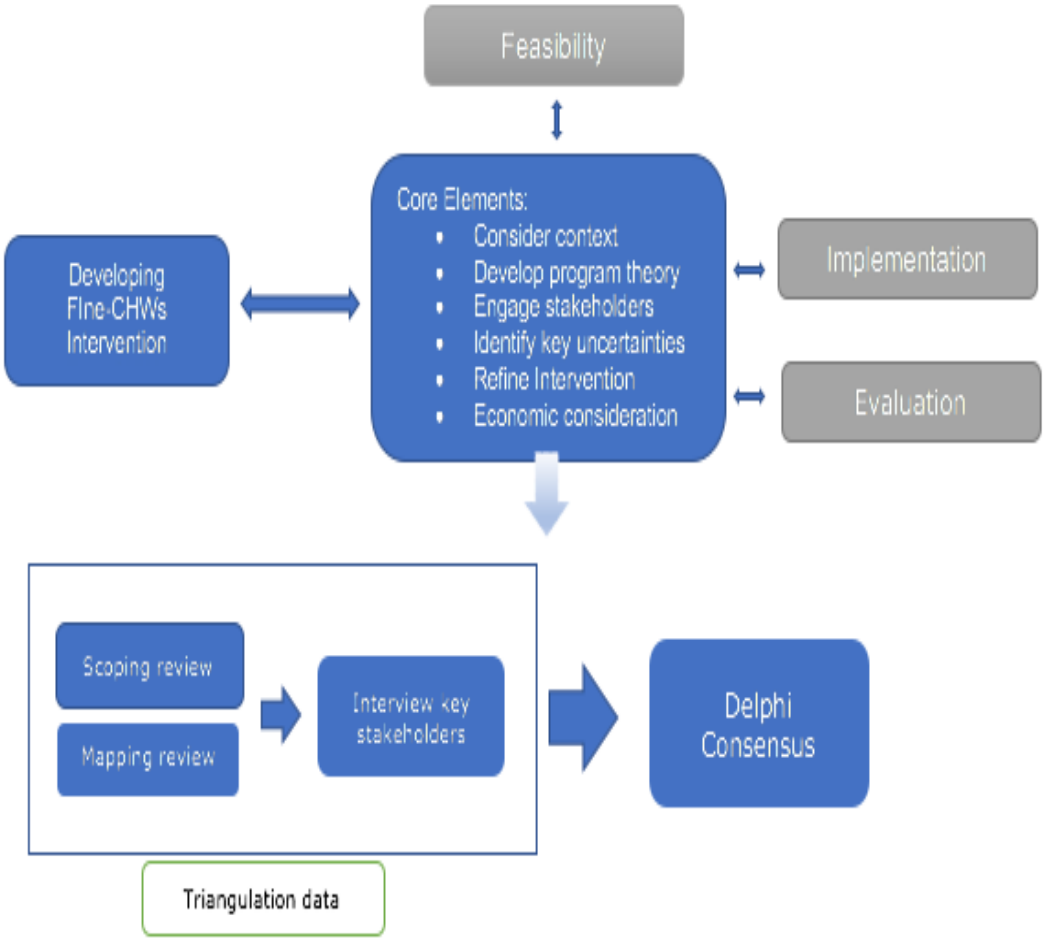


Figure 8: Study diagram adopted from new MRC Framework

Source: Skivington *et al.* (2021)

2.10. Aim and Objectives

2.10.1. Study Aim

Develop a relevant, evidence-based educational intervention for footcare to be delivered by CHWs for T2DM patients with LR-DFUs in Indonesia.

2.10.2. Primary Objectives

1. Identify the core components of the footcare education intervention delivered by HCPs for T2DM with LR-DFUs, including method of delivery; procedure; intervention provider; pre-existing specific skills; location of intervention; timing and duration of intervention; educational content and training material.

2. Identify acceptability and practicality of core components of FCI delivered by CHWs.

2.1. Explore the perceptions and experiences of patients and families, in terms of their prior learning, barriers, and facilitators of self-footcare and their view on the acceptability of footcare education being delivered by CHWs.

2.2. Explore CHWs' perceptions and experiences of barriers to and facilitators of implementing diabetic footcare education.

2.3. Explore barriers and facilitators perceived by community nurses and physicians relating to teaching CHWs and supervising CHW-delivered interventions.

3. Refine core components and modelling FCI to be delivered by CHWs (FIne-CHWs) for T2DM patients at low-risk of DFUs in Indonesia.

2.11. Thesis Structure

Chapter One introduces the project, providing an overview of its scope of DFPs in Indonesia. It specifically focuses on the role and position of CHWs and the health policy regulations pertaining to preventing NCDs in Indonesia and how the UK's new MRC Framework could be used to guide the complex intervention development.

Chapter Two provides a comprehensive review of existing literature on footcare education delivered by CHWs. This chapter also justifies the research and develops research aims and objectives.

Chapter Three presents the methodology underpinning the study, exploring the choice between a positive or a post-positivist paradigm. Additionally, it discusses the selected research method aimed at elucidating the research position.

Chapter Four presents a mapping review of FCIs delivered by HCPs to complement the evidence presented in Chapter One on footcare education provided by CHWs.

Chapter Five presents interview method including development of interview guidance, recruitment of participants interviews of key stakeholders alongside transcription and data analysis.

Chapter Six presents the outcomes derived from the interviews, which include identifying emerging themes resulting from the analysis of the interview data alongside a comprehensive discussion and conclusion complementing this chapter.

Chapter Seven presents the interventions' core components through a triangulation process that combines scoping and mapping review with interview data from the previous chapter. These components are then subjected to a Delphi consensus,

involving an expert panel in diabetes education across Indonesia, to further refine the intervention.

Chapter Eight presents the outcome of the Delphi consensus and is followed by a discussion and conclusion.

Chapter Nine discusses and concludes this thesis, reviewing and contextualizing the findings, consolidating the outcomes of this research and facilitating the reader's understanding of the connections between each part of the research paper. The strengths and limitations of the study are considered, and recommendations are made for practice and future research.

2.12. Ethical Approval

Ethics approval (No: FMHS 238-0421) was obtained from the UoN on 24 May 2021 (see Appendix B). The study was reviewed by an Indonesian ethics committee (No: 652/UNG.KEP/ EC/ 2021) on 13 August 2021 (see Appendix B). The permission to conduct research from Government of Bandung City National and Political Unity Agency (No: PP.09.01/966-Kesbangpol/VI/2021) on 17 June 2021 which was followed by the Health Office of Bandung examined the protocol before providing permission to continue the research at the study site (No: PP.06.02/9266/Dinkes/VI/2021) on 22 June 2021 (see Appendix B).

Chapter 3

Methodology and Methods

This chapter provides an overview of the research methodology employed in the study. It outlines the rationale for choosing the specific method for data collection and analysis, aligning with the research objectives and questions.

3.1. Epistemological Underpinning

Epistemology is the study of the nature of knowledge to guide methodological choices, which provides a justification of the methods used to achieve the aims of a research project. Methodologies can suggest specific methods, aligned with specific academic disciplines, and influence the utilization and development of theory. The choice of method is restricted by and reveals the underlying methodological and epistemic decisions (Little and Carter, 2007). Traditionally, researchers have had to choose between two opposing paradigms, positivism and post-positivism, and purists believe that the two paradigms cannot be combined to study certain issues because of differences in underlying paradigmatic assumptions. Positivism relates to the quantitative and the epistemological belief that social observation can be undertaken in the same way that physical scientists treat physical phenomena. On the other hand, post-positivism is associated with qualitative methods (also called constructivist and interpretivism), positing that complex human social phenomena are not amenable to quantification and positivist objectivity, but can be studied using in-depth contextual analysis (Johnson and Onwuegbuzie, 2004; Denzin, 2010).

The pragmatic paradigm offers the combination of quantitative and qualitative methods in a compatible and systematic framework, whereby researchers can benefit

from the use of both in their empirical investigations (Denzin, 2010). Pragmatism is the epistemological foundation of mixed method research, whereby researchers frequently mix quantitative and qualitative approaches to study intelligible human behaviour in the social world, to cover deficiencies in quantitative methods in addressing the complexity of research in healthcare (O'Cathain, Murphy and Nicholl, 2007), improve the quality of health prevention programmes, and to understand the success of intervention strategies (Zhang and Watanabe-Galloway, 2014).

Mixed methods offer the capability of triangulating data, connecting findings from different research approaches (and indeed researchers) to achieve a holistic and comprehensive understanding of the researched phenomena. The advantages of data triangulation include increasing researchers' confidence in their outcomes, finding creative methods for data collection, thickening and enriching data, synthesizing and integrating theories, uncovering contradictions, and obtaining completeness (Johnson and Onwuegbuzie, 2004). This approach was predicated on assuming that the measurements were accurate if other research methods produced comparable results about a phenomenon. In contrast, divergent results indicate that one or more measurement instruments are flawed (O'Cathain, Murphy and Nicholl, 2007).

Triangulation can be used to investigate complex social phenomena that combine interpretivism and positivist elements. In projects that blend qualitative and quantitative methods, the paradigmatic differences between positivist and interpretivism perspectives undermine the interpretation of convergence as a measure of validity. Advocates of triangulation in cross-paradigm projects propose an expanded conceptualization of triangulation to capture the intricate and multifaceted nature of the social world. While measurement validity cannot be claimed,

triangulating methods can uncover various dimensions of a phenomenon and enhance understanding of its complex nature (Moran-Ellis *et al.*, 2006).

In simpler terms, instead of viewing different results as indicating flawed measurements, this perspective considers them to reflect various aspects of a phenomenon. This approach, known as generating complementarity, has become a popular way to describe mixed methods triangulation. The meaning of triangulation has evolved in social sciences, broadening its scope and implications for both social phenomena and the research process. Triangulation still emphasizes the epistemological value of mixed methods and focuses more on the complex and contingent nature of the social world rather than solely on the validity of findings. Another argument for using mixed methods is pragmatic, emphasizing research's technical rather than epistemological aspects. Applied researchers overlook paradigm differences in their research practice, treating different methods as not exclusive to any particular perspective (Moran-Ellis *et al.*, 2006).

3.2. Mixed Methods Research Design

This study employed an exploratory sequential mixed methods approach for FIne-CHWs development. This allowed the initial phases to inform the design of subsequent phases, and to identify a number of issues that need to be addressed before conducting a trial (Zhang and Watanabe-Galloway, 2014). Incorporating mixed methods approaches in intervention research results in better-quality evidence for synthesis. It can expose any shortcomings in the theory or implementation of a complex intervention, as noted (Noyes *et al.*, 2019). This study undertook to move towards developing a complex FCI, for patients living with T2DM, delivered by CHWs (FIne-

CHWs), using the new MRC Framework in the Indonesian context. This study followed three consecutive steps, as shown in Figure 9 and described below.

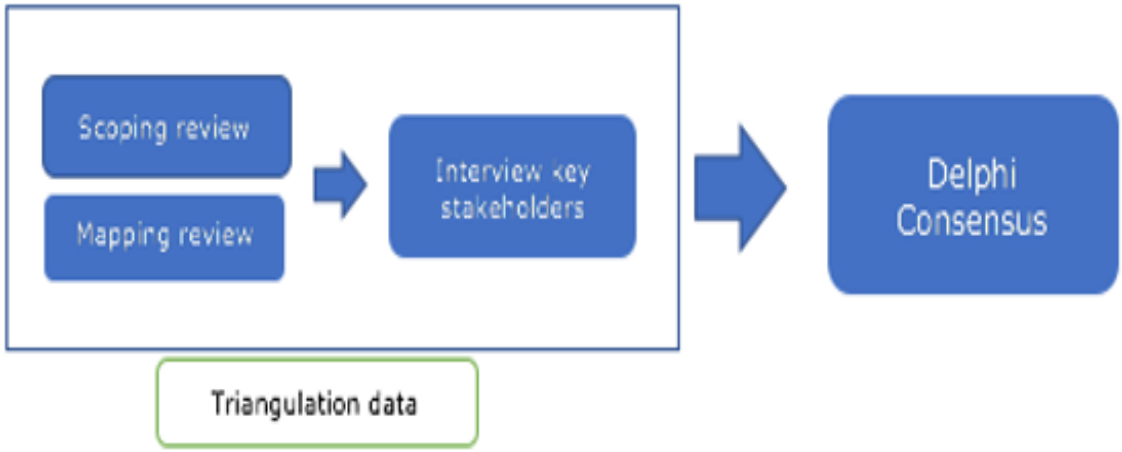


Figure 9: FIne-CHWs organogram

Source: Author

First, it summarized existing research evidence using scoping review and mapping review to identity core components of the FIne-CHWs. The review of existing literature was carried out at the beginning of the second chapter to provide a rationale for this research based on initial indications of how effective FCIs delivered by CHWs are; this summarized evidence was then completed with evidence from the mapping review in Chapter 4. The description of these core component interventions followed the TIDieR guidelines (Hoffmann *et al.*, 2014).

The second step was to conduct semi-structured interviews with patients, their family members, CHWs, and HCPs, which aimed to explore participants' opinions, experiences, and understanding of footcare, along with barriers and facilitators relating to the acceptability and practicality of CHWs delivering educational programmes in the Indonesian context. The qualitative findings from the scoping and mapping review were utilized to inform the interview schedule. The first two steps were then

synthesized using a triangulation protocol to inform the core components of the FIne-CHWs. The results were initially presented separately and subsequently reviewed to critically assess the extent to which they yielded generalizable conclusions or contradicted each other; Using triangulation approach is believed to enhance methodological rigor in mixed method study (Zhang and Watanabe-Galloway, 2014).

To obtain expert agreement on the components of FIne-CHWs, the statements regarding the core components of the FCI were subjected to a three-round Delphi consensus exercise. This exercise aimed to achieve consensus among experts regarding the identified components of FIne-CHWs. The exploration of research inquiries through various viewpoints, and by merging different methods with distinct biases is often beneficial (Johnson, Onwuegbuzie and Turner, 2007).

Conducting mixed methods studies requires significant time and resources, and researchers must possess proficiency in qualitative and quantitative research methods. This proficiency encompasses understanding basic assumptions, employing appropriate data collection and analysis procedures, and effectively interpreting the results. This expertise can be achieved either by individual researchers or through collaboration within a team of researchers, ensuring the maintenance of methodological rigour. However, a challenge identified in conducting mixed methods research is the lack of training in qualitative research (Zhang and Watanabe-Galloway, 2014).

I undertook various training modules during my PhD programme to address this issue and ensure rigour in mixed methods research. These modules included a systematic review course, research integrity module, research data management module, a foundation qualitative research module, training in thematic analysis methods, an

interview skills course, and quantitative training in statistics using SPSS (version 21). Additionally, the supervisory team has extensive experience in qualitative and quantitative research methodologies.

Formative research is usually carried out during the development or refinement of an intervention, aiming to enhance its feasibility, effectiveness, and prospects of long-term success. It utilizes qualitative and quantitative methods to gather data on participants' and stakeholders' perspectives, responses, and engagement in intervention activities. This research enables investigators to adapt initial assumptions and adjust planned objectives, strategies, and messages based on the collected information (Zapka *et al.*, 2007).

3.2.1. Scoping and Mapping Review to Present Evidence of Core Component Intervention

This study employed scoping review and mapping review, to summarize the current evidence on FCIs delivered by CHWs and HCPs. The previous scoping review of FCIs delivered by CHWs found that the core components of these interventions could not be clearly identified due to their integration within broader diabetes self-management packages (Chapter 2). While some components, such as the location, method of delivery and contextual adaptation, provided insights into how CHWs deliver FCIs, further investigation was required to fully comprehend the specific components of FCIs, such as procedure of intervention, the detailed delivery method, education content, and duration. Thus, a mapping review was necessary to collate further evidence on the core components of FCI delivered by HCPs to address the data gaps from the previous scoping review. Both reviews were employed to obtain a comprehensive understanding of the core components of FCI.

Scoping reviews, mapping reviews, and evidence and gap maps (EGMs) are types of evidence synthesis methods that have become increasingly popular in response to the demands of policymakers and other stakeholders. These methods are commonly employed to answer overarching research inquiries, with the primary aim of providing a comprehensive summary instead of concentrating solely on the efficacy of interventions. (Campbell *et al.*, 2023) (Table 5).

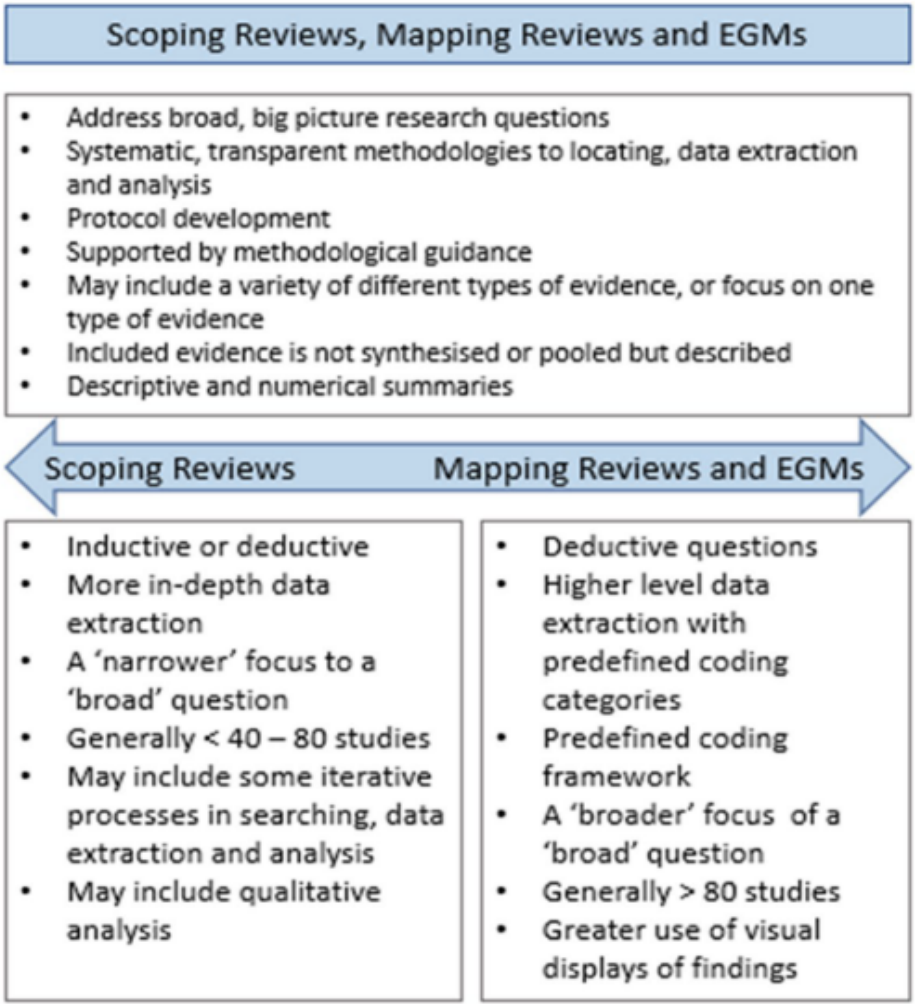
Scoping reviews enable a deeper and more exploratory method involving a smaller selection of studies and a more extensive data extraction process in contrast to mapping reviews. Mapping reviews deal with more defined questions featuring predetermined elements that can be categorized and coded, unlike the more open-ended nature of scoping reviews (Campbell *et al.*, 2023). The objectives of mapping and scoping reviews are to identify research gaps, neither review incorporates a formal quality assessment of the included studies (Grant and Booth, 2009; Saran and White, 2018; Campbell *et al.*, 2023). They do not aim to synthesize data but rather describe, categorize, and catalogue findings. A mapping review refers to the process of identifying and categorizing existing literature about a specific subject matter. A mapping review differs from a scoping review as the end result may require additional review work or primary research, and this result is uncertain beforehand (Campbell *et al.*, 2023). A scoping review includes research results in describing relevant evidence. In contrast, maps depict what is there without collating and summarizing the results of the studies. While the methodological procedures used in a scoping review are transparent and reproducible, similar to systematic reviews, the absence of quality assessment constrains the rigour of the review as is also found in mapping reviews (Grant and Booth, 2009).

Both reviews were synthesized and presented in tabular form followed by narrative commentary, the mapping review also used graphical (Grant and Booth, 2009) or descriptive reports from an output table (Saran and White, 2018; Campbell *et al.*, 2023). Data were synthesized in the included table by reviewers when disagreements or differences in the table between reviewers are discussed until a consensus is reached.

Scoping and mapping reviews aim to examine the quantity of literature, potentially based on study design and other important characteristics (Grant and Booth, 2009). Unlike systematic reviews, which can perform statistical meta-analysis to combine data, scoping and mapping reviews do not involve statistical pooling (Higgins *et al.*, 2019). Instead, these reviews present the data in a narrative format, including tables and figures when appropriate, to facilitate data presentation (Grant and Booth, 2009).

Both mapping and scoping reviews hold relevance for policymakers, as they can encompass the wide range of scientific information often required for policy-related inquiries (Campbell *et al.*, 2023), provide policymakers, practitioners, and researchers with a transparent and explicit method for identifying relevant research questions and more focused policies (Grant and Booth, 2009). Nevertheless, it is important to note that mapping methods do not amalgamate the discoveries and do not involve assessing the quality or potential bias of the studies. These aspects could restrict their usefulness in aiding certain categories of policy determinations (Campbell *et al.*, 2023). The chief features of scoping and mapping reviews are shown in Table 5.

Table 5: The Big Picture review family (commonalities and differences in approaches)



Source: Campbell *et al.* (2023)

Additional drawbacks of mapping reviews include their time-limited tendency and reliance on study design as the primary means of characterizing studies rather than conducting more comprehensive synthesis and analysis (Grant and Booth, 2009).

In the study of complex interventions, primary evidence can take the form of either qualitative or quantitative data. However, utilizing mixed method and qualitative approaches can offer valuable insights into the sources of complexity throughout the review process. Although there are not yet enough high-quality examples of these methods to fully understand their contributions to understanding the effects of complex

interventions, combining these approaches can lead to a more comprehensive synthesis of evidence (Petticrew *et al.*, 2013).

3.2.2. Semi-structured Interview was Analysed by Reflexive Thematic Analysis (RTA)

The qualitative paradigm emphasises the multiple and contextual nature of meaning and knowledge and research subjectivity as a resource for research (Braun and Clarke, 2022). Qualitative research is essential to understanding why something happens which is also helpful for identifying which are the "active ingredients" of the complex intervention, and which elements are not related to the treatment effect (Craig *et al.*, 2019). In certain situations, an explanation of the motive needs to be given: "motive" means the state of affairs upon which carrying out the action is contingent, while "genuine because-motives" are determined based on past experience (Catton and Winch, 1960). Schuetz (1953) proposed the postulate subjective interpretation of meaning based on the principles of constructing a course of action types concerning common sense experience, and social sciences adopt this principle to illuminate "social reality".

Such motives play a crucial role in analysing human interactions, revealing the motives that determine a given course of action shed light on the subjective interpretation of meaning. This is due to the unique role qualitative research can play in establishing the relative importance of outcomes, the acceptability, fidelity and reach of interventions, their feasibility in different settings and potential consequences on equity across populations (Flemming *et al.*, 2019).

Qualitative research involves various data collection methods, such as focus groups, semi-structured interviews, observation, and document review (Busetto *et al.*, 2016;

Busetto, Wick and Gumbinger, 2020). However, for the purpose of obtaining key stakeholders' opinions on FCIs delivered by CHWs, I excluded the documentation review and observation phase. The Focus Group Discussion (FGD), also known as group interviewing, is a qualitative research methodology that offers researchers the chance to systematically interview multiple respondents simultaneously. Nevertheless, it has some flaws, including less control over the interview process and susceptibility to groupthink, which can significantly affect the study's outcome (Boateng, 2012). Interviews, on the other hand, enable researchers to gain insight into a person's subjective experiences and are useful for obtaining unbiased data (Busetto *et al.*, 2016; Busetto, Wick and Gumbinger, 2020).

Semi-structured interview are commonly used in qualitative research, and are the most frequently used source of qualitative data in healthcare research (DeJonckheere and Vaughn, 2019). Semi-structured interviews follow an interview schedule with a focused structure for the discussion during the interviews but should not be followed strictly. Instead, the idea is to explore the research area by collecting similar types of information from each participant by providing participants with guidance on what to talk about, but allowing them to expound and elaborate on their own original insights (Kallio *et al.*, 2016). To develop the FIne-CHW intervention, I employed semi-structured interviews to gain a deep understanding of key stakeholder opinions and to get a sense of the dynamic properties of the context into which the intervention is to be introduced (Flemming *et al.*, 2019).

The interview data was analysed using Thematic Analysis (TA). TA is a method for developing, analysing, and interpreting patterns across qualitative data sets, which involves systematically coding data to develop themes. TA is not a methodology but

a collection method. There is a difference across the various TA methods which connect to and embed within a qualitative paradigm which clusters into three approaches: coding reliability, codebook TA, and reflexive TA (RTA). Coding reliability develops themes and codes from prior theory and research, or inductively. A codebook is applied by multiple coders to find evidence for themes. In qualitative research, a codebook contains a list of the codes used in qualitative data analysis research. This approach often produces themes that are relatively superficial or underdeveloped, in other word is typically a topic summary which maps closely onto data collection questions.

The other TA approach is codebook one, known as framework analysis, which allows researchers to compare data within as well as across a case (Braun and Clarke, 2022). Framework analysis is better adapted to research with specific questions, a limited time frame, a pre-designed sample, and other a priori issues (Srivastava and Thomson, 2009; Gale *et al.*, 2013). However, this approach is often closer to topic summary than shared meaning themes. Topic summaries do not evidence meaning organized around a central idea or concept that unites the observation. Still, the analyses report everything about a particular topic and typically focuses on surface-level or descriptive meaning (Braun and Clarke, 2022).

In this study, the interview data aimed to gather participants' opinions regarding FCI in the community to understand the acceptability and practicality of FIne-CHWs. Reflexive thematic analysis (RTA) was the type of TA employed, emphasising the role of researcher subjectivity as a primary tool for analysis. It recognises the researcher as an instrument within the research process and acknowledges that their perspectives

shape the results. This approach aligns with the principles of qualitative research (Braun and Clarke, 2022).

3.2.3. Qualitative and Quantitative Perspectives of Delphi Study

This study used a modified Delphi study. The Delphi technique is an approach used to gain consensus among a panel of experts. This is normally achieved through a series of rounds where information is fed back to panel members using questionnaires (Keeney, Hasson and McKenna, 2001).

The accuracy and superiority of the Delphi technique have shown that the Delphi method has distinct advantages in assessing the same topic over traditional group discussions, conferences, brainstorming and other interactive group processes (Hasson and Keeney, 2011). The Delphi technique provides a systematic approach to enhance decision- making, review criteria for areas where *prima facie* evidence alone is insufficient, and facilitate the development of quality (Boulkedid *et al.*, 2011). It has been used successfully in developing practice guidelines and has proven to be more reliable than other consensus assessment methods, such as the nominal group technique (NGT) (English *et al.*, 2020).

The NGT and the Delphi survey are widely employed formal methods for achieving consensus within academic research. These approaches involve gathering expert opinions on a specific subject and facilitating group agreement. However, while both methods serve this purpose, NGT distinguishes itself from the Delphi technique by utilising structured face-to-face meetings (Harvey and Holmes, 2012). The Delphi study approach is suitable for studies with large sample sizes or heterogeneous panel composition, and geographically widely separated groups (Hasson and Keeney, 2011; McMillan, King and Tully, 2016). Considering the prevailing COVID-19 pandemic

situation in Indonesia, it was necessary to adapt the methodology to accommodate the restrictions imposed by the pandemic. In-person meetings with experts were not feasible due to safety concerns, and the experts were geographically dispersed across different areas of Indonesia. Therefore, the Delphi study approaches were adopted to ensure the study could be conducted effectively under these circumstances.

Delphi has been designed as an iterative process to incorporate expert opinion into group consensus to obtain the most reliable consensus opinion from a group of experts with a series of intensive questionnaires interspersed with controlled feedback (Keeney, Hasson and McKenna, 2001, 2011). The Delphi technique provides evidence of content and face validity by gathering group opinions rather than decisions made by one person and representing "real world" opinions providing a confirmatory assessment on the subject and generating scaled items as in classical Delphi (Hasson and Keeney, 2011).

Keeney *et al.*, 2011 identified ten main Delphi categories: classic, modified, decision, policy, real-time, e-Delphi, technology, online, argument, and disaggregated. This study uses a modified (close-ended) Delphi because it recommends a method to verify face content and validity over the traditional Delphi method where the first round of traditional Delphi can make unambiguous broad statements and can lead to bias in the first place because using open-ended questions whereby broad statements could lead to bias from the outset (Hasson and Keeney, 2011). A modified Delphi study can use various methods, such as focus groups, interviews, or systematic reviews, to develop the initial round rather than the Delphi panel.

This study were used modified Delphi survey presenting closed questions followed by an opportunity for panel members to give free text comments (Keeney, Hasson and

McKenna, 2001), to encourage participants to provide a more detailed explanation of the topic in question as typical of qualitative survey (Braun, Clarke and Gray, 2017). Surveys are considered tools for exploring research inquiries that hold certain epistemological assumptions. However, experimental designs and analysing pre-collected data are also acknowledged as methods that reflect similar underlying philosophical principles (Bryman, 1984).

Within this context, social surveys are generally regarded as the preferred research instrument because they can be easily adapted to address these concerns. By employing questionnaire items, concepts can be measured and operationalized. Objectivity is maintained by keeping a distance between the observer and the observed, and external checks can be performed on the questionnaire. The study can be replicated by using the same research instrument in a different context. Additionally, the emergence of path analysis and regression techniques, which are well-suited for surveys, has helped alleviate the problem of establishing causality. This type of research is often described as positivist or empiricist in nature (Bryman, 1984). However, qualitative surveys refer to sampling a population for information, opinions, experiences, or practices (Braun, Clarke and Gray, 2017) without regard to pre and post-testing for reliability and validity. Reliability and validity checks were not conducted on the questionnaire used in this study, as the Delphi method employed in the research was specifically tailored for particular contexts and may not be easily generalized to other contexts.

In addition, Delphi's rounds include free-text responses that can provide valuable information, opinions, experiences, and practices (Braun, Clarke and Gray, 2017). Free-text qualitative surveys can be analysed using various methods, including content

analysis (Keeney, Hasson and McKenna, 2011; Wilkes, 2015), as well as discourse analysis, narrative, or thematic analysis (Braun, Clarke and Gray, 2017; Braun *et al.*, 2021). In this study, the data was analysed using the RTA approach.

The Delphi technique is acknowledged to be a method that can support either positivist or interpretivist studies (Day and Bobeva, 2005). Delphi has been described as a qualitative, quantitative, and mixed methods approach. The anonymous collection of narrative group opinion coupled with the tightly structured nature of the process and quantitatively described results renders the approach difficult to situate in a methodological category (Sekayi and Kennedy, 2017).

The Delphi method is a subject of debate regarding its classification as either a qualitative or quantitative approach. Some argue that the Delphi method encompasses positivist/quantitative and interpretative/qualitative ideals, suggesting that a combination of qualitative and quantitative perspectives should be used to assess the quality of any Delphi study. However, this recommendation has been largely ignored in previous research, as early studies primarily focused on demonstrating rigour from a predominantly quantitative standpoint, with only a few examples acknowledging the qualitative paradigm (Hasson and Keeney, 2011).

Nevertheless, an alternative approach has emerged, where the traditional positivist criteria for rigour are disregarded, and instead, strategies employed by qualitative researchers to ensure credibility are adopted. Several authors argue that the term "trustworthiness" is more suitable than reliability and validity for evaluating the effectiveness and appropriateness of a Delphi study (Hasson and Keeney, 2011). By adopting a more pluralist perspective, this study acknowledges a wide range of research options, depending on the research question being investigated.

Consequently, the choice of research method is driven by the nature of the question being asked rather than any particular methodological or philosophical standpoint (Noyes *et al.*, 2019).

3.3. Researcher Position and Reflectivity

In qualitative research, the researcher is recognized as an instrument that influences the outcomes of the study. This recognition impacts the results obtained (Phillippi and Lauderdale, 2018; Braun and Clarke, 2022). My interest in diabetes and DFUs began during my undergraduate nursing studies. It became common to encounter individuals with severe gangrene due to diabetes, waiting for aggressive treatments like amputations in specialized referral hospitals. The infected tissue emitted a distinct smell, and to alleviate the unpleasant odour, families often placed bowls of coffee under the hospital beds. This experience continued when I had the opportunity to supervise nursing students in a rural area at a public hospital.

During this time, I encountered a patient, an older man, who was awaiting the amputation of his left leg. Being in a teaching hospital, he would interact with medical interns and be interviewed by students. It was evident that he was frustrated because losing a leg would result in disability and dependency on others. This would prevent the patient from financially supporting his family and burdening their life. Witnessing patients' sorrow in the face of such unexpected and calamitous situations, which originated from minor foot ulcers and progressed to the need for amputation, I could not help but think that this entire situation could have been prevented if someone in his community had provided him with information about footcare.

To increase patients' understanding of diabetes prevention, I conducted a small research project on discharge planning. However, it became evident that delivering information to patients when hospitalized faced significant barriers regarding location, timing, and follow-up care, particularly for those from backgrounds with low socioeconomic status, who were admitted to small wards in public hospitals. The inconvenient place and timing posed real obstacles, compounded by a shortage of HCPs available to provide a comprehensive education.

On several occasions, when accompanying nursing students to provide education in the ISP-NCD post (Posbindu-PTM), I observed that CHWs had only been appointed to organize events. Moreover, the focus of nursing interns was primarily on educating patients rather than training CHWs to deliver health education effectively, and the potential role of CHWs in educating patients within the community was not fully optimized.

Overall, this experience led me to reflect on the importance of providing simple information to prevent recurring incidents of DFUs. It became clear that such information must be easily accessible within the community. CHWs could convey this information and serve as reminders within their local communities. However, it was also apparent that HCP may not always be present daily.

When considering the researcher's position, the concept of being an insider or outsider, as discussed by Braun and Clark (2022), I acknowledge that I am a woman, an Indonesian nursing lecturer but I also an outsider to the CHWs who will be delivering the intervention. Embracing my insider perspective, I aim to objectively examine the situation and view it as a valuable position for comprehending the data and crafting a narrative that aligns with the Indonesian context while minimizing biases. The

reflection and identification of biases by the researcher contribute to preliminary coding and an iterative study design, ultimately enhancing the rigor and trustworthiness of the research (Braun and Clarke, 2022).

3.4. Summary

The FIne-CHWs is first phase in developing intervention using a new MRC Framework (Skivington *et al.*, 2021). In order to understand context alongside barriers and challenges of this new intervention, a range of methods are available with increasingly well understood rationales using qualitative and quantitative evidence (Craig *et al.*, 2019). Mixed methods have been employed in developing the FIne-CHWs to understanding the contexts within which the intervention will be implemented. This involved understanding the perspectives of community actors and how they interact with health policy system. This study employed a combination of qualitative and quantitative paradigms, although qualitative paradigm played a more prominent role. The narrative analysis of scoping and mapping review and thematic analysis of individual in-depth interviews data was integrated in the Delphi study which traditionally embraced both quantitative and qualitative paradigms (Hasson and Keeney, 2011). Many epistemologists and scientists tend to adopt nuanced positions that involve a fusion of assumptions, beliefs, and preferred analytical methods (Johnson, Onwuegbuzie and Turner, 2007).

This study employed a mixed methods synthesis, which allows for incorporating multiple methods. It enables the integration of quantitative, qualitative, and mixed method evidence or data derived from primary studies, thereby facilitating data triangulation and a more panoramic understanding of the researched phenomena

(Noyes *et al.*, 2019). This methodological approach is gaining significance in health science research as it facilitates the generation of evidence regarding the effectiveness of health prevention, services, and intervention programmes. Combining quantitative and qualitative methods offers a more comprehensive understanding of research problems than employing either approach in isolation (Zhang and Watanabe-Galloway, 2014).

Chapter 4

Mapping Review

This chapter presents the mapping review approach used to summarize current evidence, which is part of the first step of developing a complex intervention using the new MRC Framework (Figure 10). The review sought to identify and collate evidence on the core components of footcare for the intervention delivered by HCPs to fill the paucity of data identified from the previous scoping review on FCI delivered by CHWs, as explained in the introduction chapter.

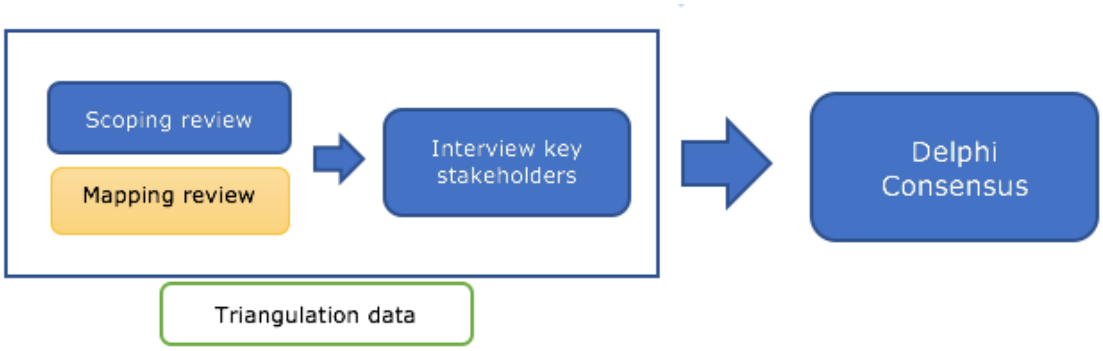


Figure 10: Organogram (Chapter 4)

Source: Author

4.1. Background

Mapping reviews are used to identify the key concepts that underlie research, allowing contextualization of in-depth systematic literature reviews in the broader literature and identification of gaps in the evidence base (Grant and Booth, 2009). In this case, the goal is particularly to summarize evidence for low-risk patients, since this study aims to develop interventions to be delivered by CHWs, and to equip them with the

necessary skills to educate patients in underserved populations about diabetes management.

The prevention of DFPs is recognized as far more essential than their cure, to reduce healthcare costs as well as to improve QoC and patient outcomes *per se*, and foot self-care awareness must be communicated early in the disease (McInnes *et al.*, 2011). It is recommended that the delivery of foot self-care educational interventions be initiated as early as possible, including among diabetic patients with low risk of foot ulcers, referred to as low-risk patients in this study, to prevent them from subsequently developing foot problems and ultimately progressing towards amputation (Fan *et al.*, 2013; Matricciani and Jones, 2015). However, it has been found that low-risk patients commonly do not receive proper footcare education, and they are commensurately disengaged from self-care practices compared to those at high risk of foot problems (Harwell *et al.*, 2001; Matricciani and Jones, 2015). Interventions are still prioritized for high-risk DFU cases, as they are expected to benefit more from preventive interventions than patients at lower risk (van Netten *et al.*, 2020). Nevertheless, the importance of routine foot examination in persons with DM and identifying the high-risk is underestimated in both inpatient and outpatient settings because of the asymptomatic nature of the disease (Alavi *et al.*, 2014).

There is limited research on the effectiveness of educational interventions on diabetic patients with low risk. Most interventions are delivered for newly diagnosed patients or diabetic patients in general as part of DSME, preventing various diabetes complications (Fan *et al.*, 2013). Recent reviews have focused on evaluating interventions for patients at risk of foot ulcers which included those with active DFUs, or excluded those with low risk patients, or used various intervention more than self-

foot care education (Adiewere *et al.*, 2018; Crawford, Nicolson *et al.*, 2020; van Netten *et al.*, 2020). There is an assumption that it is difficult to review the effectiveness of each category of such interventions because groups may respond differently to interventions that affect the magnitude of their effect on immediate and final outcomes (Fan *et al.*, 2014). A preliminary search found no current reviews of preventive interventions for diabetic patients at low risk or no risk of foot ulcers, therefore it was decided to undertake mapping of the existing evidence, as explained in this chapter.

4.2. Rationale for Review

The systematic review remains the gold standard for searching, compiling, evaluating, and summarizing the best available evidence on a clinical question. However, as the definition of evidence in healthcare has become more diverse, the types of questions that systematic reviews seek to answer have expanded, and other methods for synthesizing evidence exist, such as literature reviews, evidence maps, rapid reviews, integrative reviews, scoping reviews, and umbrella reviews. These reviews are needed to provide the best possible evidenced-based care (Munn, Stern *et al.*, 2018). In terms of their scope and content, systematic reviews have the narrowest focus, yet they are the most thorough in terms of their content, including coding, analysis, and reporting of effect sizes, intervention characteristics, and contextual factors. On the other hand, mapping/scoping approaches may employ a broader range of evidence to address questions beyond intervention effectiveness but report a more limited range of information about the reviews and primary studies they include (Saran & White, 2018).

The purpose of this mapping review was to provide a summary of current research evidence on footcare education for patients with LR-DFUs. The mapping review also examined the effects of different footcare education programmes on various interventions while scrutinising the components of footcare education interventions.

4.3. Aim of Mapping review

This mapping review was employed to identify existing evidence on intervention for diabetic patients at low risk of DFUs delivered by HCP to identify the core components of FCI. More specifically, the objectives were to: identify the components of the intervention, including method of delivery, procedure, intervention provider, pre-existing specific skill, location of intervention, place and duration of intervention, and intervention content (Hoffmann *et al.*, 2014). This review was undertaken using the Joanne Briggs Institute (JBI) guidance for conducting and reporting scoping reviews (which also applies to mapping reviews) (Campbell *et al.*, 2023), and the Preferred Reporting Items for Systematic Reviews extension for Scoping Reviews (PRISMA-ScR) (Peters *et al.*, 2020). Using this approach has the potential to benefit many stakeholders, as such comprehensive reporting allows readers to assess the appropriateness of the methods, and therefore the trustworthiness of the findings (Peters *et al.*, 2020).

4.4. Population, Concept, and Context (PCC)

4.4.1. Population

This mapping review focused on investigating studies involving patients with T2DM who are over 18. T2DM is the most common type of diabetes and accounts for over

90% of all diabetes cases worldwide. The initial assessment revealed limited studies that specifically targeted patients with low-risk foot ulcers. The exclusion criteria for this review included studies that focused on healthy individuals or those with medical conditions other than diabetes, individuals with active foot wounds, those suffering from severe psychiatric or cognitive disorders, or those who have experienced major diabetes complications such as proliferative retinopathy, cardiovascular disease, or lower limb amputation.

To obtain more evidence on this topic, I explored the evidence of FCIs provided by HCPs for patients with T2DM who fall into one of the following categories: (1) low-risk foot ulcers; (2) no current foot ulcers or without DFUs; or (3) those who receive FCI as part of their diabetes management in general, but without DFUs.

4.4.2. Concept

Interventions included structured education on footcare or self-care using different forms of health prevention, applying different methods, at various intervals, of different lengths, and with different educators, to help identify the appropriate method for a particular target population. FCIs consisted of basic foot information components for diabetic patients, including daily foot checks, receiving professional footcare and assessment, keeping feet clean and dry, protecting feet from temperature extremes, wearing appropriate footwear, minimizing the risk of foot complications, and exercises related to the legs (RNAO, 2007; ADA, 2020; Bus *et al.*, 2020). Interventions for diabetic patients in DSME pertaining to general topics of diabetes complications were eligible if patient education in footcare was evaluated with data of patients without DFUs. The review only considered interventions delivered by HCPs.

4.4.3. Context

This review assessed reported foot health outcomes, including indirect outcomes related to ulcer prevention, such as footcare behaviour assessment scores, knowledge and practice scores, and adherence to foot self-care. However, studies that only reported physiological interventions (such as muscle or nerve electrical stimulation), or general self-care interventions without foot-related content (such as insulin or BP monitoring and nutritional education) were excluded.

4.4.4. Study Types

This review considers comparative studies such as randomized controlled trials, non-randomized controlled trials, before-and-after studies, and interrupted time-series studies. To enable data analysis related to risk and benefits, observational (prospective and retrospective) and case-control studies were included. Qualitative studies comprised phenomenology, grounded theory, ethnography, action research and feminist research. Secondary research encompassed narrative reviews, evidence summaries, or systematic reviews, to gain a broad assay of the evidence. Opinion pieces, editorials and books were excluded. Studies not available in English or via the UoN Library were excluded from this mapping review.

4.5. Search Strategy

A four-step search strategy was designed to find relevant published and unpublished resources.

The following electronic databases were searched for peer-reviewed articles from the dates first indicated until June 2021. An initial step applied a scoping search, with a narrow preliminary search of PubMed, EMBASE, and CINAHL, using a set of search

terms around the major theme of the review question about the core component of FCI to identify an initial set of free-text and thesaurus terms. Moreover, consultation with a research librarian was conducted to design search strategies tailored to particular search engines (Wu *et al.*, 2012).

The second step was to implement a comprehensive search, testing initial terms in each database, after being modified and expanded as needed, to ensure thesaurus terms and free-text terms match the specific database using Medical Subject Heading and text words. The search terms were:

> Diabetes Mellitus (Mesh) OR Diabetes AND ("Footcare education" OR "Footcare" OR "Diabetic footcare" OR "Foot education" OR "Diabetes footcare" OR "Footcare knowledge" OR "Foot self-care")

The following databases were searched: CINAHL Plus with full text, EMBASE (Ovid), Medline (Ovid), Cochrane Library, Scopus, and Science Direct. Unpublished studies were retrieved from ProQuest Dissertations and Theses.

A third search was undertaken for institutional or organizational websites with public policies using the term (Guideline OR Consensus) AND "footcare") for the first 20 pages of the Google search. Studies included after the full-text review had guidelines in English and were strictly about the topic area; evidence-based (e.g., containing references descriptions of the evidence, and sources of evidence); and available and accessible for retrieval.

Fourthly, the reference lists of all identified articles were searched for additional studies (commonly referred to as a citation search).

4.6. Data Management: Study Selection and Data Collection Process

All identified articles from database searching were collated, and data were subsequently imported into EndNote VX9.1 (Clarivate Analytics, PA, USA). Removing duplicate articles were undertaken using EndNote, and other articles were deleted manually after I had examined the titles and abstracts of studies. After all duplicates were removed from included data, titles and abstracts were screened for assessment against the inclusion criteria for the review. The full text of included studies was retrieved and assessed in detail against the inclusion criteria. Contact with the authors of selected articles was undertaken for missing information if needed.

Table 6: Records by databases

Databases	Date searched	Records
CINAHL plus with full text	29/4/2021	4037
EMBASE (Ovid)	2/5/2021	144
PubMed (Ovid)	2/5/2021	92
APA PsycArticles	4/5/2021	142
Cochrane Library	2/5/2021	289
Scopus	2/5/2021	348
Science directs	2/5/2021	346
ASSIA	29/4/2021	246
Medline	2/5/2021	1147
ProQuest Dissertation and Theses	2/5/2021	1481
Total		8272

Source: Author

A third search was undertaken for institutional or organizational websites containing public policies for managing footcare education using the term ((Guideline OR "Consensus) AND "footcare") for the first 20 pages in Google search. A list of websites was obtained through preliminary Google searches and in consultation with

the supervisory team. Guidelines or consensus were scrutinized for footcare management for patients with a low risk of DFUs. A search was carried out on 21st April 2021 and found 23 websites related to footcare management and three articles reported footcare manual from international organizations were gathered from citation searching.

The PRISMA flow diagram (Page *et al.*, 2021) for the search and selection process in this review is presented in Figure 11.

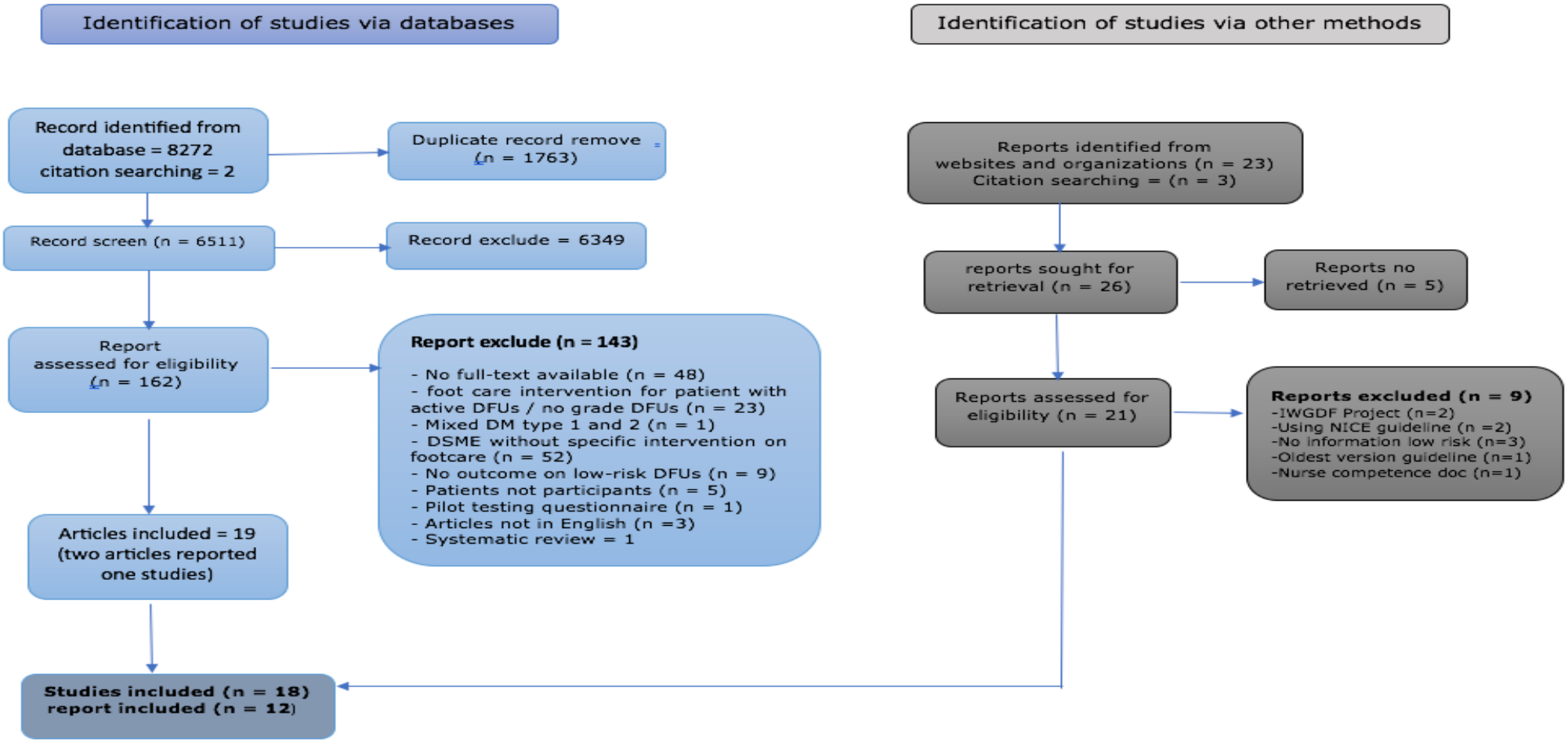


Figure 11: PRISMA flow diagram

Source: Author

In addition, 48 studies were not available in full-text articles for the following reasons: thesis previews (18), conference proceedings (4), research protocols (15), and not being available in full-text version (10). Despite emailing the authors requesting more information about their studies and asking a librarian at the Nottingham University Library, these articles could not be retrieved, thus these studies were not included in this review.

4.7. Data Extraction

Data were extracted from each publication and included in an evidence-based table using standard data extraction tools available at JBI SUMARI (Tricco *et al.*, 2018). These data had participant and study characteristics, research methods, intervention, and primary and secondary outcomes. I extracted the data and checked the data for content included in the table. Paper authors were contacted to request missing or additional data if needed, as described above.

4.8. Data Analysis and Synthesis

Disagreements or differences in the table were discussed with the supervisory team. The results presented in the evidence table included references, study design, population and outcome categories of intervention, the supervisory team reviewed data included in Tables in mapping review. A narrative synthesis was then used to summarize key findings from each study group based on type of study or specific intervention for type of risk of DFUs. The core components of FCI delivered by health professionals for T2DM patients (Table 8) are reported following the checklist and

Template Guide for Description and Replication of Interventions (TIDieR) (Hoffmann *et al.*, 2014).

4.9. Results

4.9.1. Characteristics of Sources of Evidence

The studies included in this review were published between 2007 and 2021, with the majority published after 2011. These studies were conducted in diverse countries, including the UK (n = 4), Iran (n = 3), China (n = 2), India (n = 2), Turkey (n = 2), the US (n = 2), and Japan, Canada, and Vietnam (with one study for each country).

Several studies utilized randomized controlled trial designs (n = 5), while others used group pre-test post-test (n = 4), quasi-experimental (n = 2), or cross-sectional study (n = 6) designs. One study did not report its design (Ooi *et al.*, 2007). Qualitative studies were not included in this review, as none reported the specific experiences of diabetic patients with LR-DFUs or without DFUs. Observational (prospective and retrospective) and case-control studies related to the risk of DFUs were presented in the review but were not examined for intervention components (see Appendix A), these studies were included to provide a deeper understanding of the area related to the risk of DFUs.

4.9.2. Intervention for Patients with LR-DFUs

Three articles reported FCIs for diabetic patients with LR-DFUs; two reported on one study conducted in Canada (Fan *et al.*, 2012, 2013), and one study was conducted in Vietnam (Nguyen *et al.*, 2019). To improve the effectiveness of DSME, both studies provided hands-on skills taught by nurses, followed by phone contact boosters. In Vietnam, Nguyen *et al.* (2019) used small-group education, whereas Fan *et al.* (2019)

provided one-on-one patient interaction in Canada. The intervention groups had positive outcomes in encouraging positive behaviour towards self-footcare, lowering the prevalence of foot risk factors for ulceration, and effectively reducing the occurrence of minor foot skin and toenail problems.

4.9.3. Observational and Case Control Studies Related to the Risk of DFUs

Cohort studies and case-control studies are two primary types of observational studies that aid in evaluating associations between diseases and exposures. Cohort studies can be prospective or retrospective. Prospective studies are carried out from the present time into the future, it has the advantage of being tailored to collect specific exposure data and may be more complete. Retrospective cohort studies, or historical cohort studies, are carried out at present and look to the past to examine medical events or outcomes (Song and Chung, 2010).

This review presented data from cohort studies that evaluated footcare programmes based on foot risk classification (Harwell *et al.*, 2001; Pollock, Unwin and Connolly, 2004; Kishore, Upadhyay and Jyotsna, 2015; Wu *et al.*, 2015; Wei *et al.*, 2019) (Appendix A). Wu *et al.* (2015) conducted a study in China to investigate the prevalence of risk factors among diabetic patients and found that 35.1% of patients were considered low risk, while 49% were at high risk for feet ulceration. In India, Kishore, Upadhyay and Jyotsna (2015) revealed that almost half of the diabetic patients attending a tertiary care centre had a foot at risk. Increasing duration of diabetes, lower educational, lower socioeconomic status and level of healthcare have significant correlation with foot at risk (Kishore, Upadhyay and Jyotsna, 2015).

Harwell *et al.*'s (2001) cross-sectional study in the US claimed that 30% of respondents were at high risk for future foot complications, and such patients were more likely than

their low-risk counterparts to report having an annual foot exam, using protective footwear, and perceiving themselves to be high risk for future foot complications. In the UK, Pollock, Unwin and Connolly (2004) reported that most patients had received some form of advice, with greater prevalence among high-risk patients (85.6%, 79.8–91.5) than their low-risk counterparts (77.1%, 68.1–86.2), responses to the knowledge questions revealed higher scores for high-risk patients, but there was no statistically significant difference in these scores (p=0.21) (6.8/11 and 6.5/11 for high- and low-risk patients, respectively), and the high risk patients footcare practice was better than the low risk patients foot care practice (Pollock, Unwin and Connolly, 2004). In summary, these studies emphasize the need for targeted footcare education and interventions to avoid further increasing DFUs risks.

It should be emphasized that one study conducted in the UK by Heggie *et al.* (2020) presented differing perspectives on the topic of annual screening for patients with LR-DFUs. A recent epidemiology study examined the cases of 10,421 individuals with diabetes who underwent foot screening at an NHS outpatient clinic. The study analysed data collected between 2009 and 2017 on patients diagnosed with diabetes during their first visit to screening clinics in Fife, Scotland (Heggie *et al.*, 2020). The research found that individuals with diabetes gradually transitioned from low to moderate risk. After two years, 5.1% of low-risk patients became moderate-risk, while around 9.9% and 11.3% changed after five and eight years, respectively. Peripheral neuropathy in the feet was the cause of risk status changes for the vast majority (94%). Additionally, only 0.4% of low-risk patients developed ulcers after two years, with 0.1% requiring amputation.

The study concluded that annual screening for low-risk individuals demands substantial NHS resources, which may hinder other preventive measures. There is no clear evidence to support this recommendation, and the optimal screening frequency remains uncertain. For individuals with DM, the risk of ulceration remains relatively constant over an 8-year timeframe. It may be suitable to modify the monitoring schedule from yearly to every two years for individuals at low risk (Crawford, Chappell *et al.*, 2020).

4.9.4. Core Components of Intervention (Using Comparative Studies)

The mapping review identified key themes related to the core components of FCIs. These themes included the educational materials used, the procedures employed in the intervention, including activities and processes. Additionally, the study explored the providers delivering the intervention and their background, expertise, and training. The delivery methods, such as face-to-face or multimedia, individual or group were also examined as well as the place of intervention. The timing, frequency, and duration of interventions were found to be crucial factors, and the review assessed whether the intervention was tailored to meet the patient's needs, which is an important element of patient-centred care and clinical effectiveness (Hoffmann *et al.*, 2014).

The core components of interventions could not be extracted from observational studies (cohort studies and case-control studies), because a cohort of subjects was selected based on exposure status, and outcome data (i.e. disease status, event status) (Song and Chung, 2010) whereby experimental (randomized or non-randomized design) comparative studies identify and assign samples of participants to different treatment groups for a given time duration, and analysis of their outcomes enable conclusions to be drawn which (subject to the nature of study setting, participants,

intervention, measures, analysis and interpretations etc.) can produce results that can be generalized for other analogous settings (Lau and Holbrook, 2016). However, the FCI as part DSME in general (Appendix A) could not be used for further descriptive analysis, since no specific information was available on FCI (Ghavami *et al.*, 2018; Yang *et al.*, 2020; Eroglu and Sabuncu, 2021).

This review examined the experimental study of FCI for diabetic's patients to gather information about intervention components. Table 7 presents the key data extraction from the included studies, and Table 8 presents the core components of the interventions they used.

Table 7: Included studies (FCI for patients with LR-DFUs and without DFUs)

Author/ year	Country/ study setting	Study design	N (subject) (intervention/ control)	Criteria inclusion/ exclusion	Intervention	Outcome
Nguyen *et al.* (2019)	Vietnam	Pre-test post-test, two groups	119 (60/59)	LR-DFUs	(1) Small group intensive education and hands-on skills session; (2) Footcare kit and documents; (3) 3 regular booster follow-up phone calls over 6 months.	The intervention group had significantly improved outcomes compared to the control group over 6 months in the following aspects: Improved preventive footcare behaviour ($p = 0.001$); Decreased prevalence of foot risk factors for ulceration (i.e. dry skin, corns/ callus) (OR: 0.04, 95% CI 0.01 – 0.13, $p < 0.001$).
Fan *et al.* (2012, 2013)	Canada	1 group repeated-measures	56	LR-DFUs	The intervention given over 3 weeks consisted of: (1) 1 hour 1-on-1 provider-patient interaction to discuss foot self-care strategies. (2) 1-hour hands-on practice of strategies (3) 2-10-minute telephone contact booster sessions.	Effective in reducing the occurrence of minor foot skin and toenails problems (all $p<0.05$) at 3-month follow-up. The foot self-care educational intervention was effective in improving: foot self-care knowledge, and self-efficacy behaviours (all $p<0.05$) at 3-month follow-up.
Borges and Ostwald (2008)	The U.S.–Mexico border	RCT, 3 groups	167	Excluded active foot ulceration or other foot pathology	A 5-min foot risk assessment using a monofilament, designed to encourage patients' involvement in assessing their feet. A 15-min brief foot self-care intervention that used educational and behavioural strategies, designed to increase self-efficacy for foot self-care and ultimately change foot Self-care behaviours.	A significant difference in foot Self-care behaviours between groups ($F (2, 135) = 2.99$, $p < .05$). A significant difference in the intervention ($t (47) = −4.32$, $p < .01$) and control groups ($t (46) = −2.06$, $p < .05$) between baseline and follow-up self-reported foot SCBs. Baseline diabetes self-efficacy was significantly and positively correlated with both baseline ($r = .335$, $p < .001$) and follow-up ($r = .174$, $p < .05$) foot self- care behaviours.
Fardazar *et al.* (2018)	Iran	Pre-test post-test, quasi-experimental, 2 groups	104 (52/62)	Included absence of diabetic foot	4 empowerment sessions on regular weekly basis (40–50 min. duration each).	No significant difference between the two groups of mean score of empowerments and footcare behaviour before intervention.

Table 7: Included studies (FCI for patients with LR-DFUs and without DFUs)

Author/ year	Country/ study setting	Study design	N (subject) (intervention/ control)	Criteria inclusion/ exclusion	Intervention	Outcome
						However, the mean score of empowerments and footcare behaviour of the experiment group was significantly higher than that of the control group in 1 and 3 months after the intervention ($P < 0.001$) The mean empowerment scores in all three stages of study in the experimental group showed an increasing trend compared to the control group: 18.5 ± 3.4, 23.9± 5.2, 34.7 ± 3.4 (vs. 19.01 ± 3.8, 19.2 ± 4.2, 19.8 ± 4.3).
Dincer and Bahçecik (2021)	Turkey	RCT	130 (65/65)	Included participants without diabetic foot wound Excluded patients with foot wounds	The intervention group received six sections consisting of one video with animation. Animation supported mobile educational app for diabetic footcare, and each section lasts approximately 1 minute 30 seconds. This video provides basic information on daily footcare to prevent foot ulcers in diabetic individuals.	The experimental group had significantly higher knowledge, self-efficacy and footcare behaviour levels than the control group. The knowledge level of patients in the experimental group concerning diabetic footcare was 3.6 (1.6–5) before the animation-supported M-DFCE, and 4.6 (1.6–5) 1 month after receipt of education. There was a significant increase in the knowledge level of the patients in the experimental group about footcare ($p = .001$). The diabetic footcare self-efficacy levels of the individuals in the experimental group increased significantly after the animation-supported M-DFCE (first assessment 59/90 (6–90], final assessment 76 [31–90]) ($p = .001$). The diabetic footcare behaviour score was 52 (16–72) before the app-supported education compared to 63/75 (30–75) 1 month after education. There was a significant increase in diabetic footcare behaviour level in the experimental group ($p = .001$).

Table 7: Included studies (FCI for patients with LR-DFUs and without DFUs)

Author/ year	Country/ study setting	Study design	N (subject) (intervention/ control)	Criteria inclusion/ exclusion	Intervention	Outcome
Rahaman *et al.* (2018)	India	RCT	101 (51/50)	Excluded patients with history of previous or present foot ulcer	Both groups received routine care which consisted of education regarding glycaemic control, dietary advice, exercise, medications, and footcare provided by the health-care personnel in the OPD. In addition, the intervention group was shown a short audio-visual display and given a pamphlet on diabetic footcare. After 1 month, both groups completed the questionnaire following which they received routine care. In addition, the intervention group was again shown the audio-visual display. At 3 months, both groups completed the questionnaire for the third time.	Knowledge scores in the intervention group at first, second, and third visits were 9.8 ± 1.8, 10.2 ± 1.6, and 11.0 ± 1.7, respectively. The knowledge scores in the control group at first, second, and third visits were 9.9 ± 1.7, 9.8 ± 1.6, and 10.0 ± 1.8, respectively. The change in knowledge score was statistically significant ($P < 0.001$) at the third visit compared to first in the intervention group, but not in the control group ($P = 0.62$). Practice score improved significantly ($P < 0.001$) in the intervention group in the second visit, but not in the control group.
Ooi *et al.* (2007)	UK	Evaluated the effect of group size and areas in which knowledge seemed to be most affected	59	Newly diagnosed T2DM (less than 1 year) without any diabetic foot infection or ulcers	Patients attended a 2-hour teaching session between November 2005 and March 2006.	A statistically significant improvement in footcare knowledge after the teaching session compared with before (69% to 85%, $P < .001$). Patients in the smaller group ($n < 10$) had significantly higher scores compared with the bigger groups ($n > 10$; $P < .025$).
Fujiwara *et al.* (2011)	Japan	Pre-test-post test	324	Low-risk and High-risk patients (IWGDF grade 1-3)	Group 0 (patients free of diabetic neuropathy) received 1 footcare session per year, comprising an education programme on nail cutting and foot self-care skills, with the aim of reducing the incidence of foot ulceration.	The 2-year footcare programme resulted in a decrease in the severity score of tineae pedis (Wilcoxon's signed rank sum test; $Z = -3.740$, $P < 0.001$). The percentage of patients free of tinea pedis increased from 14.8% (n = 13/88) to 37.5% (n = 33/88)
Moradi *et al.* (2019)	Iran	Quasi-experimental	160 80/80	No history of DFU	Within 3 months 90 text messages were sent as a message per day for each patient in the intervention group. The maximum size of each message contained 160 characters.	Patient diabetes footcare awareness significantly improved in the intervention group after training ($P<0.001$). The mean scores of preventive behaviours of diabetic

Table 7: Included studies (FCI for patients with LR-DFUs and without DFUs)

Author/ year	Country/ study setting	Study design	N (subject) (intervention/ control)	Criteria inclusion/ exclusion	Intervention	Outcome
					They were asked to pay attention to these texts, read them, and run them. Patients were followed-up for 3 months after the training to maintain their behaviours.	foot significantly increased in the intervention group ($P < 0.001$).

Source: Author

4.9.4.1. Sample Characteristics of Comparative Studies

The comparative analysis comprised nine studies conducted in various countries, including Canada, India, Iran, Japan, the UK, the US, Turkey, and Vietnam. The studies included participants from both high and low-resource countries, with sample sizes ranging from 56 to 324 participants. However, most of the included studies did not report specific clinical outcomes such as the incidence of foot ulceration, amputation, callus development, fungal infection, or duration of hospital admission for DFPs as these are several outcomes used to measure success of FCIs (Dorresteijn and Valk, 2012), except for two studies that reported the effectiveness of FCI in reducing minor foot skin and toenail problems at a 3-month follow-up for diabetic patients with LR-DFUs (Fan *et al.*, 2013) and free of tinea pedis (Fujiwara *et al.*, 2011).

Nonetheless, all studies reported process outcomes, such as footcare knowledge scores and patient behaviour assessment scores, as expected outcomes in patient education for preventing DFUs. Statistically significant improvements were observed in footcare knowledge (Ooi *et al.*, 2007; Fan *et al.*, 2013; Rahaman *et al.*, 2018; Dincer and Bahçecik, 2021) footcare behaviour (Borges and Ostwald, 2008; Fan *et al.*, 2014; Fardazar, Tahari and Solhi, 2018; Moradi *et al.*, 2019; Nguyen *et al.*, 2019; Dincer and Bahçecik, 2021), self-efficacy (Borges and Ostwald, 2008; Fan *et al.*, 2014; Dincer and Bahçecik, 2021), and footcare practice (Rahaman *et al.*, 2018).

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
Nguyen *et al.* (2019)	Nurse educator Minor foot conditions assessed by medical doctors	(1) Video clip "Diabetic foot complication, facts and figures". (2) PowerPoint presentation (3) Group discussion	Community health centre	Foot assessment followed by multifaceted education session and hands-on practice in small group (8-10 participants/ group). Received written education materials (brochure, booklet, A3-footcare steps guide waterproof tip sheet) and footcare kit. Telephone booster and follow-up. Foot assessment.	60–75 min of small group multifaceted education. 3 regular booster follow-up phone calls over 6 months (at weeks 2, 10 and 20)	Family support is vital for elders in Vietnamese culture.	A. Awareness about diabetes and foot complications. DFU: definition, consequences, risk factors and complications; why is daily foot self-care important with diabetic patients? B. Knowledge about appropriate foot self-care. Daily foot self-check; appropriate foot self-care (do's & don'ts); appropriate footwear (hints) C. Seek help (when, where, how) - identifying foot problems. D. Practice foot self-care. Demonstrate foot self-care: wash, dry, moisturize, check feet, and trim nails; how to choose footwear; take-home message
Fan *et al.* (2012, 2013)	Nurse	2 one-on-one, face-to-face interactive teaching sessions, followed by 2 telephone contact booster sessions	Family health centre	Screening following intervention for eligible participants	Session 1: 1-hr lecture presentation and discussion Session 2: 1-hr foot self-care hands-on practice training. Both sessions given within the	The intervention incorporated activities addressing 3 sources of self-efficacy and provided patients opportunities to practice recommended foot self-care strategies,	7 topics related to awareness of risk factors; importance of thorough annual examination of feet by an HCP; daily self-care and self-monitoring of foot including daily washing and drying, moisturizing, inspecting foot for problems; massaging foot, and foot exercise; footwear; nail care; when to seek HCP help.

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
					first week, covering all 7 topics. The telephone contact booster sessions were each of 10-15 min duration, offered once a week over 2 weeks.	hypothesized to enhance patients' knowledge of foot self-care and perceived self-efficacy.	
Borges and Ostwald (2008)	HCP	Risk assessment: received a 5-min foot examination using the LEAP Abbreviated Diabetes Foot Screen. Self-footcare group received risk assessment for lower extremity amputation (LEA) and were asked to demonstrate the use of the monofilament and calculate a risk score. They received a brief (15-min) foot self-care intervention. Follow-up: participants demonstrated foot self-care using a foot self-care kit, containing a basin, a gallon of water, antibacterial non-	Non-emergency care in two community hospital EDs	Intervention in ED as patients awaited completion of visits, with no delay in ED care or prolongation of the visits	1. Usual care 2. A risk assessment group (5 minutes) Brief footcare self-care intervention (15 minutes) Follow-up 1-month visit	The guidelines for diabetes foot self-care are explicit and concise, so integrating foot self-care education into short windows of opportunity in office waiting rooms or EDs may prove effective for Mexican-American patients.	Intervention combined patient self-assessment of LEA risk with provider risk assessment and distribution of monofilaments which demonstrates the presence of "protective sensation" and a reduced risk of developing plantar ulcers.

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
		deodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror.					
Fardazar *et al.* (2018)	Doctor, diabetes expert, and mental health professional	Intervention through lectures, practically doing feet examination and special feet exercises, playing films, practicing, group discussion, question and answer, providing educational pamphlets and CDs. Followed by individual counselling about footcare with the presence of a doctor and diabetes expert, and psychological counselling with a mental health professional was provided in the clinic. Suitable socks for diabetic foot prevention were distributed among experiment group.	Two diabetes clinics	Facilities, limitations, needs and weaknesses of patients were identified after analysing data, and the empowerment plan was designed and implemented accordingly. The experimental group then participated in the Footcare Principles programme, based on empowerment strategies.	4 sessions of 40–50 min duration. For each of the subgroups, 4 sessions of empowerment were held on a weekly and regular basis. Follow-up at 1 and 3 months.	The experimental group participated in the Footcare Principles programme, designed based on empowerment strategies by providing stress management. The empowerment model was introduced at the Michigan Diabetes Education and Training Center.	4 steps presented in 4 sessions: 1. General introduction of diabetes, its mechanisms, and complications. 2. Definition of diabetic foot, types, aetiology, identification at-risk foot, risk factors, and warning signs. 3. Description of footcare principles (daily foot examinations, nail care and foot skin care measures, appropriate footwear [shoes and socks] selection criteria, and special foot exercises). 4. Stress management and providing solutions to overcome issues related to footcare.
Dincer and Bahcecik (2021)	Application developed by 15 experts in diabetic foot and mobile	The use of the mobile app was taught to patients by having them try out the app several	Diabetes clinics	Individuals in the experimental group were first informed	The intervention group received the Animation-supported mobile	Animation-base education. Animations can increase the	The app consists of cartoon animation video and contains the basic information required for successful footcare with educational

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
	technologies (certified diabetes nurses, certified wound care nurses, university experts in diabetes, university experts in mobile design, teaching technology experts, software specialists, etc.)	times under the supervision of the researcher. Patients were also taught how to reinstall the application if it became deleted, and their user-name and password were written down on a piece of paper and given to them.		about the use of the mobile app. The app was downloaded on the patient's phone by the researcher and a username and password created to protect privacy and confidentiality. The experimental group used the app to receive footcare education at home. Individuals received push notifications to do so twice a week. Push notifications containing visual cartoon images were sent twice a week to members of the experimental group to encourage continued use.	education apps for diabetic footcare each section lasting for approximately 1 minute 30 seconds. The 6 sections comprise a single video with animation.	effectiveness of teaching through their colourful and visual content and can make education more meaningful.	content covering all guidelines for footcare in diabetes (ADA, 2017; IDF, 2017) The video script was divided into 6 sections: (1) Diabetes and Foot Problems, (2) Daily Footcare, (3) What Kind of Socks? (4) What Kind of Shoes? (5) Nail Care and (6) Things to be Considered in Daily Life.
Rahaman *et al.* (2018)	HCP	The intervention group was shown a short audio-visual display and given a pamphlet on diabetic footcare.	Endocrinology outpatient department (OPD), All India Institute of Medical Sciences (AIIMS)	At baseline, the intervention and control groups were given questionnaires to fill out. Both groups then received routine care, which consisted of education regarding glycaemic control, dietary	A short audio-visual display (~9 min) on footcare	Audio-visual footcare patient education module in outpatient setting is an effective means to improve footcare knowledge and	The patient education module consisted of an audio-visual display and a pamphlet. First, a script covering all important preventive aspects of footcare practices as advised by ADA and National Diabetes Education Program (NDEP)

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
				recommendations, exercise, medication, and footcare provided by health workers at the OPD. In addition, the intervention group was shown a short audio-visual presentation and given a pamphlet on diabetic footcare. After 1 month, both groups filled out the questionnaire again, after which they received routine care. In addition, the intervention group was again shown audio-visual impressions. At three months, both groups completed the questionnaire for the third time.		practice in diabetic patients.	A short audio-visual display (~9 min) on footcare education was prepared. An educational pamphlet covering important aspects of footcare was made with the help of Centre for Community Medicine, AIIMS, New Delhi. The YouTube links of the audio-visual aid prepared are: https://youtube/N6W1ooSLdf8 and https://youtube/fgCifUg2pIA
Ooi *et al.* (2007)	Podiatrist	All sessions were provided individually.	Not reported	Patients recently diagnosed with DM or foot complications were recruited for educational sessions. All the teaching sessions had a similar amount of information about footcare and were	7 sessions and attending a 2-hour teaching session between November 2005 and March 2006. The first group consisted of teaching sessions	Not reported (NR)	All the teaching sessions had a similar amount of information about footcare, including risk factors for arterial disease, appropriate footwear, prevention of foot injury, and complications of DM.

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
				presented by a single podiatrist.	with more than 10 patients and the second with fewer than 10 patients.		
Fujiwara *et al.* (2011)	Nurse	Group 0 (patients free of diabetic neuropathy). Patients of this group received one session of footcare per year.	Endocrinology department	Discrimination of diabetic foot risk class. Patients were divided into groups 0–3 according to the diabetic foot risk classification of the IWGDF (Peters & Lavery 2001, IWGDF 2007). After discrimination of diabetic foot risk class, all patients joined the footcare programme administered by a footcare professional nurse according to the diabetic footcare programme. The study design was based on the conceptualization of the disease management for stratification of diabetic footcare. Each process cycle of disease management consists of identification, assessment, stratification,	The programme consisted of 30–60-min sessions per patient for 2 years. The frequency of the footcare sessions was determined by the risk classification.	A nurse-administered footcare programme based on the IWGDF's risk classification according to risk of DFUs Assessment evaluation of diabetic foot (initial phase or pre-treatment footcare). Patients underwent foot assessment according to the practical criteria for screening patients at high risk for DFU and the classification system developed by the IWGDF.	The contents of self-footcare skills included daily inspection of the feet, hygiene and advice on buying appropriate shoes. The patients were educated to avoid barefoot walking, prevent foot infection and burn, and not to remove the callus by oneself. Patients with callus were referred to an orthopaedic centre for fabrication of custom-made insoles or off-loading shoes

Table 8: Core components intervention delivered by health professional for T2DM patients low risk and without foot ulcers

Author, Year	Intervention Provider	Methods of delivery	Where	Procedures	Timing and duration of intervention	Tailoring	Educational content
				intervention and outcome evaluation of all patients.			
Moradi *et al.* (2019)	Not reported	Educational interventions were conducted in the intervention group, and the control group only received routine training. In the educational intervention, after receiving the cell phone number of the patient in the intervention group, on the same day, and at the same time, the same message was received regarding DFU prevention behaviour.	Community health centre	The educational intervention group received same time each day, the same messages regarding the preventive behaviours of the DFU. Within 3 months 90 text messages were sent as a message per day. Patients were instructed to read and practice the texts, with a three-month follow-up to track progress.	Within three months, 90 text messages were sent as messages per day to every patient in the intervention group. They were asked to pay attention to the texts, read them, and put them into practice. The maximum size of each message is 160 characters. Patients were followed up for three months after training to maintain their behaviour.	Educational intervention effectiveness was assessed via mobile calls on footcare knowledge and footcare practices in patients with T2DM.	Daily check feet for cuts, redness, sores, ulcers and blisters, daily washing and drying feet, using moisturizing creams to protect foot from drought, using shoes and cover properly for feet, properly trimming toe nails, not cutting off the edge of toe nails, not tampering with the warts and crests, and visiting physicians regularly.

Source: Author

4.9.4.2. Educational Contents

According to Hoffman *et al*. (2014), a comprehensive explanation of an intervention should include a detailed description of the physical and informational materials utilized, much like the ingredients needed for a recipe. The material provided to participants encompassed basic footcare information including:

1. Awareness about diabetes and foot complications, definition of the diabetic foot, its types, aetiology, the identification of at-risk foot, risk factors and warning signs; (Fan *et al.*, 2014; Fardazar, Tahari and Solhi, 2018; Nguyen *et al.*, 2019)
2. Daily self-footcare including daily washing, inspecting foot for problems, moisturizing, massaging foot and wearing proper shoes and socks and toenail care was the main educational content from all comparative studies (Ooi *et al.*, 2007; Fan *et al.*, 2014; Nguyen *et al.*, 2019; Dincer and Bahçecik, 2021)
3. Seek help (when, where, how) (Fan *et al.*, 2013, 2014; Nguyen *et al.*, 2019)
4. Importance of an annual foot examination by a HCPs (Fan *et al.*, 2013; Moradi *et al.*, 2019).
5. Stress management related to footcare (Fardazar, Tahari and Solhi, 2018).
6. Foot exercise (Fardazar, Tahari and Solhi, 2018).

This review also identified data about content of diabetic FCIs from manuals of footcare education from websites and organizations and also through citation searching. Reports were identified from various organizations, including NICE (2020), the ADA (Boulton *et al.*, 2018), and the IWGDF (Bus *et al.*, 2020), along with "Footcare education in diabetic patients at low risk of complications: a consensus statement" (McInnes *et al.*, 2011) (Appendix A). These manuals provide DFU risk

classification and the steps that should be followed by patients according to their risk classification.

Patients with no risk factors present except callus alone (NICE, 2020), or who are categorized as being at the low-risk grade 0 based on the IWGDF classification (Bus *et al.*, 2020), are advised to have annual foot assessments with the importance of footcare being emphasized, and patient's aware-raising is recommended for those who may progress to moderate or high risk (NICE, 2020). In addition, the ADA (Boulton *et al.*, 2018) recommends that patients with a very low risk (ADA risk category 0) should engage in education on topics such as routine footcare, athletic training, appropriate footwear, or injury prevention while patient with low-risk of foot ulcers (ADA risk category 1); LOPS ± longstanding, non-changing deformity also requires prescriptive or accommodative footwear.

Patients at moderate or high risk of developing DFPs are referred to foot protection services (NICE, 2020). All other categories are considered "at risk" or (IWGDF risk 1-3), and require more frequent foot screening, regular inspection, and foot examination than patients who are not at risk. Patients at risk of DFUs are advised to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors (Bus *et al.*, 2020). Patients at risk of foot ulceration (IWGDF risk 1-3) should be instructed (and then encouraged and reminded) to: inspect the entire surface of both feet daily, and the inside of the shoes that will be worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toe nails straight across; and avoid using chemical agents or plasters or any other technique to remove callus or corns (Bus *et al.*, 2020). This educational content is similar with footcare education was recommended by

Ireland's National Model of Diabetic Footcare (National Diabetes Working Group, 2011).

Notably, the IWGDF refers to their document as "Guidance", rather than a "Guideline", to underline that these documents are written for a general situation, and may require modifications for specific contexts. As acknowledged in their summary guidance, principles in the IWGDF Guidance need to be adapted to local circumstances. Specific recommendations in the Australian guideline concerning the indigenous population or rural and remote areas exemplify such "local translation" (Diabetic Foot Australia, 2016).

Information available from footcare guidelines taken from several websites indicates that the educational content for medium-risk and high-risk DFUs is similar (National Diabetes Working Group, 2011) and this is also found in personal footcare guidelines for the elderly without diabetes (The Scottish Goverment, 2013). Such basic information used to educate diabetic patients is commonly referred to as "self-footcare educational content".

4.9.4.3. Procedure of Intervention

Some FCIs were administered to patients after HCPs had examined their feet and determined the risk of foot ulcers (Borges and Ostwald, 2008; Fan *et al.*, 2014; Nguyen *et al.*, 2019). Following the discrimination of the diabetic foot risk category, patients were enrolled in the footcare programme, which HCPs administered according to the diabetic footcare programme. Fujiwara (2011) allocated patients into groups 0–3 according to their IWGDF (2007) diabetic foot risk classification.

Prior to the intervention, patients with a low risk of foot ulcers were screened by evaluation of their foot sensation, circulation, deformities, and prior foot ulceration history. The following were assessed as indicators of low risk for foot ulceration: 1) normal protective sensation as determined by a 10 g monofilament; 2) normal circulation of the lower extremities as determined by the presence of pedal pulses; 3) absence of foot deformities such as bunions, mallet toe, hammer toe, or claw toe as determined by the researcher; 4) patients' self-report of no history of ulceration or amputation, and the absence of ulceration (Fan *et al.*, 2013, 2014; Nguyen *et al.*, 2019)

4.9.4.4. Place of Intervention

The intervention was conducted in various settings across the studies. One study took place in a hospital (Borges and Ostwald, 2008), while the others were carried out in community health centres (Fan *et al.*, 2014; Moradi *et al.*, 2019; Nguyen *et al.*, 2019), diabetes clinics (Fardazar, Tahari and Solhi, 2018; Dincer and Bahçecik, 2021), and endocrinology outpatient departments (Fujiwara *et al.*, 2011; Rahaman *et al.*, 2018). The location of intervention was not reported in one study (Ooi *et al.*, 2007).

4.9.4.5. Intervention Provider

The educators who delivered the FCI in the studies reviewed were predominantly nurses (Fujiwara *et al.*, 2011; Fan *et al.*, 2014; Nguyen *et al.*, 2019), podiatrists (Ooi *et al.*, 2007; Moradi *et al.*, 2019), or unspecified HCPs (Borges and Ostwald, 2008; Rahaman *et al.*, 2018). One study used a multidisciplinary approach, involving physicians, nurses, and mental health professionals (Fardazar, Tahari and Solhi, 2018). Prior to the footcare education intervention, medical doctors assessed minor foot conditions before the nurse delivering footcare education (Nguyen *et al.*, 2019).

In study that employed multimedia platforms to deliver the intervention, the development was overseen by experts in diabetic foot and mobile technologies. These experts included certified diabetes nurses, certified wound care nurses, university experts in diabetes, university experts in mobile design, teaching technology experts, and software specialists (Dincer and Bahçecik, 2021).

4.9.4.6. Timing and Duration of Intervention

The intervention was administered through face-to-face interaction. The duration of the main session ranged from 20 to 120 minutes for the group, excluding the time spent on telephone contact reinforcement. Borges and Ostwald (2008) spent a relatively short time on education (20 minutes) compared to other studies, due to differences in the intervention settings (emergency department).

In two studies (Nguyen *et al.*, 2019 and Fan *et al.* 2013), participants received a telephone contact booster 2–3 times after the main session, each of which lasted approximately 10–15 minutes, offered once a week over two weeks (Fan *et al.*, 2013, 2014), and three regular booster follow-up phone calls were undertaken over six months (at weeks 2, 10, and 20) by Nguyen *et al.* (2019).

Multimedia platforms, such as mobile education apps, audio-visual aids, and pamphlets, were utilized in two studies to disseminate information (Rahaman *et al.*, 2018; Dincer and Bahçecik, 2021). The average duration of the Intervention in these studies was 9 minutes per session. Borges and Ostwald (2019) conducted a brief FCI in the emergency department while patients waited to complete their visits. The study found no delay in emergency department care or prolongation of the visit when patients received brief self-management footcare education during a short intervention period.

4.9.4.7. Method of Delivery

The educational FCIs were delivered in multiple forms, most often in face-to-face meetings. One study reported using varied methods to convey the information through lectures, practically demonstrating feet examination and special foot exercises, playing films, practicing, group discussion, question and answer, providing educational pamphlets and compact discs (CDs), followed by individual counselling about footcare with the presence of a doctor and diabetes expert, and psychological counselling with a mental health professional provided in the clinic (Fardazar, Tahari and Solhi, 2018). Individual face-to-face interactions included short patient teaching sessions in the emergency department (Borges and Ostwald, 2008), interactive teaching sessions (Fan *et al.*, 2014) or sessions delivered by a podiatrist (Ooi *et al.*, 2007). Small groups sessions was administered to groups of 8-10 participants in many studies (Ooi *et al.*, 2007; Fujiwara *et al.*, 2011; Rahaman *et al.*, 2018; Nguyen *et al.*, 2019).

Through the telephone contact booster sessions, participants were empowered to solidify their understanding of foot self-care, address any unresolved concerns, and review the critical components of daily self-care practices. This approach serves as a reminder to consistently prioritize these strategies in one's daily routine (Fan *et al.*, 2014; Nguyen *et al.*, 2019). To support proper footcare and prevent diabetes-related complications, patients were equipped with essential educational materials, including a brochure, booklet, and waterproof tip sheet outlining footcare procedures (Nguyen *et al.*, 2019). Additionally, a foot self-care kit comprising a basin, a gallon of water, antibacterial non-deodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror was provided (Borges and Ostwald, 2008).

Furthermore, one experimental group received suitable socks for diabetic foot prevention (Fardazar, Tahari and Solhi, 2018).

In addition, Moradi (2019) used text messages to deliver the intervention through the patient's mobile phone. Over three months, 90 text messages were sent (at a rate of one message per day).

4.9.4.8. Tailoring Intervention

Several studies have been conducted on diabetic FCIs in different countries. In Vietnam, family support was incorporated as an essential aspect of the intervention, considering the cultural norms for elders (Nguyen *et al.*, 2019). Stress management was also included in the intervention in Iran (Fardazar, Tahari and Solhi, 2018). Mobile phone delivery was utilized in two studies, one of which used animation-based patient education to make education more engaging (Dincer and Bahçecik, 2021).

4.10. Discussion

The present study conducted a mapping review to identify the core components of FCIs offered by HCPs to patients affected by T2DM with low risk of and without DFUs. In total, 18 studies with varying designs were included in this review to gather evidence of FCI. Of these, 12 comparative studies reported on groups of patients, including two that included LR-DFU patients, seven that included patients without DFUs, and three that included patients undergoing DSME. Additionally, six observational studies were also included. Furthermore, this review included 12 reports and manuals of footcare education from websites and organizations. The review included studies across diverse countries representing low- and high-resource settings. Further analysis was performed to identify the evidence of core intervention

components for patients with low-risk and without DFUs to inform the development of FCIs delivered CHWs.

There is limited evidence available to support effectiveness FCI for diabetes patient with LR-DFUs since only two studies examined this group. These interventions showed positive diabetic patients' behaviour for those with low-risk foot ulcers. Combined interventions with patients without DFUs and those with LR-DFUs were then employed to gain comprehensive evidence on the core components of FCI that review showed the effectiveness of the educational intervention across different groups of foot ulcer risk.

It is worth noting that the study evaluated interventions for LR-DFUs and had a broader scope of interventions for those without DFUs. Educating patients without wounds can encompass all types of DFU risks including those with LR-DFUs. At the same time, it is also less complex than tackling the complexity of present wounds, which require more specific treatment to avoid infection. Foot infection in a person with diabetes presents a serious threat to the affected limb and must be evaluated and treated promptly. All open wounds are colonized with potential pathogens that HCPs should promptly treat (Schaper *et al.*, 2017). Therefore, the intervention specifically developed for T2DM patients without DFUs is considered to have less risk than the intervention mixed with those with active DFUs. Notably, this intervention is developed for non-professional health workers such as CHWs who have undergone short training to undertake this education role in DFP prevention.

The trial and comparative studies included in this review provide evidence that preventive educational interventions for patients at risk of DFUs can be effective. The reviewed observational studies found data regarding assessing the risk of foot

ulceration. However, two studies conducted in the UK showed that interventions to prevent foot ulceration are effective (Crawford *et al.*, 2020; Heggie *et al.*, 2020). Nevertheless, it is generally considered unclear who would benefit most from receiving the interventions, so a change in the monitoring interval from annually to every two years for those at low risk would be acceptable (Crawford, Chappell *et al.*, 2020). Annual screening for people at low risk requires considerable NHS resources, at the expense of other preventative strategies or treatments (Heggie *et al.*, 2020).

However, the context of low-resource countries such as Indonesia, where DFUs are prevalent in patients over 50 with T2DM, differs significantly from that of developed countries like the UK. DFU patients are typically younger and experience peripheral neuropathy and poor glycaemic control. Many patients already present with extensive foot ulcers upon their initial visit (Yunir *et al.*, 2022). This finding emphasizes that the different settings may have different preventive strategies and approaches, leading to different health policies to tackle the incidence of DFUs. Furthermore, footcare education should be provided to all diabetic patients to prevent foot complications (Diabetic Foot Australia, 2016). This recommendation was also made to adapt to the particular needs of the indigenous population in Australia, who are considered to be at high risk of developing foot complications, and who therefore require foot checks at every clinical encounter and active follow-up.

Structured education on footcare or self-care is aimed at individuals with diabetes, their family members, or caregivers, as appropriate, at the time of diabetes diagnosis (NICE, 2020). The similarity in the information provided for individuals with mid-risk and high-risk foot ulcers, as well as personal footcare for elderly individuals, further supports the consistent basic content of education for all types of risk DFUs, including

those without DFUs across various sources, such as the guidance documents of ADA (2008), NICE (2020), IWGDF (2007), National Diabetes Working group (2011), and the Scottish Government (2013). The mapping review revealed basic footcare advice for those with LR-DFUs. However, apart from similar content concerning daily self-footcare, some studies also included awareness about diabetes and foot complications, seeking help (when, where, and how), while also emphasizing the importance of foot screening by HCPs; this advice was also recommended by all manuals.

Stress management was also included in the intervention in Iran (Fardazar, Tahari and Solhi, 2018). Psychological interventions may have the potential to improve self-care and reduce the morbidity and costs associated with DFU (McGloin *et al.*, 2021). Foot exercise was also offered for patients (Fardazar, Tahari and Solhi, 2018). Diabetic patients should be taught a home exercise regimen that focuses on preserving or improving ankle and foot range of motion. Activating ankle dorsiflexion, plantarflexion, inversion, and eversion ten times twice daily, as well as manually mobilising the forefoot into dorsiflexion, will help to improve foot range of motion, reduce peak foot pressure, and possibly prevent breakdown (Ritzline and Zucker-Levin, 2011).

While cross-sectional studies cannot show effectiveness, the observational studies found data regarding assessing the risk of foot ulceration (Harwell *et al.*, 2001; Pollock, Unwin and Connolly, 2004; Kishore, Upadhyay and Jyotsna, 2015; Wu *et al.*, 2015; Wei *et al.*, 2019). The classification of risk DFUs is needed prior to FCI in order for subsequent targeted treatment (Diabetic Foot Australia, 2016).

An intervention targeting LR-DFUs was effective in reducing the prevalence of foot risk factors for ulceration; the intervention significantly reduced minor foot problems,

such as calluses, skin dryness and cracking, infection, and trauma, which contribute to ulceration in diabetic patients who are at low risk for foot complications (Nguyen *et al.*, 2019). Treatment of pre-ulcerative signs is a critical element in DFU prevention (Schaper *et al.*, 2017). These procedures include removing abundant callus, protecting blisters, draining them if necessary, treating ingrown or thickened nails, and prescribing antifungal treatment for fungal infections. Such treatment should be repeated until the pre-ulcerative sign resolves and does not recur over time, preferably by a trained footcare specialist (Schaper *et al.*, 2017). However, this pre-ulcer treatment should also be considered for inclusion in a preventive programme if the intervention is delivered by CHWs who receive short training as footcare educators, taking into account the safety of patients and CHWs, so that these problems should be referred to HCPs. Hence, it is crucial to minimize invasive procedures conducted by CHWs and instead prioritize footcare education as a means to prevent and promote awareness about DFPs.

A variation in the mode of delivery, ranging from individual to small group discussions, was identified in this review, and educational material such as pamphlets was employed for patients to take home (Fardazar, Tahari and Solhi, 2018; Nguyen *et al.*, 2019). The small-group approach was used to promote engagement and encourage participation, and supplementary take-home materials were provided to reinforce the message conveyed during the face-to-face sessions. The materials were tailored to reflect local usages, norms, and practices pertinent to the intervention context (Adarmouch *et al.*, 2017).

In addition, the study also employed follow-up booster sessions using telephone contact, conducted 2-3 times and lasting around 10-15 minutes each, for low-risk

participants. A telephone follow-up led by nurses improved adherence to the diabetes therapeutic regimen, including footcare; the intervention lasted 12 weeks, with each session averaging 20 minutes and 16 phone calls per individual (Nesari *et al.*, 2010). The benefits of telephone support in chronic disease management include reminders to comply with regimen, prompting adherence to diabetes self-care, improved self-esteem, and a sense of worthiness. The convenience and low cost of telephone support make it a promising tool in managing chronic diseases (Wu, Forbes and While, 2010).

This review encompasses intervention providers from various HCPs, such as nurses, physicians, and podiatrists. However, no information regarding their training is provided, to deliver the educational intervention, the healthcare provider must demonstrate their knowledge and skills since the absence of symptoms in diabetic patients does not exclude the possibility of foot disorders, such as asymptomatic neuropathy, peripheral artery disease, pre-ulcerative signs, or even an ulcer. The skills required for such interventions include a comprehensive examination of the patient's feet while lying down and standing up and an inspection of their shoes and socks. Therefore, HCPs who provide such instructions must receive periodic education to enhance their skills in caring for patients at high risk for foot ulceration (Schaper *et al.*, 2017).

This review highlights several strategies that were employed to tailor FCIs. One study by Nguyen (2019) involved family members in the intervention, recognizing the cultural importance of family involvement. It is crucial to evaluate whether diabetic patients and their close family members or caregivers have understood the messages, are motivated to act and adhere to advise, and possess sufficient self-care skills (Schaper *et al.*, 2017). The review emphasizes the need for culturally tailored

interventions that are context specific, particularly a culturally sensitive design of educational interventions, particularly concerning literacy skills and cultural specificities in developing countries or among minorities (Adarmouch *et al.*, 2017). It is essential to display and deliver information in a culturally relevant manner to engage patients and promote understanding through simple behaviours that can be incorporated into daily self-care (Schaper *et al.*, 2017).

To conclude, the structured footcare education delivered by health professional using different method of delivery included length, duration, and number of sessions, content (i.e., in-person and technology-based, individual or group-based). Considerable variation in intervention components were found in all intervention categories in this review. However, this review found the important information regarding dose and duration of intervention, basic educational material including the foot self-care kit which can complete core components of intervention.

4.11. Strengths and Limitations

4.11.1. Strengths

Mapping review identifies research gaps, which is particularly important for interventions implemented with insufficient evidence (Saran and White, 2018). Employing this review approach made it possible to search for more extensive evidence related to LR-DFUs and diabetic patients without DFUs, as there is limited evidence available specifically for the former. A broader set of criteria was used, encompassing any study design and including manuals and other types of patients with risk of DFUs. The mapping review allowed for the selection and grouping of patients, addressing the scarcity of FCIs for LR-DFUs. The use of mapping approaches enables

incorporating a more comprehensive range of sources to find evidence on the core components of FIne-CHWs, addressing questions beyond intervention effectiveness, particularly in areas where sufficient evidence is lacking.

The studies in this review originated from various countries, including Western, Middle Eastern, and Asian countries. This diverse range of countries provides a broader context for the intervention, suggesting that the outcomes of this review can be applied to develop interventions in various settings.

4.11.2. Limitations

Certain studies within this review exhibited heterogeneity in various aspects, such as the length, duration, and number of sessions, as well as the content, method of delivery, and the mix of healthcare providers involved in multifaceted education methods, including teaching footcare practices. This heterogeneity posed challenges in consolidating findings regarding specific interventions (Carpenter, Dichiacchio and Barker, 2019). However, a mapping review allowed for a flexible and descriptive examination of the evidence, thereby addressing the scarcity of evidence in FCIs for diabetic patients with LR-DFUs.

This review was limited to search source of evidence written in English, which poses challenges in accessing healthcare policies and guidelines from non-English sources, particularly for health policy and procedures. This restriction resulted in limited information worldwide, especially from low-resource countries where the intervention is intended to be developed. However, the primary research included in this review was conducted in diverse countries, representing both high and low-resource settings. As a result, this review presents broader evidence to inform the development of the FIne-CHWs.

4.12. Conclusion

The present review used a mapping review approach to identify research gaps pertaining to interventions for LR-DFUs. Such an approach enables the researcher to categorize the evidence collected during the review process systematically. The study focused on two categories of individuals: those with diabetes without DFUs (including those at-risks), including patients with LR-DFUs. The evidence was considered relevant for developing core FCIs for both groups, despite their differing clinical presentations per guidelines from international organizations. Notably, both groups were characterized by the absence of active ulcerative wounds, considered serious conditions warranting further medical attention.

The current evidence showed that the promotion and prevention of DFUs has received less attention than treatment for existing ulceration, and that LR-DFUs patients might not be aware of the risk of diabetic foot complications. This situation calls for more support for HCPs to deliver preventive care, and reorientation of the care approach away from an exclusive focus on serving patients with present symptoms toward pre-emptively attending to those at lower risk of developing them. Notably, the observational study also provided data on the position of LR-DFU patients in healthcare services regarding screening and prevention strategies from high-resource countries which have different health service resources and delivery methods compared to low-resource ones. The findings indicate that more consideration should be given to the latest studies in the UK on screening for DFU risk (Crawford *et al.*, 2020; Heggie *et al.*, 2020)., which should be carefully adapted for different settings worldwide.

The mapping review approach employed in this study offers a broader scope of evidence regarding the risk of DFUs. Although the focus of this investigation centres on individuals without active DFUs, the ultimate objective of the study is to develop an intervention programme to be delivered by CHWs. These non-professional healthcare providers have undergone brief training and are tasked with serving the community. It is important for planners of CHWPs to consider the effectiveness and safety of specific intervention to be delivered by CHWs which must explore current evidence and evidence-based guidance (Glenton, Javadi and Perry, 2021). Accordingly, an educational intervention targeting patients without wounds is deemed a safer and more cost-effective approach for patients and CHWs. This approach is particularly valuable since patients without DFUs may still be at risk of developing such wounds, as they may have previously experienced DFUs or may possess underlying risk factors.

According to Schaper (2016), diabetic patients must learn to recognize potential foot problems and understand the necessary steps to take when issues arise. Education, when presented in a structured, organized, and repeated manner, can significantly contribute to preventing foot problems. This is achieved by enhancing patients' footcare knowledge, awareness, and self-protective behaviour and fostering the motivation and skills necessary to adhere to such behaviours. This approach is particularly crucial for low- and middle-income countries, where the shortage of HCPs is prevalent (Perry and Hodgins, 2021). Furthermore, the IDF (2021) reports that nearly 90% of undiagnosed diabetes cases are concentrated in these countries, this condition leading to poor glycaemic control and peripheral neuropathy. Notably, most patients in such contexts present with extensive foot ulcers during their initial visit

(Yunir *et al.*, 2021). Different recommendations are necessary to prevent DFP in such settings effectively.

The comprehensive review of interventions for low-risk patients identified the core components of intervention. This included patients without DFUs, as this group was deemed suitable for referral to the FIne-CHWs. However, information about the required capacity and skills of CHWs to implement the FIne-CHWs remains limited. Unlike recommendations available for CHWs' involvement in managing maternal and children's health (Gergen, Crigler and Perry, 2013) there is currently no established list of CHWs interventions for the prevention of NCDs, particularly in the context of footcare. Given this gap, gathering input from community stakeholders on the acceptability and feasibility of the FIne-CHWs is crucial. To address this, the study utilized semi-structured interviews with key stakeholders involved in diabetic foot prevention within the community. This approach aimed to supplement the findings from the scoping and mapping review with insights directly from those engaged in the field.

The core components of intervention from scoping and mapping review were then used to inform the interview schedule for the semi-structured interviews explained in the following chapter.

Chapter 5

Semi-Structured Interview Methods

This chapter presents the semi-structured interview method, including development of interview guidance, recruitment of participants interviews of key stakeholders alongside transcription and process analysis data (Figure 12). The previous scoping and mapping review informed the interview schedule in semi-structured interviews and then the outcome interview data along with the scoping and mapping review were used to inform core components of FIne-CHWs.

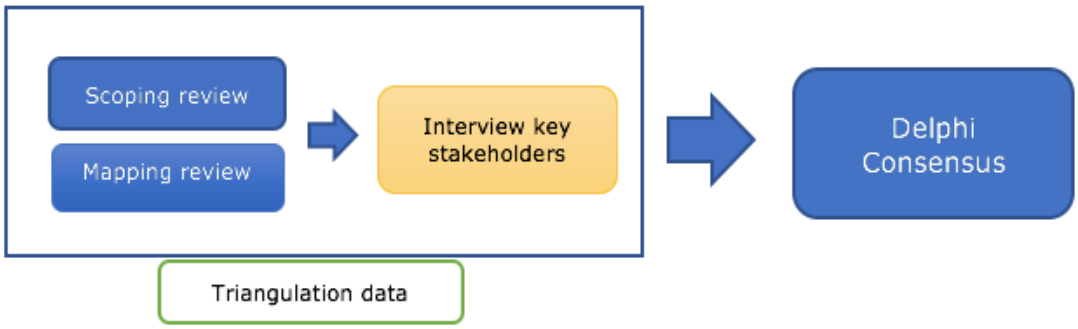


Figure 12: Organogram (Chapters 5 and 6)

Source: Author

5.1. Aims and Objectives

This study aims to develop a relevant, evidence-based educational intervention for footcare to be delivered by CHWs for T2DM patients with LR-DFUs in Indonesia, by achieving the primary objectives stipulated in section 2.10.2, including the specific research objectives of this interview chapter (to identify acceptability and practicality of core components of FCI delivered by CHWs), by undertaking to explore:

- The experiences of patients and families, in terms of their prior learning, barriers, and facilitators of self-footcare and their view on the acceptability of footcare education being delivered by CHWs.
- CHWs' perceptions of barriers to and facilitators of implementing diabetic footcare education.
- Barriers and facilitators perceived by community nurses and physicians relating to teaching CHWs and supervising CHW-delivered interventions.

5.2. Rationale for the Method

The mapping review presented in the previous chapter identified potential core components of an educational FCI. However, it is crucial to tailor the intervention to the specific healthcare context in Indonesia. Indonesia is a low-resource country where diabetic patients have different contexts regarding their educational and socioeconomic status. Additionally, limited healthcare resources further contribute to the heightened risk of DFUs among patients in Indonesia. It is essential to take the context of the intervention into consideration when designing preventive measures (Blackwood, 2006).

Additionally, complex intervention research requires early and strong engagement with patients, practitioners, and policymakers, to ensure interventions are acceptable, applicable, cost-effective, scalable, and transferable across contexts (Skivington *et al.*, 2021). Qualitative research is well suited to providing the evidence for a developing complex intervention because it explores people's views and experiences, the underlying issues, and how these are shaped by contextual factors, such as where and how the intervention was administered and by whom (Zapka *et al.*, 2007). It achieves

this through creating an in-depth understanding of the patient experience (Smith and Firth, 2011), and identifying the "active ingredients" of complex interventions (Zapka *et al.*, 2007)

In addition, this method is also used to assess the extent of the potential benefits or harms of an intervention, its acceptability to different stakeholders, the feasibility of implementation in different settings, and the potential consequences of different interventions on equity across populations (WHO, 2014), without anticipating unforeseen barriers, well-designed complex interventions could fail. Barriers can be cognitive, behavioural, organizational, sociocultural, or financial. They may occur early in the intervention process or during steps not previously considered or deemed necessary (Campbell *et al.*, 2007).

This qualitative study is reported using Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Appendix F), a single 32-item checklist grouped into three domains (research team and reflexivity, study design and data analysis and reporting), thus creating a comprehensive checklist covering the main aspects of qualitative research (Tong, Sainsbury and Craig, 2007).

5.3. Development of Interview Schedule

I conducted semi-structured interviews, audio-recorded and supplemented by memos and reflective field notes. The interview guidance (schedule) was developed prior to the interview based on the emergent findings from the reviewed literature (as expounded in the previous chapters such as content of foot care education in section 4.12), including questions on barriers and support for the implementation of FIne-CHWs, which was the main topic of the interview. The interview schedule also

covered questions about the delivery method, procedure, intervention provider, specific pre-existing skills, intervention location, duration, and content (Hoffmann *et al.*, 2014) (Appendix C). Semi-structured interviews include a short list of 'guiding' questions that are supplemented by follow-up and probing questions that are dependent on the responses of the interviewer-interviewees. All questions should be open-ended, neutral, and clear, using familiar language and avoiding jargon (DeJonckheere and Vaughn, 2019).

Participants in the semi-structured interviews comprised three groups: patients and family members; CHWs; HCPs (nurses and physicians). All participants were interviewed with a set of main questions, but with a different emphasis for different groups of participants. For example, all participants were asked about their experiences in foot problem prevention and possible barriers and support for developing FIne-CHWs. However, patients and their families were asked more about their experiences of diabetic footcare and what they expected from the FIne-CHWs; CHWs were asked about their confidence as intervention providers in delivering FIne-CHWs while questions for nurses and physicians were focused on health policy regarding preventive measures for DFPs. A set of questions guided the interview process in this study; however, it remained fluid, as interviews are an iterative process. This may lead to modifications in the guiding questions as the research progresses (DeJonckheere and Vaughn, 2019).

The interview schedule was divided into three parts; opening, interview questions and closing. The opening session aimed to establish rapport by introducing the interviewer and explaining the duration of the interview, followed by explaining media preferences as interviews were done remotely using video calls. I also emphasized that the

interview data would be anonymized and treated as confidential. The interviews started with easy context-setting questions before moving on to more difficult or in-depth questions using the flexible interview protocol and supplemented by follow-up questions, probes and comments (DeJonckheere and Vaughn, 2019).

5.4. Sampling Framework

There are several steps to designing and conducting a semi-structured interview, one of which is deciding which stakeholders will provide the best information to answer the research question (DeJonckheere and Vaughn, 2019). Stakeholders include individuals targeted by an intervention or policy, those involved in its development or delivery, or those whose personal or professional interests are affected (Skivington *et al.*, 2021).

This study aimed to develop core components of FCI in the community. The interviews needed to capture the community member's previous experience in managing diabetes prevention, such as diabetic patients and their family members who usually visit ISP-NCD (Posbindu PTM). CHWs are unregistered healthcare providers who manage ISP-NCD. HCPs are also responsible for delivering interventions to diabetic patients and serve as supervisors to CHWs. Hence, meaningful engagement with the right stakeholders is needed to expect positive impacts and increase prospects for achieving policy or practice changes when developing intervention (Skivington *et al.*, 2021).

A purposive sampling framework was applied to recruit 30 participants (ten patients, five family members, ten CHWs, three nurses and two physicians). In qualitative research no calculation of statistical power is necessary, instead, qualitative

approaches seek an in-depth and detailed understanding, and typically use purposeful sampling (DeJonckheere and Vaughn, 2019). A sample in qualitative research is not a purely objective, scientifically neutral entity; the recruitment process can be described as goal-oriented, and the best material does not necessarily come from the most stringent or clearly defined samples (Robinson, 2014).

5.5. Inclusion and Exclusion Criteria

Investigators identify the essential characteristics of the target group using inclusion criteria in order to answer to the study question. Typical examples of these are geographic, clinical, and demographic traits (Patino and Ferreira, 2018). Hence, geographical factors comprised an essential consideration in this study, since the CHWs and patients and their families should visit same ISP-NCD, as the HCPs who are in charge of supervising their health programmes.

Exclusion criteria are features of potential study participants who meet the inclusion criteria but have additional characteristics that could interfere with the study's success or increase their risk of an unfavourable outcome (Patino and Ferreira, 2018). This study initially intended to include only those patients at low-risk of DFUs. However, as per request of the Research Ethics Committee Universitas Padjadajaran, Indonesia. this study also included patients with previous experience with DFU while excluding those with active DFUs. The inclusion and exclusion criteria for key stakeholders are presented below.

HCPs

- Community nurses and physicians working at Puskesmas (PHC) Babakansari and Arcamanik.

- Have experience of working with CHWs for more than three years.

Patients

- Have a T2DM diagnosis.
- Without DFUs (Patient low risk and at-risk).
- Live in administrative blocks in areas of service of the PHC Babakansari and Arcamanik and have regularly visited the ISP-NCD.
- Have the ability to do daily activities independently.
- Are aged 18 years or older and are able to speak, read, and understand Indonesian.
- Can be contacted by telephone or any social media platform.

Patients excluded from the study were unable to communicate verbally, had type 1 diabetes or presented with gestational diabetes, had active DFU wounds or reported cognitive impairment, mental disorders or other severe complication.

Family members

- Family member of the patient participant.
- Living with the patient participant.
- Aged 18 years or older and able to speak, read, and understand Indonesian.
- Can be contacted by telephone or any social media platform.

CHWs

- Certified CHWs.
- No required criteria of level of education.

- Live in an administrative block in the service area of PHC Babakansari and Arcamanik and run the ISP-NCD.
- Aged 18 years or older and able to speak, read, and understand Indonesian.
- Contactable by telephone or any social media platform.

5.6. Recruitment Process

The study site settings comprise two PHCs (Puskesmas Babakansari and Arcamanik) located in Bandung, the capital city of West Java, Indonesia.

The official invitation letter approved by the UoN's Faculty of Medicine and Health Sciences Research Ethics Committee was sent to administrative staff members at PHCs to introduce myself and the research proposal. The study was conducted during the second COVID-19 pandemic, under this policy, there were restrictions on visitors to the PHC. The head of PHCs selected one of their nursing staff to be a gatekeeper for recruiting participants. The gatekeeper contacted potential participants using WhatsApp's messenger, and then conveyed the potential participants' contact details to me, after getting their permission. The participants were contacted to inform them about the study and sent the participant information sheet by email or SMS. They had three days to decide whether to take a part or decline the interview.

5.6.1. Recruitment of health workers in PHC (physicians and nurses)

I conducted video calls with gatekeepers to inform them about the FIne-CHWs study and the recruitment process. The recruitment process is outlined in Figure 13. The gatekeepers then invited physicians and nurses working in PHC to participate. After being introduced, I explained the study protocol and participant information sheet and

invited them to join. Interested participants contacted me to provide verbal consent (Appendix D) and schedule their interview.

5.6.2. Recruitment of patients and families

Diabetic patients within the PHC catchment area were approached by gatekeepers to determine their interest in joining the study. Those who met the inclusion criteria and expressed interest were provided with the gatekeepers' contact information. I then personally contacted these individuals, informing them about the FIne-CHWs study and sharing information sheets. Those who agreed to participate gave documented verbal consent and scheduled for remote interviews.

5.6.3. Recruitment of CHWs

The recruitment process for CHWs began with gatekeepers offering some CHW leaders the opportunity to participate in the FIne-CHWs study. The gatekeepers provided the phone numbers of the CHW leaders and suggested that they also offer the opportunity to other CHWs in the community. The list of CHW participants and their phone numbers were obtained from the CHW leaders. I contacted the CHWs using WhatsApp and shared the participant information sheet and verbal consent while arranging the interview schedule

5.6.4. Ethical Consideration

I contacted those who agreed to participate in the interview to gain consent and discuss the participant information sheet. Remote interviews were conducted due COVID-19 restrictions, as Indonesia was implementing local-scale social restriction during the fieldwork period, which affected undertaking data collection in community settings. Participants were interviewed remotely using WhatsApp video calls on smartphones

or other applicants (MS Team and Skype). I sought explicit permission to conduct and record the interviews via a remote verbal consent confirmation form.

The verbal consent provides a script for telephone/contact with the participant and confirmed that I was speaking to the relevant person. In this verbal consent (Appendix D), The patient participants' involvement was known by the witness on the participant's side as per the recommendations of the Indonesian ethics committee. I then signed the verbal consent form and send it back to participants by gatekeeper email.

Furthermore, the time and date of the interviews was sent by email or WhatsApp message. Participants were informed they could call me during working hours to confirm or cancel appointments without any reason for their wholly voluntary decisions. Participants were assured that their names and personal details would remain confidential and anonymous in reporting the research results and that their treatment, care or employment rights would not be affected by their decision to participate or decline. Participants were informed that they could withdraw at any time without giving a reason, although if they did withdraw, their data collected could not be erased.

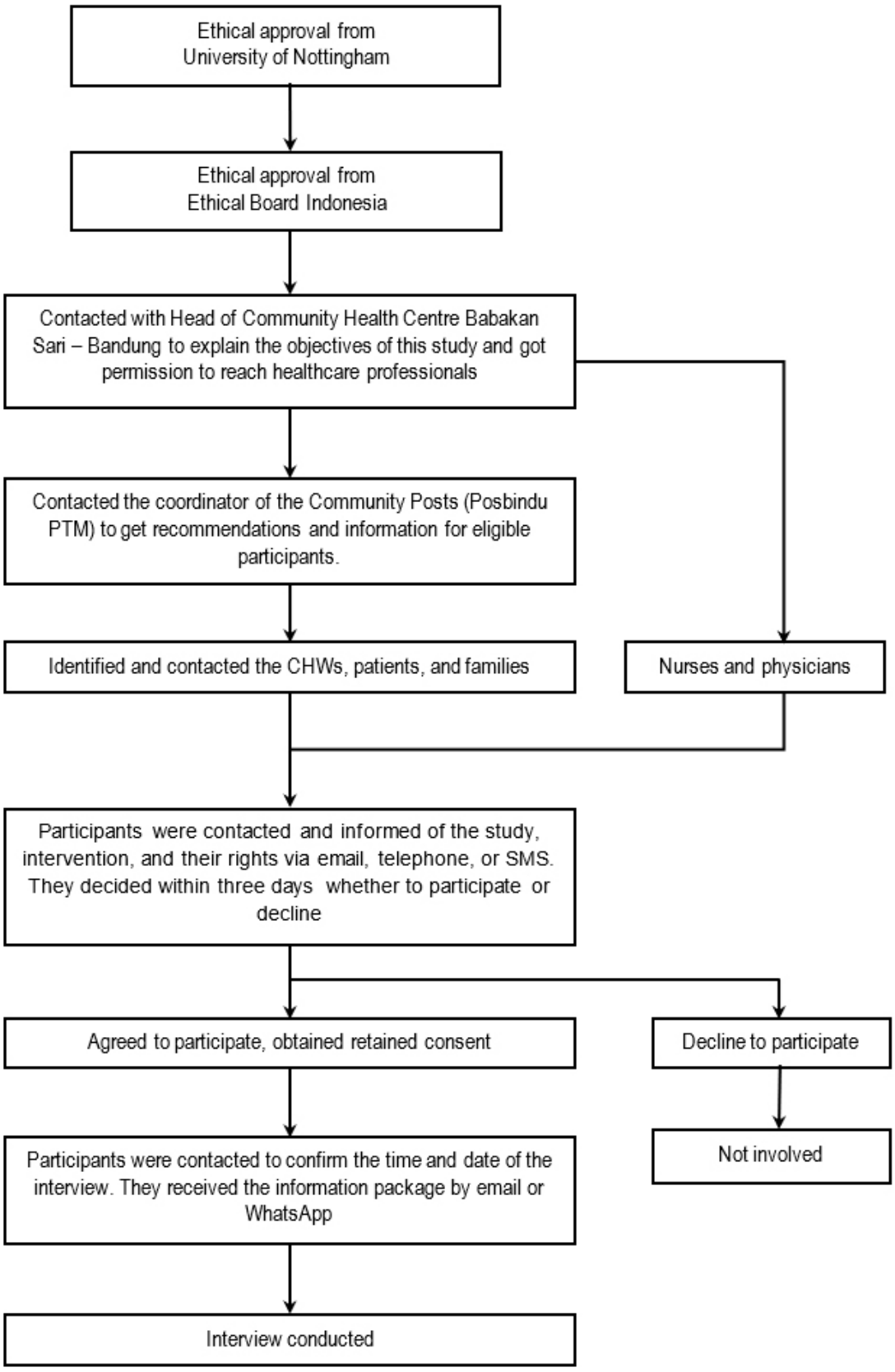


Figure 13: Recruitment process

Source: Author

5.7. Data Collection

5.7.1. Overview

Conducting Semi-structured interviews can be a daunting task for researchers who are not familiar with qualitative approaches. As part of my PhD programme, I underwent training in Research Integrity and Research Interview Skills prior to conducting individual interviews. To enhance my interviewing prowess, I also engaged in regular practice sessions, received constructive feedback from my supervisors, and held discussions with an experienced ethnographer working at the UoN.

Smartphones, with their omnipresence and differentiated capabilities, offer the broad methodological potential for social science and are promising tools that generate new opportunities for researchers and data collection processes (Deakin and Wakefield, 2014; Kaufmann and Peil, 2020). Notably, WhatsApp is a popular American freeware that offers cross-platform centralized instant messaging and voice-over-IP services. It allows users to send text and voice messages, make voice and video calls, and share images, documents, and user locations. The platform is known for enhancing anonymity and privacy. Participants were interviewed remotely using WhatsApp video calls on smartphones. Interviews lasted between 45-60 minutes. Most Indonesians use this medium for communication. Data for 2019 reveals that around 63.3% of Indonesians own a smartphone, while 83% or approximately 143 million internet users in Indonesia use WhatsApp as a primary medium of communication (Katadata.co.id, 2020; Liputan6.com, 2020).

WhatsApp has deployed an end-to-end encryption protocol to enhance security by restricting message decoding solely to the sender's and recipient's devices, rendering it as secure as an in-person exchange. Therefore, the messages exchanged are only

decipherable by the devices possessed by the interviewer and the interviewee, which safeguards the confidentiality of personal communications (Metz, 2016). This makes it an ideal tool for qualitative studies. The use of WhatsApp has been commended for saving time, enhancing participation, and enabling the gathering of qualitative data by interview. However, some experts warn that the quality of interviews may suffer due to a lack of interaction between the researchers and participants, which could limit in-depth probing and detailed data suitable for qualitative analysis (Mavhandu-Mudzusi *et al.*, 2022).

However, consideration could be given to other applications, especially if participants were more familiar with Skype, Microsoft Teams, and Google Meet. Interviewees were asked prior to the interview if they wished to use video or audio only. If the interviewee did not wish to use video, or technical problems prevented video conferencing, the interview was equivalent to a traditional telephone interview. If there was a failure in the connection/technology attempts were made to re-connect or rescheduling the interview. Text options were used to ask and answer questions if there was serious and protracted damage to quality of connection; this text were copied and pasted into the interview transcription in addition to the spoken text. Since the researcher was interested in analysing every word to prevent missing important views, field notes were taken during the interviews and were organized and typed up immediately after the interviews ended.

Conducting pilot interviews is suggested for novice researchers to acquire skills before the actual interview. These test interviews can be performed with peers or volunteers which then provide researchers with opportunities to explore language, clarity of questions, and aspects of active listening (McGrath, Palmgren and Liljedahl, 2019).

Semi-structured interviews were piloted using one patient, one nurse, and one CHW. These participants were included in the final sample (and data analysis), as no significant modifications were required following the review of the pilot interviews' outcomes. Separate pilot studies are not required in qualitative approaches because data collection and analysis are often progressive, meaning that the following or subsequent interview in a series should be 'better' than the previous one because the interviewer may have gained insights from earlier interviews to improve interview schedules and specific questions (Holloway, 1997). It can also be used when "the researcher lacks confidence or is a novice, particularly when using the interview technique (Mikuska, 2017).

The pilot interview data were analysed to decide whether the data obtained answered the research questions and research objectives. The interview transcript was translated to English then discussed with the supervisory team alongside the preliminary analysed data, the supervisory team then scrutinized the data provided from the pilot interviews and suggested changes to how answers were followed up on to get a greater depth of answers, and also to meet with an ethnographer to learn more how to frame the interview question to gather deep and riches interview data. This advice improved my interview and I started to use more open ended rather than closed question. In addition, a vignette question (Appendix D) intended to gain understanding about role of CHWs as educator in ISP-NCD was edited as I found that CHWs did not have experience delivering footcare education to the patients, and therefore found the vignette questions difficult to answers. This led to a change in the prompt questions.

5.7.2. Conducting Interviews

To ensure obtaining high-quality data in the FIne-CHWs study, I employed two strategies recommended by DeJonckheere and Vaughn (2019): avoiding a transactional question-answer approach and fostering an unfolding and iterative interaction between the interviewer and interviewee.

The interview started with general conversation to build rapport and relax the participants. I clarified the purpose and likely benefits of the study in the initial stage, to set the scene, and build a trusting relationship. Challenges that may be faced with remote interviews include the possibility of participants feeling embarrassed or uncomfortable being filmed, because seeing themselves on screen can often be a source of anxiety even though total non-verbal indicators cannot be clearly evaluated in comparison to traditional face-to-face interviews (Deakin and Wakefield, 2014). I was careful to observe the participant's feelings and physical behaviours. If their body language or behaviours indicated that they may be uncomfortable or distressed, I paused the interview and recording. If participants remained perturbed, I also offered the opportunity to discontinue.

Participants were informed of their right to pause or stop interviews or withdraw from the study at any time, as well as to interrupt and ask for clarification if needed. One patient participant, after 40 minutes of the interview, showed less concentrate by asking for question to be repeated, and apologizing because he yawned several times, stating that he had slept badly the previous night, I offered him to postpone the interview to another time, considering the patient's condition, and I felt that the point of data saturation had effectively been achieved for this particular interview. The

interview was discontinued, and the patient did not contact me to rearrange another meeting.

Five participants stated that this was their first time being interviewed, and that they felt bad if their answers were not satisfactory to the interviewer. In this situation, the researcher also needs to identify the power and culture dimension (McGrath, Palmgren and Liljedahl, 2019). The issue of power relations between participants and researchers should be anticipated prior to the interview (DeJonckheere and Vaughn, 2019). Patients and CHWs in particular may feel that researchers or HCPs occupy a more powerful position than them, and may feel obligated or coerced to participate, and assume the interviewer expects certain responses and answers (leading to social desirability bias), and believing that they themselves are being assessed and judged by the interviewer. This is especially important in Indonesia, where the culture often involves a strong hierarchy and shared values. A hierarchical culture means that people generally accept significant power differences between those of "higher" and "lower" status in the hierarchy, such as nurses and patients (Susilo *et al.*, 2013). Protecting the interviewees' information, adequately informing interviewees about the study purpose and format, and reducing the risk of exploitation were some strategies used to reduce power imbalance in the interviews (DeJonckheere and Vaughn, 2019).

The study involved conducting interviews with 29 out of 30 participants as initially planned. Initially, five family members were going to be interviewed, but only three were interviewed as no new themes emerges from this group. On the other hand, the number of nurses was increased to five, adding two more nurses to the original plan to obtain more opinions until no new themes emerged. The total number of participants

was considered adequate to achieve data saturation, which refers to the point at which no new themes emerge (Guest, Bunce and Johnson, 2006).

Table 9: Interview participants

Type of participants	Intended number	Number interviewed
Nurse	3	5
Physician	2	2
Patient	10	9
Family members	5	3
CHWs	10	10
Total	30	29

Source: Author

Furthermore, Braun and Clark (2021) propose initially estimating a preliminary, expected range for the sample size, either lower or upper, that can yield sufficient data to effectively capture the intricate and multifaceted patterns associated with the phenomena under investigation. Researchers should then make an on-the-spot determination regarding the ultimate sample size, which the sufficiency of the data should influence in terms of richness and complexity for addressing the research question. However, this decision should also consider the practical acceptability of the sample size within the context of the research community's standards and requirements (Braun and Clarke, 2021). The data storage and management procedures observed in this study are described in the following section.

5.7.3. Data Storage and Management

Prior to commencing data collection, I completed a data management plan using DMPonline (https://dmponline.dcc.ac.uk/) provided by UoN and submitted it to the Faculty of Medicine and Health Science Research Ethics Committee. I also used the UoN's storage facilities for all working data. UoN licenses Microsoft OneDrive ISO

27001 information security management compliant services that allows secure and controlled sharing of data amongst the research team. UoN OneDrive encrypts both data in transit and at rest and is approved against the University's Handling Restricted Data Policy (Data Protection Policy UoN, 2023), in accordance with the UK Data Protection Act (2018).

The interviews were recorded and transferred to UoN-provided storage, where they were stored digitally in a password-protected file. I transcribed and anonymized the interviews. The anonymized transcripts were stored on the OneDrive with an account provided by the School of Health Science, UoN. Transcripts and recordings were archived with the given ID Number. The interview recordings were saved in a password-protected file on OneDrive. All other data (research data) will be stored securely for seven years, after which the data will be safely disposed of in compliance with the UoN policy.

Under the 2018 Data Protection Manual, the University is considered to be the Data Controller (legally responsible for data security), and the Chief Investigator of this study (Prof Sarah Goldberg) is the Data Custodian (managing access to data). To protect participants' rights, I used minimal personally identifiable information when reporting data.

5.7.4. Field Notes

Field notes are widely recommended in qualitative research to document necessary contextual information, such as researchers' thoughts, ideas, and personal questions regarding their research observations and interviews (Philippi and Lauderdale, 2018). Field notes on interviews can be made during or after the interview by taking short, keyword-based notes during the event while maintaining participation and eye contact

with participants. These short notes can be helpful in remembering important detailed aspects in the interview. It is suggested that field notes be written immediately after the interview ends, when the researcher's memory and impressions of the encounter and related data are still fresh (Phillippi and Lauderdale, 2018; DeJonckheere and Vaughn, 2019).

Qualitative research acknowledges the role of the researcher as an instrument within the research and shapes the results. Critical reflection after each interview or focus group encourages the researcher to assess their performance, biases, and feelings. The interviewer needs to begin to reflect on both the process and the content of the interview immediately after it (while being mindful of reflection-related issues during it). The process of reflection through field note creation encourages interview technique improvement and refinement of study approach and questions (Phillippi and Lauderdale, 2018; McGrath, Palmgren and Liljedahl, 2019). Collecting interview data using active listening and talking less by respecting silent moments was a successful strategy to encourage participants to talk more about their opinions, however for a few patient and CHW participants, silences appeared to make them feel uneasy, particularly when they were asked about specific knowledge they were not familiar with.

In order to make the interview process more comfortable for participants, I ensured that they were well-informed about the study's purpose and format. I also made an effort to paraphrase the questions in a language that the patients were familiar with. To prevent any feelings of intimidation, I set a relaxed tone for the interview and asked if the participants wanted to take a break or reschedule if they felt tired.

Field notes can also be helpful for the researcher to understand the situation around interaction, mainly when participants expressed their thought using religious language to strengthen their arguments, this also provides essential context to inform data analysis (Phillippi and Lauderdale, 2018). Following transcription of the interviews, the field notes can add critical nonverbal content into the interview transcript (Phillippi and Lauderdale, 2018).

5.7.5. Transcription

Interview data were transcribed verbatim immediately after each interview. Verbatim transcription refers to the word-for-word reproduction of verbal data, where the written words are exact replications of the audio recorded words (McGrath, Palmgren and Liljedahl, 2019). Non-verbal expressions such as pauses, giggles, and other cues were also identified in the transcription process, as clues to important events in the interview.

Translation (where necessary) plays a crucial role in qualitative research, as it facilitates the accurate representation of participants' meanings across different languages. In cross-language research, a key concern is to ensure that translation captures the same meaning and maintains cultural relevance in both the original language (non-English, i.e., Indonesian in this study's context) and the language used for the study (English) (Choi *et al.*, 2012). This process is essential for ensuring the reliability and credibility of qualitative research (Yunus *et al.*, 2022).

In the research context discussed, participants were interviewed in Indonesian; subsequently, the recordings of all 29 interviews were transcribed and translated into English. The transcription of verbatim interviews was carried out by three Indonesian individuals who shared the same cultural background as the research participants,

aiming to enhance the accuracy and meaningfulness of the transcripts (Choi *et al.*, 2012). To ensure linguistic coherence, I and another bilingual nurse translated all the anonymized documents into English. During the translation process, the translator considers the unique circumstances and cultural context of both societies, aiming to develop a comprehensible translation on multiple levels (Choi *et al.*, 2012) .

The translator needs to comprehensively understand the participants' culture and language, as this helps mitigate potential threats to data validity. The use of forward and backward translation, which is believed to yield the most effective rhetorical translation, was not employed in this study due to the considerable time, financial, and labour requirements associated with this approach, as well as its tendency to produce literal translations that may pose challenges (Yunus *et al.*, 2022). The translation was done manually and was revised using Google Translate. However, since the interview was conducted in Indonesian, the revised text must be examined to prevent any loss of meaning. The translation from Indonesian to English may result in some loss of clarity and accuracy, due to variations in grammar and nuances in communication between humans (Fitria, 2021).

Additionally, during the development of the thematic analysis, the supervisory team examined quotes from the translated transcripts. In cases where there was less understanding of the intended meaning among the team, I cross-checked the Indonesian transcripts to ensure accurate representation or provided additional contextual explanations to enhance comprehension for all team members. If the researcher possesses bilingual proficiency, they can compare the translation with the original data themselves (Yunus *et al.*, 2022). Furthermore, the data as part of a PhD student's thesis needed to be written in English. In this step, identifying the analytical

structure and finding similarities and differences between the experiences of different team begins as a process of familiarization of data.

5.8. Data Analysis

5.8.1. Overview

Reflexive thematic analysis (RTA) was used to analyse the qualitative data (Braun and Clarke, 2022), because the preliminary analyses found that the interview datasets were rich and complex from different group participants. In RTA, research subjectivity is the primary tool as it is treated as a resource for doing analysis. Examining and interpreting RTA has the potential to yield outcomes spanning a spectrum, varying from uncomplicated descriptive explanations to intricate theoretical-immersed ones (Braun and Clarke, 2022). It is feasible to progress from basic codes to comprehensive themes in interpretation, yet there is also a chance of arriving at a simple descriptive overview lacking profound analysis (Braun and Clarke, 2022).

The analysis was conducted using the inductive approach in which there was no attempt to fit data into existing theory. The participant's perception of the reality, shaped by and embedded within the local context, culture, and health policy and represents a particular reality which requires deep interpretation through using the researcher's lens. Furthermore, the RTA also provides a coherent and compelling interpretation of the data, grounded in, or anchored by participants' accounts. NVivo version 10 was applied to the organization of qualitative data and the identification of quotations to identify codes and subsequently develop illustrative themes (Braun and Clarke, 2022).

5.8.2. Process of Analysis

The analysis process followed six phases (Braun and Clarke, 2022) to develop a rich, nuanced analysis to address the research question.

5.8.2.1. Data set familiarization

Familiarization can be achieved by reading data that involves closeness or familiarity (immersion) and distance (critical engagement) (Braun and Clarke, 2022). In this phase I read and thought about text-based data items, repeatedly viewing visual data items and working with transcripts of audio data. This process allows for deep engagement with a rich diversity of meaning and highlights interesting data. To make sense, contesting, and questioning how the data could be different while making notes.

5.8.2.2. Data coding

Code is the smallest analysis unit that captures particular meaning within the data set, relevant to research questions. In qualitative research, semantic codes are generated from the explicit or surface meanings of the data without delving into deeper layers of interpretation. These codes are produced through a descriptive analysis of the data, which aims to present the content of the data in the respondent's own words. On the other hand, latent coding involves identifying concealed meanings, underlying assumptions, ideas, or ideologies that may influence the descriptive or semantic content of the data. This level of coding requires the researcher to adopt a more interpretive approach, taking a creative and active role in the analysis (Braun and Clarke, 2022; Byrne, 2022).

In this coding process, the supervisory team and I explored the diversity and patterning of datasets, developing codes and applying code labels to particular parts of data. NVivo version 10 was applied to the organization of qualitative data and the

identification of quotations to identify codes and subsequently develop illustrative themes, capturing semantic meaning by understanding the explicitly expressed meanings, and then to group codes. However, data sets from different groups express less obvious meaning which then leads to the decision to use latent codes to engage deeper to build conceptual meaning or unconscious meaning.

5.8.2.3. Initial theme generation

The focus of this step was engaging with data codes to locate similarities of meaning, clustering together the potentially connected codes and exploring these initial themes. All the 29 interview transcript data were stored in Microsoft 365 One Drive and allowed the supervisors to access data. I discussed the interview data with supervisory team to develop initial themes from the first six interview transcripts, this step allowed me to draw interpretation from the descriptive to get enriched and in-depth interpretation, from semantic to latent meaning. The initial theme generation was discussion within several supervision meeting to avoid premature and descriptive interpretation. When multiple researchers are involved in qualitative analysis, a collaborative and reflexive approach is recommended, focusing on generating rich interpretations of meaning rather than striving for consensus (Braun and Clarke, 2022).

It is important to acknowledge that qualitative analysis does not aim to provide a single or definitive answer, and proponents of RTA should be aware of this. Braun and Clarke (2013) emphasize the importance of recognizing the diversity of interpretations that can arise from qualitative analysis.

In this process, using the NVivo likely had constraints for the interpretative complex ideas from the dataset. I then decided to use initial hand-coding to allow flexibility of coding interpretation and avoid premature clustering or presenting the descriptive

interpretation (Braun & Clack, 2022). However, I sometimes used NVivo to locate interview quotes as it was more practical than finding them in the printed transcript interview data.

5.8.2.4. Theme development and review

Themes were defined by meaning units and conceptually coherence, which have distinct central organising concepts (Braun and Clarke, 2022). In this process, the supervisory team and I explored the similar idea of meaning and understanding this idea with different context, including community culture and health policy, through the inductive approach, the broad idea that a number of different codes were clustered together, so that the conceptual idea and something more latent can be identified and interpreted to generate tentative themes and overarching themes. Overarching themes can be defined as umbrella concepts or ideas that embrace a number of themes. this also demonstrates some broader concepts to anchor several themes together (Braun and Clarke, 2022).

5.8.2.5. Theme refining and naming

The process of refining analysis in qualitative research involves the development of themes and their integration with the final phase of RTA. To ensure the validity and reliability of the findings, this step was carried out through supervisory meetings where the final themes and subthemes were discussed in detail. During these discussions, special attention was paid to identifying overlapping or contrasting ideas in one theme.

This step was purposed to check internal theme clarity, organization and flow, and the overall story of the analysis (Braun and Clarke, 2022). To avoid inadvertently misinterpreted what participants said through data translation, the audio recordings

were checked for the data segments quoted. In addition, I ensured that each theme was clearly demarcated and fit into overall the story about the data.

5.8.2.6. Writing up

Analytic writing was started by generating an initial theme. This step presents a coherent and persuasive story about the datasets that address the research question.

5.9. Summary

The semi structured interview method presented several steps that followed COREQ guidelines for reporting qualitative studies. This step started with recruiting participants and ended with the reflexive thematic analysis to analyse data. The findings of the interviews are reported in the following chapter.

Chapter 6

Semi-Structured Interview Findings

This chapter present the finding of interview data. RTA revealed five emergent themes from the interview data, which are presented in Table 10 and discussed below. The strengths and limitations of this interview study are also considered.

Table 10: Themes and subthemes relating to stakeholders' perception on FIne-CHWs

Theme	Subtheme
1. Community knowledge and experience in foot prevention	1.1 Community beliefs surrounding DFPs (general knowledge about diabetic foot);
	1.2 Community practice on diabetic footcare prevention (no guidance on diabetic foot prevention)
2. Enhanced healthcare uptake by expanding CHW's role	2.1 Community empowerment (feasibility of extending diabetes educator role)
	2.2 Capacity of CHWs to gain new knowledge and skills
3. Community embeddedness	3.1 Benefit of proximity to the community
	3.2 Drawbacks of proximity to the community
	3.3 Pre-service training for intervention providers
	3.4 CHWs' supervision
4. CHW resources (recruitment and selecting CHWs)	4.1 Motivation underpinning being CHWs
	4.2 Remuneration
	4.3 CHWs' ability to learn.
5. Community training approach	

Note abbreviation: CHWs (CHW); HCPs (GP = General Practitioner and N = Nurse) Patients and families (Patients and Families)

Source: Author

6.1. Results

6.1.1. Theme 1: Community Knowledge and Experience of DFU Prevention

All three groups of participants (patients and their family members, CHWs, and HCPs) were familiar with the basics of managing diabetes, which stresses diet control,

medication adherence, and regular exercise as three strategies for preserving normal blood glucose levels. The HCPs shared current health policy and clinical practice guidelines for approaching diabetic patients, which is commensurate with the experiences of CHWs, patients, and their family members' opinions of various measures in diabetes management.

> *The procedure for treating diabetic patients is still the same, namely measuring BG, giving medication based on the results of BG tests, then checking BG every two months for people who visit Prolanis (PHC programme for insurance patients).* **(N3)**

The community's general knowledge of diabetes management did not directly indicate understanding of the importance of the prevention of DFPs. Further analysis of the data revealed two subthemes related to participants' experience of footcare in the community: **Subtheme 1.1:** community beliefs surrounding DFPs (general knowledge about diabetic foot); **Subtheme 1.2:** community practice on diabetic foot prevention (no guidelines for diabetic foot prevention).

6.1.1.1. Subtheme 1.1: Community beliefs surrounding DFPs (general knowledge about diabetic foot)

Patients and CHWs share the same neighbourhoods, which resulted in a shared understanding of foot prevention in the community. Community knowledge and practise is based on prior experiences with shared information, perceptions, and attitudes regarding diabetes, its consequences, the treatment, and the prevention of foot problems. The participants recounted their experiences with diabetes and its complications; they expressed experiencing unexpected symptoms when first diagnosed with diabetes (including feeling tired, sleepy, thirsty, itchy, and numb).

Nearly all of the patient participants identified these symptoms as typical before learning they had diabetes. Most participants admitted that they did not know those symptoms were related to diabetes until they felt sick and sought medical help.

> *(...) I felt thirsty and I like to drink cold and sweet food. But I didn't know (...) diabetes symptoms (...) I was sick, there was a wound around the back-heel joint... well, at first it was itchy, after I scratched it, it got bigger and bigger (...) the wound looked like an ulcer. So, I went to the doctor, I was checked, "Do you have symptoms of diabetes?", "Oh, I don't know doc, I just found out that I have diabetes".* **(P7)**

> *Sometimes the patient also didn't know that they had sugar [diabetes] because when they came to the health centre (PHC), their leg was injured, we saw the wound was leading to gangrene, then we asked, "Do you have a history of sugar [diabetes]?" The answer must have never been checked, then we just checked from there, only to find out that the patient does have sugar [diabetes], but indeed for diabetes now, you could say it seems a bit late due to further complications.* **(GP1)**

CHWs and patients had a similar language regarding personal knowledge about diabetes and diabetic foot. They mentioned the terms "dry diabetes" and "wet diabetes" to explain situations that happened for diabetic patients related to the risk of amputation. "Dry diabetes" is a term for diabetes with black scars on the skin without open wounds, while wet diabetes is a type of diabetes with wet sores and abscesses on the wound that takes a long time to heal, which leads to amputation (Widayanti *et al.*, 2020). This term does not exist in the medical field; it is a popular designation.

(...) about what should be done by patients with wet diabetes and also for patients with dry diabetes. Yeah, about prevention, for example, what the right time is for eating regularly, what kind of food should be eaten, for example, going for treatment, and taking breaks regularly, don't be too emotional. If they feel stressed, their blood glucose will increase. **(CHW10)**

My neighbour has diabetes. At first, it was itchy, and it was scratched. And then, finally, it was getting wet [wound exudate]. He said it was wet diabetes, not dry diabetes. In fact, his foot was amputated. **(P9)**

Some diabetic patients also referred to the community's experience of identifying minor foot problems while treating them using prior knowledge and practices, which were believed to be efficacious in managing their condition. Tinea pedis is a fungus infection that is frequently misunderstood as *Kutu air* (water fleas) in Indonesia.

(...) I think it lesion because of a kind of "kutu air" [water fleas/tinea pedis] due to the side effects of detergent or "lelecengan" [Sundanese language]. I don't have sores on my feet now, but I feel hot around the soles of my feet when I walk. **(P2)**

(...) it's just "kutu air" [water fleas] between my toes, but just using the ointment and it would be better, Alhamdulilah [thank God]. **(P6)**

In general, a lack of understanding surrounding the causes of DFP among community members prompts them to rely on locally circulating information, which is presumed to be accurate. Misconstruing the aetiology of diabetic wounds results in misinterpreting appropriate diabetic foot management. Consequently, individuals may

possess limited awareness of the potential risk of DFUs and the consequential possibility of lower limb amputation.

6.1.1.2. Subtheme 1.2: Community practice on diabetic foot prevention (no guidance in diabetic foot prevention)

Some patients and CHWs exhibited a degree of knowledge regarding routine footcare practices, including protective measures such as utilizing slippers while at home, performing foot washing, and engaging in foot exercises. This knowledge was acquired through participation in a university-led research initiative on diabetes management and via health education delivered by medical or nursing interns focused on diabetic foot prevention.

> *I have participated (in university research) for three months (...) They told and gave me a book about footcare, doing exercises using a piece of paper that was being rounded like a ball for foot exercise. Sometimes at home, when I just woke up, I was doing a foot exercise… They taught me about wearing socks; we had to cut our nails. Our feet must be washed and dried with a towel, we wear shoes, so we do not stumble, and we also use warm water.* **(P4)**

> *The health promotions unit usually does health education in the morning using videos and leaflets for the patients. Previously if there were some students, we also involved them (...). There were some nursing students and others.* **(GP1)**

Patients and CHWs who took part in the diabetes management research project reported possessing more comprehensive knowledge when compared to those who did

not participate in the study. Additionally, a nurse who underwent a brief course in wound care exhibited a more profound comprehension of diabetic foot prevention strategies. Nonetheless, two nurses acknowledged that their knowledge of foot prevention was applied exclusively as a research protocol due to insufficient time to educate patients daily.

> *We did it only for research, we did not teach patients on daily basis. Yeah… because we do not have time.* **(N1)**

The GPs had a better understanding of diabetic foot prevention by imparting comprehensive knowledge regarding preventive strategies. One GP acknowledged that the PHC had recently received a presentation from an internist who expounded diabetic foot prevention just a few weeks prior to the interview; which focused on encouraging patients to regularly check their own feet, this information was subsequently shared during an educational session for elderly patients who visited the PHC to commemorate World Diabetes Day on 14 November 2021.

> *(...) we also just had disseminated on the prevention of diabetic feet a few weeks ago from the health office, next, we will share it for the NCD programme because this has just been informed.* **(GP2)**

Utilizing external sources of information as a primary source of information in practice footcare in the community was due to the absence of specific guidelines for preventing foot problems known as foot self-care, One GP acknowledged that footcare was not included in “Minimum Service Standards in Diabetes Management in the Community”.

Diabetes is included in MSS [Minimum Service Standard]. But I don't think there is a target for diabetic footcare education from the health office. It's just the DM without any complications. **(GP2)**

HCPs emphasize maintaining BG levels within the standard as the main prevention of diabetes complications, followed by wound care to manage DFU, as narrated by nurses about the diabetes management at the PHC

We never did foot screening because we have many patients so we would spend a lot of time. So, if a patient has symptoms [sores], we do screening [blood test] for treatment. If there are no symptoms, we never did screening (...). Foot screening is not included in the programme [diabetes]. So, not all nurses know it. In conclusion, diabetes programmes are only for treatment. Controlling diabetes requires medication and blood glucose testing in manual procedures. We don't have a target if this goal is not in the procedure manual. And it also takes a lot of time, so we rarely do it. We did foot exercises together, effectively using time, place, and media tools. **(N3)**

The nurse's clarification above regarding foot screening to determine risk classification was not presently implemented in the PHC's protocols due to the absence of manuals and objectives for diabetes management and the unavailability of allocated time to perform the foot screening procedure. Concurrently, it was recognized that HCPs required further education on preventing diabetic foot complications. Significantly, foot exercises were identified as the preferred FCI for demonstration purposes in the community.

(…) And usually, before did screening diabetic patients/examination by doctors…we performed a foot exercise to prevent diabetic ulcers (…) because feet exercise was easy to memorize. **(GP1)**

We did not teach skill (other prevention measure in footcare), we just told them by demonstrated using newspapers for foot exercises (…) that's because this topic is easy to do, the tools are easy to get, only used newspapers, it just brings a newspaper. **(N3)**

Foot exercises have emerged as a popular and recurring method of self-footcare within the community in contrast to other preventive measures. Some patients and CHWs believed in preventing DFU by practicing foot exercise, which is one step of exercise using paper or newspaper. Five of the nine patients interviewed had performed these special leg exercises.

It was like… our feet are turned around and moved while sitting. I performed it for several times. And then, stood up with that paper/ newspaper then it was opened, crumpled up, and opened again by our feet" or did exercise used a paper that was been rounded like a ball for foot exercise. **(P4)**

To summarize, external sources of information, such as participation in university diabetes management research or education provided by student interns, appear to inform footcare practices within the community. In contrast, patients, CHWs, and nurses not exposed to these resources may lack adequate knowledge of footcare practices. HCPs have recognized the absence of procedural guidelines for preventing diabetic footcare, resulting in inadequate attention to this aspect of diabetes

management at PHC facilities. Notably, DFU risk screening is not currently incorporated into standard procedures. However, foot exercises were found to be the most practised intervention among the three groups and are believed to reduce the incidence of DFUs effectively.

6.1.2. Theme 2: Enhance Healthcare Uptake by Expanding CHW's Role

The Posbindu PTM (Penyakit Tidak Menular/ Non-Communicable Disease) community programme is implemented to manage NCDs, including diabetes, in the community. The Posyandu, a ISP-NCD mother-and-child established over three decades ago, was later supplemented by the NCD-ISP (Posbindu PTM). Posyandu-Posbindu is a community-driven health service managed and operated by the community in collaboration with technical supervision from HCPs at the nearest the PHC (Puskesmas) (Oendari and Rohde, 2021). The ISP, with its CHWs, functions as a community empowerment unit on health-related issues responsible to the village committee (sub-district) level. At the same time, medical and technical supervision is provided as necessary by the HCPs at the PHC.

> *Preventive measures in Posbindu PTM focus on screening disease for the elderly, not focusing on one disease. They will measure BP, weight, height, blood glucose, cholesterol, body imbalances, urinary and sleep disturbances, cataracts, that's all, not just focus on diabetes. The data will inform the focus management topics for the next meeting. If there were problems with diabetes so health education will focus on diabetes… and next month we performed progressive training, followed by foot exercises. Next month's topics will be based on data analysis screening results.* **(N3)**

One of the nurses described the monthly activity in ISP-NCD, which focuses on screening the NCD in the community, and not merely for diabetic patients. Patients who had diabetes were then directed to further intervention in the Prolanis programme managed by HCPs in PHC. Prolanis is a chronic disease management programme targeted at diabetic patients and hypertension under the NHI scheme. The Prolanis programme is a multi-faceted intervention involving both pharmacologic and non-pharmacologic strategies (e.g., patient education, physical activity, monitoring, and reminder system) (Khoe *et al.*, 2020). However, the participating patients could not recall any health education, particularly in diabetes prevention in Posbindu PTM, since this activity was focused on screening the NCDs in the community; those who were indicated or diagnosed with diabetes were then suggested to join Prolanis.

> *I think every month, the PHC holds a Prolanis [education programme for those who have health insurance]. They received health education, so they did not get information at the Posbindu (...), so we never had diabetes education at Posbindu. Still, suppose there were community members who suffered from acute diabetes. In that case, the health workers would ask CHW to remind patients to visit PHC regularly (...) because every month at the PHC, they participate in Prolanis.* **(CHW1)**

> *Activities in Prolanis have included health education (...). Usually, prolanis is for the elderly; they do diabetic foot exercises, and then PHC provide BP and blood glucose checks every month, and HbA1c and blood tests every six months. Then, there are health checks by a GP, and the pharmacist gives them medication.* **(GP1)**

It is a prerequisite for diabetic patients to have national health insurance (NHI) to participate in the Prolanis programme. Those without insurance may not have access to important information regarding diabetes management and preventing complications. To address this issue, a nurse suggested that CHWs play a vital role in disseminating information through FIne-CHWs to increase patients' knowledge and awareness of diabetes complications.

> *There are around 200 people who have diabetes, but only 60 have taken part in Prolanis; not all of them could be taught in PHC, and this [FIne-CHWs] may reduce mortality. So [perhaps] people who do not join Prolanis will get information from CHWs in Posbindu.* **(N2)**

Prolanis was not known to one patient interviewee. There were various reasons why patients chose not to participate in the programme, such as disinterest or reluctance to visit the PHC frequently or preferring to attend Posbindu instead.

> *Few participants are in Prolanis, with less than half joining despite visiting Posbindu.* **(P3)**

> *Some people have expressed reluctance to visit health services regularly. I recommended joining Prolanis, but some were uninterested, citing boredom.* **(P2)**

Additionally, some diabetic patients were not enrolled in the Prolanis programme due to complicated bureaucracy, which could be a hindrance. A GP shared an experience of how the health system policy can prevent patients from accessing essential services within the Prolanis programme.

Yes, in fact, there are over 40 patients with DM. The administrative tasks became complex due to the regulations set forth by the BPJS (National Health Insurance). Now, I must refer the patient first to an internal medicine doctor at the hospital. After that, they attached RRP [Referral Programme], named RRP Prolanis. After obtaining the RRP, we can enrol patients in Prolanis programmes. Many patients avoid the hospital due to long wait times. So, the patients wanted to join Prolanis, but complex rules prevented them. **(GP1)**

The Prolanis programme focuses on controlling blood glucose within usual standards, taking the medication regularly, and managing diet. For those with DFU primary focus is on wound care. One of the nurses in charge of the Prolanis programme revealed that she knew almost nothing about footcare education at the end of the interview of this study. This account also indicated no comprehensive diabetic footcare prevention in the Prolanis programme.

I'm still learning about wound care because we have different focuses (interventions) at PHC, so we treat patients when they already have wounds. Through this (discussion) I became "Ngeh" [affirmation of understanding], why we don't take preventive measures and footcare for diabetic patients? **(N2)**

Mostly interview participants mentioned Prolanis as a special programme for diabetes and hypertension patients; Prolanis as a special programme for diabetic patients held by PHC is indirectly the cause of the lack of focus on diabetes prevention, especially diabetes footcare prevention in the community, thus resulting in less optimum CHWs' role, especially for diabetes prevention at Posbindu PTM (ISP_NCD). The possibility

of extending CHWs' role to deliver FIne-CHWs was explored though **subtheme 2.1:** community empowerment (feasibility of the extended role of diabetes educator); and **subtheme 2.2:** capacity of CHWs to gain new knowledge and skills.

6.1.2.1. Subtheme 2.1: Community empowerment (feasibility of the extended role of diabetes educator)

The development of Posbindu PTM has resulted in some CHWs having dual responsibilities in managing both the ISP (Posyandu and Posbindu), which are conducted on the same day. According to one CHW, they have become accustomed to working the Posbindu PTM (ISP-NCD) alongside their other duties.

> *When Posyandu hmmm, let's say we started at 08:00 in the morning, we would focus [service] on toddlers while waiting for health workers from the health centre (PHC) to come. We weighed the toddlers first at the Posyandu, usually around 9-10 am. Then the HCP arrived; After waiting for some people to arrive, we updated information through a WhatsApp group for Posyandu and Posbindu. In Posbindu, the activities include measuring BP and weight and asking about eating patterns.* **(CHW5)**

The HCPs acknowledge the valuable roles that CHWs play, including their function as educators. According to one nurse, CHWs within the PHC catchment area may be equipped to provide health education based on their experience demonstrating foot exercises to visitors at the ISP.

> *The CHWs here are pretty smart. Usually, they do some simple health education that can be done by CHW, such as diabetic foot exercises*

(other than other jobs in Posyandu). CHWs can do simple measurements such as abdominal circumference, weight, and height measurements… and fill the cohort. **(GP1)**

Regarding implementing FIne-CHWs in the community, the nurse competent in wound care, along with the GP, believed that CHWs would be able to deliver FIne-CHWs educational sessions. They noted that the educational content is simple and appropriate for the general population, mainly aimed at preventing DFUs.

(…) because ordinary people do it, I think CHWs can do it because this is basic [footcare]; even with CHWs with lower education, this information [footcare] is familiar in their daily life. **(N3)**

(…) in my opinion, these preventive measures should not be a problem, there is something important that everyone should be aware of - the importance of thoroughly washing every part of your feet., which maybe not all HCPs know in detail. Even though the knowledge is simple, it's just like that; there shouldn't be a problem with prevention. **(GP2)**

The above data is supported by several CHWs who believed that the diabetic patients would accept new information from CHWs. In addition, one of the CHWs felt excited to do the different tasks from their usual activities in managing ISP (Posyandu-Posbindu).

I feel patients will also be happier to be told how to take care of their feet. So, it will be right to do if its procedure is available. **(CHW4)**

I'm excited because I want to know what the CHWs can do, so it makes me excited. **(CHW8)**

Furthermore, a GP expressed optimism that implementing FIne-CHWs could have a sustained positive effect in alleviating the burden of DFUs within the community, reducing the incidence of amputation and indirectly mitigating the financial costs associated with treating long-term complications of diabetes.

What is clear is that the complications of diabetic foot cases will be reduced, especially for amputations. The chances of long-term amputation will decrease. Actually, if you think about preventing diabetic feet, it's easy to pay attention to your feet. Hopefully, if it had been known from the beginning, the amputation would not happen. And for operational financing, all costs can be diverted to other things. Diabetic patients often experience symptoms of depression, such as feeling unmotivated, which can reduce their overall quality of life. Fortunately, with proper treatment, the community's quality of life can improve significantly. **(GP2)**

Overall, all three groups of participants who were interviewed acknowledged the significance of the CHW's function as an educator and the potential impact it could enhance service uptakes, particularly in reducing the incidence of DFUs. The practicability of FIne-CHWs within the community to prevent DFUs was acknowledged as a possibility that could be implemented under the present circumstances.

6.1.2.2. Subtheme 2.2: Capacity of CHWs to gain new knowledge and skills

The CHWs are expected to participate in community programmes from the local government under the MoHA. Specifically, for community health programmes, the CHWs receive task-sharing and technical guidance from HCPs (under the MoH and also receive technical guidance for ISPs (Posyandu-Posbindu PTM) (Oendari and Rohde, 2021). There is no educational attainment to become a CHW (MoH, 2012). The capacity of the CHW's to learn new skills and the educational level they would need to deliver the FIne-CHW intervention was explored in the interviews. Some HCPs were concerned that the CHWs did not have sufficient education to learn the necessary knowledge and skill. According to one GP, not all CHWs would be able to deliver FIne-CHWs.

> *Even though there are many kader (CHWs) and they want to, there's no guarantee they can <laugh>. Sometimes it's just the name of the kader, but sometimes the contribution is lacking.* **(GP2)**

Commensurate with the HCPs perspective about CHWs competence, one of the CHWs' leaders who identified herself as a young CHW indicated that not all the CHWs would have the capacity to extend their role as educators such as for the FIne-CHWs.

> *Perhaps due to (limited) knowledge, maybe… only a few CHWs understand. The other CHW maybe help us.* **(CHW5)**

Other CHWs who supported this argument also mentioned their role as a supporting CHW, as opposed to the main CHW or CHW leader; the data indicated that receiving training from the PHC was not a priority for supporting CWHs because their role was

focused on assisting with specific tasks that were deemed not to require advanced knowledge and skills in Posyandu-Posbindu PTM.

> *I'm 60 and have been a kader [CHW] for ten years. My education level is elementary school. I am supporting kader. There are leading kader responsible for several sections … I helped measure the children's heights. Then I gave food supplements, that it is (…). I have not participated in training even though I have been invited because sometimes I have a different schedule. For educating diabetic patients, I could not do because I am busy taking care of my grandchild.* **(CHW9)**

> *I only help with activities at Posbindu (ISP-NCD); I rarely attend training because, in my administrative block, there are two posts; one post has seven CHWs, and only one attended training (…) For Posbindu training, the training is different; only one person was chosen.* **(CHW6)**

The primary concern regarding the workforce was the shortage of existing CHWs who are suitable qualified to deliver FIne-CHWs. Even for their general/current role, CHW performance often seemed inadequate (Surjaningrum, 2018). The data indicated that the PHC limited invitations to the leader or main CHWs to have training in knowledge and skill.

Concerning CHW qualifications, a family member with experience of managing CHWPs in the community stated that it was necessary to classify CHWs from the many available CHW in the community in order to choose those who are able to take

on more of the division of tasks from HCPs, particularly taking on expanded roles as diabetes educators.

> *(...) Then it needs CHW classification from the health professionals so that some of the nursing tasks can be delegated) (...) but the CHW should be real CHW; if I see it like that... the current capacity still needs to be increased. Then after (they are) given knowledge (then) is given limited authority (such as) prevention of disease.* **(FM2)**

The preceding statements emphasized the need for CHWs to be "the real CHWs", implying that they should improve their ability to accept task delegation from HCPs. Assessment of CHWs based on their capacity and capability to deliver FIne-CHWs sessions is necessary prior to training them in the intervention.

6.1.3. Theme 3: Community Embeddedness

The role of CHWs as an intermediary between the community and formal healthcare services has yielded numerous advantages, particularly for medically underserved or disadvantaged populations who are more likely to avail themselves of CHW services. A GP acknowledged specific community members within the PHC catchment area who were considered the most appreciative of CHW services and needed their presence. This group is likely to place more value on and have a greater need for the role of CHWs as community health providers.

> *Actually, going back to the environmental background, yes, it means that if we are here, there are indeed those from the middle and above [socioeconomic status] who are a bit difficult for us to target; they probably didn't choose the Puskesmas (PHC) as a place for treatment,*

of course, they didn't choose kader and chose Posbindu <laugh>, but for some regions or sub-districts [low socioeconomic] they likely can work more together with CHW. They can still accept the CHW role; it might be more at the level of the population's needs; now, if that's the case for the lower socioeconomic groups, they are close to CHW. **(GP2)**

Maybe for the lower middle-class people, when the kader provide health education about diabetes, they will accept it, but for the upper-middle-class people... usually, they already have their own doctor <laugh>. **(N4)**

Furthermore, for patients from low socioeconomic background, further incentives were considered necessary to increase community participation in ISP or educational sessions such as serving snack or food for attending to the community event. All of the group participants agreed that this factor was critical to the success of the intervention.

<laugh> usually, health education is attractive if there are prizes for the lower class; there must be a reward... like being fed. If it was different from that, only a few people came. **(N4)**

There was a common perception that people of lower socioeconomic status more greatly valued CHWs' provision of community service, whereby they appear to have close relationships among themselves. Sharing experiences through living together in the same place has enabled CHWs to identify with people within the community, while

at the same time patients were familiar with the presence of CHW. All of the CHW participants were aware of the diabetic patients in their community.

> *(…) yes, one (of my friends), her eyes are blurry; another felt itchy all over her body. There are six diabetic patients near my house as far as I know.* **(CHW1)**

One nurse stated how important the position of CHWs is in the community; this account indicated people's trust in CHWs makes people more accepting of them, which is a positive factor in increasing the uptake of health services.

> *CHWs can say like a second-hand chief of the administration block, and patients will obey them, follow their instructions.* **(N1)**

The CHWs are community members who are intermediaries' position between the community and health services. This role is particularly significant for individuals from low socioeconomic backgrounds who value CHWs more than those from higher socioeconomic classes. The intermediate position of CHWs has implications for the trust and distrust that people have regarding the expanded role of CHWs in delivering FIne-CHWs. The subthemes discussed below present the challenges and facilitators associated with the intermediary position of CHWs between the community and formal healthcare services, and explore the implications and strategies to address this issue and mitigate the trust and distrust concerns. **Subtheme 3.1:** benefit of proximity to the community; **subtheme 3.2:** drawbacks of proximity to the community; **subtheme 3.3**: pre-service training as an intervention provider; and **subtheme 3.4:** CHWs' supervision.

6.1.3.1. Subtheme 3.1: Benefits of proximity to community

The proximity of CHWs is a key factor contributing to patients' trust in them. This advantage is particularly evident in neighbourhoods where community members live nearby. Additionally, some patients preferred to receive health education from CHWs who were their close friends, citing greater levels of comfort in such situations. One patient specifically mentioned a preference for being taught by familiar CHWs to reduce the stress associated with the process of learning about health issues.

> *Yeah, I trust them, but they who are close with me. If they are not, I don't believe them …. It will be comfortable if we are close. We can make jokes or have fun. If I'm wrong, I can ask, so there's no need to stress about what will happen later, right?* **(P9)**

Echoing the patient's sentiments, some CHWs believed that the community would be more willing to disclose their health conditions to them because of their proximity to the community. Some CHWs also considered it easier to approach people they were already acquainted with, as patients were less likely to reject them.

> *Because, as I know, sometimes the community is closer to the CHWs. So, when there's something wrong, they tell us, maybe it's about health conditions in particular. Compared to the others. The CHW is the person who is the closest to the community. So definitely, they want. Yeah….* **(CHW5)**

> *especially for diabetics, I hope I can teach them, because [they are] all my close friends, InshaAllah [God willing], they will accept me.* **(CHW1)**

In addition to feeling personally close to CHWs, the proximity of the place of intervention for both CHWs and patients is another benefit of community programme. Most interview participants suggested using a community venue to deliver the FIne-CHWs programme such as the community administrative block office or the community hall or alternatively at the patient's house. These venues were suggested due to their proximity to the community and its community ownership, including monthly ISPs (Posyandu-Posbindu PTM) activities.

> *(…) CHW (house) is nearby. Instead of going to PHC, which is far away, it is better to be near here, for the sake of my health too. It can be held in Posbindu or in house… because CHW's house is still surrounding this area.* **(P3)**

> *If the patient's house is close to mine, if I have time and they have time, InshaAllah, I will just go to their house. Teach them how to clean their feet properly and correctly, take care of them.* **(CHW4)**

The choice of intervention place for delivering FIne-CHWs is consistent with health professionals' preferences for intervention sites, as they also have regularly scheduled visits to the ISP to supervise Posbindu-Posyandu activities.

> *If counselling is held at Posbindu (ISP), we will definitely have time for that. For example, if the day and time have been scheduled, then we can definitely make it.* **(GP2)**

In summary, the personal and physical closeness of the CHWs to patients in the community provides advantages through the shared social and cultural life, resulting in a social bond that can lead to mutual caring. CHWs with cultural sensitivity can be

more acceptable to diabetic patients than HCPs. Delivering the FIne-CHWs programme in community venues further strengthens the sense of belonging within the community. Understanding the context of the intervention is crucial for the success of FIne-CHWs. CHWs' understanding of the community's potential and barriers, as well as the people and context, is one of the strengths of using CHWs as an intervention provider.

6.1.3.2. Subtheme 3.2: Drawbacks of proximity to community

CHWs work in a unique position in the community; as community members and service providers, they live together in the same area. Their relationships with their relatives, friends, and neighbours provide advantages but can also lead to disadvantages in building trusting relationships essential for healthcare uptake.

> *... Sometimes at the community... you know, everyone is different, right? There are people who gives (positive) response, and some of them don't.* **(CHW9)**

Being close only sometimes guarantees trust; conversely, familiarity with the CHW may lead to them being less trusted. Patients did not trust CHWs for a variety of reasons, including the fact that they were not good role models (not caring for their own health), lacked the necessary training or abilities, or were not trained HCPs.

> *Mrs. Iis is my niece, all of the kader (CHW) are also my relatives. Mrs. Iis herself (kader suffers from diabetes). She also doesn't get well, she felt itchy… so she has to get well first.* **(P8)**

The distrust towards CHWs originates from the community itself, primarily in Indonesian cultures, where the close mutual relationships among community members

make it easy for them to recognize the background of the CHWs, including their friends, family, and people residing in the same neighbourhood. This issue can act as a barrier to expanding the role of CHWs in delivering FIne-CHWs. Therefore, to address the trust issue within the community, it is necessary to enhance the capabilities of CHWs.

6.1.3.3. Subtheme 3.3: Pre-service training as an intervention provider

Before delivering information or training to community members, CHWs need to be trained by HCPs in order for patients and family members to trust them. The patient participants needed to be confident that the CHW was qualified to provide FIne-CHWs sessions.

> *... as long as they have knowledge, I believe. They will be taught first, right? it means they have the knowledge, so they will teach me yeah... I believe in them <laugh>.* **(P7)**

> *If they get training, sure, I trust them [CHW].* **(P1)**

The impact of training might increase the self-confidence of CHWs, as demonstrated by two CHWs who participated in university research projects; with the knowledge gained from previous training, one of the CHWs indicated confidence by stating that they were able to educate diabetic patients at Posbindu without the presence of HCPs.

> *But it's okay if they [HCP absence] as long as there is a recommendation [delegation of tasks] from the PHC. [If] They ask whether we can do it or not. "Yeah, I'm ready" (...) They know that we are kader, we usually convey health education, and we collaborate with*

the PHC, [because] we cannot be separated from our community. **(CHW7)**

Furthermore, one of GPs believed that requiring the CHWs to pass an examination and providing a certificate to evidence this would increase CHWs confidence that they could demonstrate their competence.

If the kader participate in diabetes foot exercise training and get a certificate, it will increase their confidence. **(GP1)**

Because the current practice focused on wound care management, diabetic foot training was also suggested for nurses who admitted they lacked knowledge on the subject as it would be nurses who will train CHWs to deliver FIne-CHWs sessions.

Not all nurses understand about footcare, except for those who is responsible as the leader of diabetes programme, and not all understand about footcare. **(N3)**

Maybe we should do some training for nurse before implementing this [footcare education] in community. **(N2)**

CHW training might address the mistrust of community members concerned about their knowledge and skills in diabetic foot prevention. In addition, training will increase the CHW's self-esteem and confidence alongside gaining the respect from healthcare workers. Formal competency-based certification must be awarded after they have completed training to demonstrate that they have the ability to become an educator; it also boosts their confidence while ensuring they have acquired the appropriate competencies. Furthermore, it is essential that HCPs who serve as trainers

for CHWs possess a comprehensive understanding of diabetic foot prevention to ensure the seamless transfer of knowledge.

6.1.3.4. Subtheme 3.4: CHWs' supervision

Most patients and family members doubted the CHWs' capacity and capability to provide professional standards of healthcare education. The patients were concerned about the background knowledge of CHWs, and that they would not be able to answer all their questions from the community members. They considered it necessary for a nurse or physician to supervise the CHWs, and adequate supervision would be another way to increase trust in the service.

Furthermore, because they knew the CHWs personally, the community assessed their capacity and capabilities in light of personal impressions. They unintentionally made unfair comparisons among both CHWs and HCPs. However, such existential perceptions are nevertheless instrumental in-patient trust in and utilization of services.

> *Sometimes people are different. If it's not from the doctors, they don't really believe what people say. If there is a doctor accompanied, they will believe it and it will be better.* **(P4)**

> *There will be questions from patients that the kader (CHWs) can't answer; the health worker can answer them.* **(P7)**

One family member described the situation when CHWs provided services in the community, the presence of HCPs at ISP increased the confidence of CHWs, as well as creating a sense of trust in the community, by conferring veracity on CHW-delivered content and practise.

> *For the kader, if they wanted to respond [answer the question] they were afraid of being wrong but if the CHWs were accompanied by a Puskesmas officer (HCP) when CHW shared knowledge [teaches the patients], it looked like CHWs getting smarter" (…) posyandu officers [CHWs] were not confident, even though the Puskesmas officer (HCP) just sits, just-drinks coffee, but they have brought a different atmosphere psychologically… I did not know how... there was some kind of placebo effect [spellbinding]… for the posyandu officer (CHWs) and the community members.* **(FM2)**

CHWs are potential human resources for ensuring that health services are provided to all people, particularly those from disadvantaged backgrounds. CHWs recognised that their role in society is dependent on the delegation of tasks from HCPs; without the support of health professionals, access to serve the community is limited. A CHW expressed that disseminating footcare education within the community would be unfeasible unless the nurse granted them permission to share the information.

> *The important thing is that nurses must be willing to guide us as kader... if we insisted on doing this, but it's useless if nurses don't want to [teach] us. The important thing is that they want to guide us as kader or to accompany us.* **(CHW4)**

HCP believed that a deficiency in the knowledge and skills of CHWs could engender community dissatisfaction and mistrust towards CHWs. Conversely, the HCPs more extensive knowledge and competencies would alleviate this issue.

I'm afraid that CHW sometimes gets confused. I worry that patients suddenly ask questions and they can't answer. Because in terms of knowledge, we understand more about the disease. So, when they have a question they don't understand, we help answer it. **(GP1)**

HCPs should be present [when CHWs provide interventions], to gain people's trust and make them [CHWs] more confident if they receive questions [from community members]. **(N3)**

Moreover, HCPs expressed reservations regarding CHWs' aptitude to convey information precisely. They are apprehensive that CHWs may not furnish information with the same level of detail as HCPs and therefore opine that the participation of healthcare workers could enhance the community's acceptance of CHWs.

Sometimes there is a possibility of missed [educational content]. The way it is conveyed from one person to another is different, and health education goals still need to be achieved. For example, if you want to clean your feet, there may be missing points or lack of attention to detail… maybe to keep people's trust in kader (CHWs), maybe for some people, if there are health workers, they will believe more "oh, this is true, what the kader teaches". **(GP2)**

Patients and family members believed that the presence of HCPs while CHWs delivered interventions could foster trust in the CHW. This belief was also shared by nurses and physicians, who thought their presence would help CHWs answer patient's questions about specific topics and ensure that CHWs had conveyed the correct

information. Trust between CHWs and patients and CHWs and HCPs is strengthened when the CHWs are supervised by HCPs.

6.1.4. Theme 4: CHW Resources (Recruitment and Selection of CHWs)

The recruitment of CHWs with appropriate characteristic is a pivotal determinant of the programme's success, as they must possess the capacity to assimilate the requisite knowledge and skills and embody the proper attitudes for the task at hand. Drawing from his experience as a village administrator, a family member outlined some of the criteria the community deemed essential for CHWs. The family member emphasized the appearance of CHWs as healthcare providers when rendering services in Posyandu.

> *what I'm saying is that it's about placement, there must be psychological screening, don't put people who are beautiful, but they have high BP, bu... eh, it's troublesome <laugh> not only having knowledge but also their appearance (...) the performance is then supported by a way of interacting... able to make sense because after all, they are kader, their job is to talk to people (...).* **(FM2)**

A family member with prior experience overseeing the CHWP stressed the significance of selecting CHWs who possess sound knowledge and an empathetic disposition, enabling them to forge robust relationships with community members. The family member also identified communication skills as a vital attribute that CHWs should possess.

To ensure an equitable recruitment process, personal preferences ought to be avoided when selecting CHWs. Another family member recounted their experience with a community programme wherein the new village head favoured individuals based on

proximity, resulting in CHWs being perceived as politically affiliated and lacking societal respect while on duty.

> *In my time, I was the village head... If you changed the village head then the passengers changed, the passengers here are the people (involved). Changed to a different one [village head] then the previous kader is no longer active, like that. (...) the Puskesmas (PHC) should not recruit CHW; it's from a politician, whoever it is, whatever colour it is [colour is a symbol of a political party] ... well this is one of the reasons that people's respect decreased... so don't have activists there, it's just a pure community... housewives.* **(FM2)**

A nurse with over 20 years of experience overseeing CHWPs delineated additional criteria to consider when selecting CHWs. The nurse underscored age, educational attainment, and motivation to engage in community service as the three pivotal factors.

> *I mean, they are elderly... so it's difficult to do reporting, maybe, it will be better if the kader are under 50 years old and also [have a high] education level and also, they have a passion for work. If they really want to be taught ...yeah, actually. we can ask them for help. But in reality, sometimes, yeah, it's a bit difficult to write reports they said that they can't... just can't do that (...).* **(N5)**

> *The criteria (of kader) are the enthusiastic ones. CHWs who are ready to help and encourage patients' health.* **(CHW7)**

To recruit CHWs effectively, specific criteria should be taken into account. CHWs should be regarded as educators and possess good emotional intelligence and practical

communication skills while independent of political influence. Selection based solely on proximity to the incumbent village ruler should be avoided. Additionally, CHWs should maintain a professional appearance to command respect from the community. To ensure the successful delivery of FIne-CHWs educational sessions, three critical recruitment characteristics must be considered: age, educational attainment, and high service motivation. These three characteristics will be discussed in greater detail in subsequent sub-themes. **Subtheme 4.1:** motivation underpinning being CHWs (the primary requirement to become CHWs); **subtheme 4.2:** CHW remuneration; **subtheme 4.3** CHWs' ability to learn.

6.1.4.1. Subtheme 4.1: Motivation underpinning being CHWs

The motivation of CHWs to support their community is considered crucial, with many CHWs citing a desire to help their neighbours as their primary motivation for undertaking the role. This altruistic motivation to contribute to and support the community was deemed necessary by CHWs. One senior CHW even recounted how she dissuaded prospective young CHWs from expecting financial compensation for volunteering in the community.

> *Let's be a kader. This is a social service, so there is no salary. If you want a salary, you can work in a factory and reach 2 million [rupiahs] a month [but being CHWs]; the reward is for the afterlife—Insha'Allah [if Allah will it].* **(CHW7)**

> *(...) they don't want to. (...) maybe other people work to earn money, but this is social work; we don't get money but give our time, right? <laugh>, spend much time on social work, maybe once a month. No one else if it's not us. That's what I thought.* **(CHW10)**

Altruism is a concept that refers to a selfless concern for the welfare of others. It can stem from a desire to improve the lives of those in need, regardless of who they are, or from a sense of emotional attachment to friends and family (Elster, 2006; Mattis *et al.*, 2009). In the context of CHWs, altruism is a significant factor in motivating individuals to volunteer for the role. CHWs are appreciated for their willingness to contribute to the community's well-being, even at personal expense.

Most CHWs cited helping others as the primary reason for volunteering, followed by the opportunity to acquire new knowledge that would benefit their families. They did not expect financial rewards for their efforts, but believed that God would reward them.

> *Yes, it's just voluntary to be a kader; I want to be with the community, be close, know the situation of being a kader, and also gain knowledge. It will improve my knowledge; I can give a health education and help patients be healthy. And whether it's an increased add workload or not, I think I used to have a lot of work every day. However, this can be useful for many people. So, we don't keep and share our knowledge with others - I mean, we are volunteers. We are the senior kader; asking about the honorarium is embarrassing. We are just volunteers, not civil servants; why do we ask for an honorarium? God will give it if we are sincere.* **(CHW7)**

In some situations, CHW even spends money to support ISP-NCDs (Posyandu) for transportation, consumption, and other costs.

Last time we received Rp 50000 [GBP 2.50-3.00] a month from the government, but I was happy. We save some of the money from the Posyandu (maternal and child post) to manage the Posbindu (NCD-Post), to buy water and stationery. **(CHW3)**

The primary motivation for individuals to volunteer as CHWs was their desire to assist others, with some citing religious reasons as well. Another cause identified was gaining new knowledge to support their own families. However, the CHWs noted that younger volunteers appeared to have a different attitude towards this community role, affecting its sustainability.

6.1.4.2. Subtheme 4.2 CHW remuneration

Most CHWs had extensive community service experience, having managed ISP for mothers and children (Posyandu). One CHW reflected on how long she had been a CHW and how she had suppressed her desire to retire because no other new CHW was prepared to take her place.

Until now, my child is 24 years old. I've joined Posyandu as a kader since my children were in middle school. I am 56 years old, over half a century, and already have two grandchildren. <laugh> "I couldn't [retire being CHW]; you could ask someone else; I want to retire; I'm old now. Ask those who are still young", "I can't, I should work", there are many reasons. So, if we do that again, it's okay because there is no one (…). Maybe they don't want to be a kader because they don't get a salary. [It is] for social activities, if there is no kader, the community will not be able to be involved actively (…). **(CHW10)**

Some CHWs expressed concern that people were no longer interested in volunteering, with the lack of financial benefit from being a CHW being one reason for this change. This shift in motivation could impact the sustainability of the CHWP.

> *It's decreased, the number of CHWs. Several years ago, it was a lot but now it's few.* **(CHW5)**

> *They are already willing to become a kader, have a soul to serve, and are sincere in helping the community but I think limited kader with this characteristic altruistic <laughs>, Yes, it's still a few number, there are, but maybe not too many.* **(GP2)**

Almost all interviewed CHWs stated that altruistic motives were the main reason for volunteering. However, CHW also pointed out that not everyone accepts working without incentives, especially younger people.

> *Sometimes the kader... the young kader. Sometimes they say, "Is there fee for that, Mrs. Iis?" For me, I just want... to encourage the community, sincerely. I don't really care about salary.* **(CHW7)**

To tackle this issue, a nurse proposed a solution by highlighting the need for increased emphasis on the financial incentives provided to CHWs. This suggestion stemmed from anticipating future challenges, such as the potential for more complex and demanding CHW tasks, which may include the delivery of FIne-CHWs educational sessions.

> *My suggestion is how to improve the welfare of the kader, too; please note it for the future. Moreover, later if there is a new task, it might be*

even more difficult, they are also very helpful in implementing the PHC programme. **(N2)**

if it's only 50,000 [rupiahs] monthly, the CHW probably never complain, although sometimes it's not enough with 50,000 rupiahs [GBP 2.50-3.00]. **(FM2)**

In Indonesia, CHWs typically offer their services voluntarily and only receive a nominal reimbursement for transportation expenses provided by the local government. However, the community often supports CHWs through informal means such as offering food and monetary compensation. Introducing formal financial rewards for CHWs may disrupt this informal payment system and potentially compromise the existing relationship between the CHWs and their community.

With a note, remember to increase the capacity, if the problem is related to finance, don't worry... many people will pay attention [helping CHW financially]. CHWs will be bought by the community of fried bananas <laugh> (...). That's just an example, sometimes, if members of the community have sustenance [some of the money]. CHW was given an envelope [was given money] (...) so this. also don't keep buying and selling. if buying and selling would not accept, it is a kind of charity, as long the (CHWs) belief is, that the keyword is ... to give the best to the patient. **(FM2)**

Consideration needs to be given if reimbursement is provided; this may change the role and motivation of CHW within the community as a volunteer. Although the

provision of allowances and transportation could make the programme more acceptable and increase CHW motivation.

6.1.4.3. Subtheme 4.3: CHWs' ability to learn

Some CHWs are community leaders with long experience in volunteering and understand the constraints and support in the specific context that the intervention will be implemented. However, one nurse reported the challenges of managing the performance of the senior CHW's in certain tasks, specifically managing community data. He was concerned that the age of the CHWs could affect their performance.

> *On average, they have long experience as kader, there are many CHW who are 45 years old and over, many of them are seniors. And the community also knows them.* **(GP1)**

> *I mean they are elderly... so it's difficult to do reporting, like that Maybe, it will be better if the kader are under 50 years old. So, for writing report, sometimes it takes a bit longer to understand.* **(N5)**

To support nurse concerns around the capacity of CHWs to undertake new assignments as educators at FIne-CHW. Some CHWs recalled previous training challenges to elicit further information.

> *If we didn't understand, we have to ask first (...) but we are old, it must be detailed one by one and recorded. If there is health education in the village, we pay attention to it. If you don't know it, we'll ask again. Maybe it's difficult for us to understand <laugh>.* **(CHW10)**

Moreover, during the interviews, a patient and a CHW expressed their appreciation and optimism for the younger generation of CHWs. They believed that younger individuals have a greater ability to acquire new knowledge and establish connections with older people. This particular issue was raised by former CHWs and the current CHW leader, who were interviewed as patient participants.

> *I think they are young (CHWs) <laugh>. They are not like previous kader who were old. Now, if they are taught by the clinic (PHC), they can do it… Yeah, the elderly is easy to be managed by young kader.* **(P9)**

> *Now, the young kader have more experience. I am sure they can understand quickly about the health education that be given (by HCPs).* **(CHW7)**

Based on the data, it appears that the recruitment of CHWs should prioritize the ability to learn and acquire new knowledge and skills and demonstrate this capability. The emphasis on recruiting younger CHWs may be related to their higher level of education compared to previous generations. Since the late 20th century, pedagogical developments and more universal secondary school enrolment has led to significant improvements in education for the younger generation, resulting in higher levels of education compared to their predecessors (Kurniawati *et al.*, 2018).

Commensurate with these participants' opinions, there is no specific educational requirement to become a CHW in Indonesia. However, it is generally expected that CHWs possess basic literacy and numeracy skills, including reading and writing.

The chosen ones were not seen from their educational background or socioeconomic background. **(FM2)**

However, the level of formal education was not considered to be related to the contribution the CHW would make to the community. Enthusiasm for volunteering was considered more important.

Some kader (CHWs) have graduated from high school but are lazy [do not make a significant contribution] and are not interested in getting involved [in the CHWP] in this area, but kader (CHWs) with low education have great interest, although not always. **(N3)**

Level of education could indicate a person's ability to learn new knowledge and skills. One CHW expressed concern that her level of education could create a poor performance as an educator. She felt insecure about it and assumed that someone with a higher level of education was more capable of learning new knowledge.

I could not do anything; I'm afraid that other people will be educated and graduate from school, while I'm not. I'm afraid I can't do it. I'm worried I won't be able to. on how that my way of speaking and knowledge is not like other people who have a high level of education. **(CHW6)**

If the kader is from the middle to upper class, it's possible; the low-level economy people (usually) also have a low education level, and their capability to understanding(material) isn't enough. **(N5)**

In summary, it is essential to consider the level of education and age limitations when selecting CHWs to deliver the FIne-CHWs educational sessions. However, it is also important to note that education is not the sole factor to be considered and that motivation and enthusiasm for the role are also significant attributes. Additionally, age should also be considered as it is perceived to be linked to the CHWs' ability to perform their duties effectively.

6.1.5. Theme 5: Community Training Approach

The primary objective of the ISP-NCDs (Posbindu PTM) activity is to promote and prevent NCDs among individuals aged 15 years and above. However, the majority of visitors to Posbindu are elderly individuals, including those who have diabetes (Alfiyah and Pujiyanto, 2019). Many of the CHWs involved in this activity are also senior community members, which aligns with the age group of most diabetic patients. All three groups of participants have expressed concerns about the patient's ability to comprehend and retain the information provided during educational sessions at ISP-NCDs and their ability to remember or perform the necessary self-care tasks.

> *I was taught in Prolanis programme at the Puskesmas (PHC). I have to wash my feet often, not to wear shoes that are flabby and rough socks. Don't cut the nails like that... soak them in hot water. It was often reminded but I always forgot again.* **(P3)**

One of the CHWs confirmed the data mentioned above by sharing their observations on the outcome of health counselling sessions at Posbindu. The elderly participants expressed that they often forgot the new information provided by the CHWs, leading the CHWs to remind them of the information during subsequent meetings frequently.

If it's only for a while, moreover they are old and tend to forget. Within an hour, if they forgot then they could ask again <laugh> barho [Sundanese, meaning forgetting when you are done], yes it's next month, repeat again, then we have to ask patients/visitors do they still remember or forget, for example if they still remember, thank goodness, we will repeat direction of that guidance. **(CHW4)**

The difficulties of the patients leaning new information was mirrored by the difficulties the CHWs experienced learning new information following training. Some CHWs admitted that this was one of their areas for improvement in understanding the educational material provided in training and was a concern raised by nurse participants.

If we did not forget, we used to forget completely [information from training] < laughs>. **(CHW2)**

Kader training... there is usually training for CHW, Yeah, they have been taught like that. Sometimes in this area, we teach them again and again... teach them… forget it again… and again… <laught> even though that's just the same topic. **(N5)**

In order to tackle the challenge of learning difficulties, the three groups of participants suggested devising learning strategies that would facilitate the understanding and retention of educational materials by both the CHWs and the patients. One GP proposed a method that involved presenting educational materials accompanied by illustrative pictures and using simple language. This approach aimed to enhance

participants' comprehension while enabling them to retain the information more effectively.

> *Using multiple images is preferable. Because it's usually more accessible for people to understand and remember what we explain, it's different from explaining with just words. For example, "this is what a DFU looks like", and [the picture shows] it has no complications. So, people can easily remember.* **(GP1)**

> *if would be better if a book is provided, it's possible. We can explain it later. If someone asked further questions. The elderly usually forgets or doesn't understand. They will ask, how about this and that… So, we can explain further.* **(CHW5)**

Family members helped patients recall new information from training and to remind them to adhere to health regimens, making them a potential resource to be involved in FIne-CHW education sessions.

> *My mother forgets a lot, so she can remember later with the help of her children and husband, who can provide assistance.* **(FM1)**

Moreover, it was suggested that emphasizing hands-on practice would aid in the retention of information by the patients. A nurse expressed the belief that this approach is particularly practical for elderly patients since they can directly witness the demonstrations and subsequently practice them frequently at home. By engaging in hands-on activities, patients are more likely to retain the knowledge and skills imparted during the educational sessions.

(…) must be demonstrated often practiced, like that... so I don't forget. **(P7)**

they better get a demonstration skill [footcare]. So, they see [every step]. It is more effective to teach footcare practice. Mainly because they are at an advanced age, [they] do not like reading books, so it is easier to see, hear, and be more effective than asking them to read. **(CHW3)**

The duration of the intervention also affected the participants' concentration ability with one hour considered the maximum length of an educational session with shorter sessions preferable for concentration and engaging the patient.

(...) CHWs, too… and a community that is given health education too... would make them bored; they don't concentrate either. Usually, it just takes 15 minutes, their concentration has already been dispersed <laugh>. **(N4)**

To address the health needs of the specific community, particularly elderly patients visiting ISP-NCD posts, it is essential for CHWs to exhibit sensitivity and employ appropriate approaches. The training of CHWs should encompass the implementation of learning strategies aimed at facilitating the delivery of interventions and supporting patients in acquiring and retaining new information. One practical approach involves demonstrating proper footcare practices and furnishing patients with a comprehensive book that contains illustrated pictures and step-by-step interventions. This resource can enable patients to practice footcare practice at home with the assistance of their family members.

6.2. Discussion

The semi-structured interviews undertaken with three groups of participants – namely CHWs, HCPs (GPs and nurses), and patients and their family members – aimed to gauge the acceptability and feasibility of the FIne-CHWs. Interview data revealed several barriers and facilitators to implementing this intervention in the Indonesian context. The opinions and perceptions of participants in delivering and receiving footcare education in the community were presented in five themes around community experiences in diabetic foot prevention; enhance healthcare uptakes by extending CHW role: less focus on optimizing the community programme; community embeddedness; CHW resources; and community training approach. These themes are discussed in this section, along with the strengths and weaknesses of the research design, the implications for practice and conclusions.

The acceptability of the FIne-CHWs programme was acknowledged by all participants, as CHWs providing services within the community were highly appreciated by patients and their families. However, some concerns were raised regarding the capabilities of the CHWs, which need to be addressed through pre-service training and ongoing supervision from HCPs. Moreover, issues pertaining to the selection and recruitment of CHWs, including their motivation, age, and education, were identified as critical factors that influenced their capacity to deliver the FIne-CHWs programme.

This study also revealed several strategies to teach low-literacy patients, who can struggle to retain new information. The FIne-CHWs programme was expected by HCPs participants to contribute to enhancing community knowledge on diabetic footcare prevention, filling the gap in provision for patients who do not have insurance

and are not eligible for the Prolanis programme or experience other barriers to attending its sessions or accessing its resources.

Preventing foot ulcers in diabetic patients is crucial for reducing the significant burden of foot ulceration on both patients and healthcare resources (van Netten *et al.*, 2016). Many patients already present with extensive foot ulcers upon their initial visit to referral hospital in Indonesia (Yunir *et al.*, 2021). Studies conducted in several regions of Indonesia have shown that patients with low levels of education have poor performance in foot self-care behaviours (Mahdalena and Ningsih, 2016; Sari *et al.*, 2021). This study was conducted in urban communities, with varied socioeconomic backgrounds. FIne-CHWs is likely to be implemented for disadvantaged populations who have limited access to health service.

Diabetes education is provided via the Prolanis programme, which is a diabetes care programme for patients with health insurance. However, patients in this study perceived barriers to accessing the Prolanis programme which could lower the level of adherence and interest in the programme (Asfiani and Ilyas, 2017). These barriers include the complicated and slow procedures to referred patients to Prolanis, which lead to patient dissatisfaction, confirming the findings of a study conducted in Bandung (West Java) (Akbar, Gondodiputro and Raksanagara, 2020), studies have found similar barriers to patient's accessing other underutilized diabetes education programme, resulting in recommendations to develop diabetes education programme that suit the needs, beliefs, and lives of diabetic patients (Horigan *et al.*, 2017).

All the participants agreed that CHWs have the potential to empower the community to deliver FIne-CHWs. This finding was supported by Perry and Hodgins (2021) who argued that CHWs can increase the effectiveness of the PHC programme particularly

for those patients with low-income. It is becoming increasingly clear that CHWs can play an important role in screening and managing such diseases, such as hypertension and diabetes (Perry and Hodgins, 2021). The community generally viewed community CHWs as a valuable source of information for delivering healthcare knowledge to the community. However, concerns were expressed by all the participants, including the CHWs themselves, regarding their ability to provide diabetes foot education effectively. The perception of CHWs' capacity and capability may be affected by the tight-knit community and shared living conditions in nearby areas.

Understanding patient's perceptions and experiences are essential to developing personalized strategies for diabetes management that may influence people's responses to their disease and treatment (Widayanti *et al.*, 2020). The findings in this study indicated that CHWs often come from low socioeconomic backgrounds, and they provide access to essential health services in poor communities; similar findings have also been reported by studies worldwide (Ormel *et al.*, 2019; Wagner, Asiimwe and Levine, 2020; Perry and Hodgins, 2021). Sharing similar life experiences; both geographically, socially and linguistically creates a sense of caring among communities (Glenton and Javadi, 2013), and builds a relationship of mutual trust among community members (LeBan, Kok and Perry, 2021). Similar understanding around community appointments arises as CHWs deeply understand their culture (Bhattacharyya *et al.*, 2001).

In this study, patients and CHWs referred to "wet diabetes" and "dry diabetes", which are examples of popular community designations commonly found among CHWs and patients in Indonesia, whereby they conceptualize the disease in their own narratives

(Widayanti *et al.*, 2020; Sari *et al.*, 2021). These lay concepts influenced their coping strategies and behaviours in managing the disease (Widayanti *et al.*, 2020).

Information can be passed from the CHWs to other community members, including self-correcting any misunderstandings circulating among community members. A study to improve misconceptions around breastfeeding practice in the community addressed beliefs that formula milk was consistently ranked "most healthy" and "most natural" comparable to breastmilk. Using a gossiping approach among mothers about positive breast milk was reported to enhance the effect of media promoting breastfeeding to drive positive behaviour in breastfeeding practice; part of a social movement, and thereby create a sense of social pressure to adhere to related behaviours (White *et al.*, 2016). Thus, employing CHWs as agents to deliver FIne-CHWs can be regarded as an effective strategy for promoting positive behaviour within the community, given the intrinsic rapport that CHWs have with their own local communities, as described above.

This approach considers the community's existing knowledge and understanding, allowing CHWs to disseminate information and educate community members in a relatable manner tailored to their specific needs. By leveraging the expertise and trust of CHWs, the dissemination of FIne-CHWs can contribute to the adoption of positive behaviours and practices among community members. Moreover, a direct link between community respect for CHWs would increase CHW motivation as CHWs feeling proud of their role improves their self-esteem (Kok, Dieleman *et al.*, 2015) which increases CHWs' confidence to serve those they were familiar with, while at the same time, some patients feel more comfort and assessable being taught by CHWs (Surjaningrum, Minas, *et al.*, 2018).

A trusting relationship requires CHW to act as an intermediary position between the community and health services (Kok, Ormel *et al.*, 2017) to improve service delivery and service uptake (Grant *et al.*, 2017) and to be more effective in promoting healthy behaviour change (WHO, 2020). However, the closeness of the CHW to patients may increase or decrease patient's acceptance of them. Patients may prefer to receive services from people they know well and trust, though they may not want to accept services from close neighbours if these services are regarded as particularly sensitive, such as the promotion of sexual and reproductive health (Glenton and Javadi, 2013).

However, this study found that diabetic patients do not object to disclosing their disease, as Indonesian's perceive that better footcare will result in healthier feet (Sari *et al.*, 2021). In this study, some participants were sceptical of expanding the role of CHWs as educators in FIne-CHW due to their limited understanding and background in this area, and such scepticism was also noted by scholars (Surjaningrum, Minas, *et al.*, 2018; LeBan, Kok and Perry, 2021).

Participants suggested that the distrust of CHWs could be alleviated if they received proper training and supervision from HCPs while conducting FIne-CHW sessions, echoing the findings of Kok, Ormel *et al.* (2017). CHWs are often asked to address issues beyond their expertise, particularly when their scope of practice is restricted to health-related matters for which they have been trained. These challenges will likely impact recipient satisfaction and utilization of services. Despite promotional tasks being perceived as less challenging than curative tasks (Glenton and Javadi, 2013), some CHWs participants did not feel confident in delivering FIne-CHWs, and suggested the need for more training prior to delivering FIne-CHWs.

The significance of training in promoting the trust of communities and demonstrating the competence of CHWs is widely recognized (Kok, Ormel *et al.*, 2017). Provision of training to CHWs has been shown to enhance their technical proficiency, social skills, and understanding of the complexities of clinical care and authoritative guidance, which can potentially improve the quality of care (WHO, 2020; Schleiff *et al.*, 2021). The lack of training may compromise the quality of care provided by CHWs (Glenton and Javadi, 2013). For instance, initial investigations focused on observing the impact of footcare training for nurses and CHWs, have demonstrated an enhancement in their capacity to deliver footcare to individuals with diabetes in Makassar (eastern Indonesia) (Sjattar *et al.*, 2019).

Training was also found to improve CHWs' knowledge and skills regarding health promotion, leading to increased confidence and motivation, better communication, improved delivery of health counselling, and effective negotiation with pregnant women in Java (Tumbelaka *et al.*, 2018). Additionally, formal certification based on competence is recommended to increase CHW self-esteem and patient confidence in CHW services (WHO, 2020). For instance, highlighting the training and certificates of CHWs has been shown to be an effective strategy in increasing patient confidence among Bangladeshi migrants in the US (Islam *et al.*, 2013).

Training is also required for the HCPs already employed in the health system for new skills to perform their expanded role in part-time support and supervision of the CHWs (Aitken, 2013). However, barriers to diabetic footcare prevention in Indonesia have been identified, including a lack of knowledge among HCPs in PHCs, resulting in poor diabetes treatment at public primary-care facilities (Seuring *et al.*, 2019; Sari *et al.*,

2021). Similarly, this study indicates a lack of nurse knowledge in diabetic foot prevention who would be potentially supervising the CHWs.

Additionally, adequate supervision from HCPs during the delivery of FIne-CHWs sessions is crucial in promoting community trust and ensuring compliance with patient management requirements (WHO, 2020). The participants in this study requested the presence of HCPs whilst the CHWs were delivering FIne-CHWs in the community. Supportive supervision should include regular monitoring of CHWs at their tasks, obtaining feedback from CHWs to consider potential programme improvements, and ensuring the safety and well-being of CHWs at their work (Jaskiewicz and Deussom, 2013). Supervision plays a vital role in strengthening the relationship between CHWs and health professionals, as well as fostering a positive relationship between CHWs and the community, which can significantly impact the perception and beliefs of the community towards CHWs (Kok, Broerse, *et al.*, 2017; Westgate *et al.*, 2021)

All the participants considered that the acceptance of the community toward the CHWs would be enhanced if they were recognised and given support from HCPs. Inadequate supervision, on the other hand, can result in demotivation among CHWs and a lack of legitimacy in the eyes of the community (Kok, Dieleman *et al.*, 2015). Furthermore, some studies in Indonesia showed that ongoing supervision was essential to achieve meaningful change and sustainability of CHWPs by helping CHWs remember points received during training and put them into practice (Tumbelaka *et al.*, 2018) alongside the increasing ability of nurses and CHWs to perform footcare (Sjattar *et al.*, 2019).

Effective supervision requires sufficient allocation of time and resources. HCP participants recognized that the timing of FIne-CHWs sessions needs to align with their schedules to enable them to supervise ISP (Posbindu-Posyandu) activities

successfully. However, the role of CHWs between PHC under MoH and sub-district under MoHA can be an obstacle. Although CHWs receive task assignments from HCPs and report to them, they do not fall under their coordination. Instead, CHWs are expected to submit reports to the sub-district. This scenario can impede the execution of the FIne-CHWs.

The capacity of CHWs to acquire new knowledge and skills is essential. Some participants in this study expressed concern about the limitations CHWs may face in expanding their role in delivering FIne-CHW education sessions due to their existing responsibilities in managing ISP-mother and child post (Posyandu) and ISP-NCD (Posbindu PTM). The CHWs' resources are shared, and the posts are held simultaneously (Pratono and Maharani, 2018). Patients and nurse participants expected young and well-educated CHWs for delivering FIne-CHWs. This expectation may be influenced by the experience of working with senior CHWs who had difficulty with data recording. However, this bias may not be fully justified, as older CHWs can provide a wealth of experience and knowledge that younger one's may lack (Aitken, 2013).

There is some debate regarding the deployment of older CHWs. Concerns have been raised about their ability to cover their assigned geographical areas as effectively as younger CHWs in Nepal (Jaskiewicz and Deussom, 2013). However, older CHWs may have an established position as community leaders and more credibility than their younger counterparts. A study on the CHWP in Nepal found that older CHWs were effective in offering counselling to women and family members on birth preparedness, institutional delivery, new-born care, family planning services and other basic health services. Senior CHWs who were considered to have less mobility can still be effective

in providing services and promoting recommended health practices due to their high levels of respect and recognition within the community (Jaskiewicz and Deussom, 2013). Therefore, while there may be biases and concerns surrounding the deployment of older CHWs, their experience and community position can make them valuable assets to CHWPs.

In addition, the participants in the study also highlighted the importance of higher education among CHWs selected for an extended role in the FIne-CHWP, as it can significantly impact their abilities. It has been observed that younger CHWs tend to have higher education levels (Bhattacharyya *et al.*, 2001) and they may also possess more energy to perform their tasks (Jaskiewicz and Deussom, 2013). WHO (2020) reported evidence suggesting that CHWs with higher levels of formal education before joining the workforce are more effective in tasks such as registering patients, diagnosing childhood illnesses, and providing appropriate advice to clients. Studies conducted in Surabaya, Indonesia, have suggested that CHWs with higher education levels are better suited to take on expanded roles in managing perinatal depression, as they possess better problem-solving abilities and knowledge and are more open-minded (Surjaningrum, Jorm, *et al.*, 2018).

WHO (2018) emphasizes the importance of appropriate education levels for CHWs based on their cognitive abilities and the specific tasks they will be performing. In Indonesia, CHWs managing ISP-NCDs (Posbindu PTM) were formerly required to have a minimum educational level of year 12 schooling (MoH-RI, 2012); however, this educational attainment is not specified by the new CHWs manual (MoH-RI, 2019). This level of primary and secondary education provides essential skills and experiences not available to illiterate individuals. Additionally, secondary education

introduces scientific concepts that facilitate the understanding of biological and medical concepts (Aitken, 2013). Despite the benefits of an educated CHW, turnover rates for such individuals are relatively high due to a lack of career advancement and educational opportunities within the CHW role (Kok, Dieleman, *et al.*, 2015; WHO, 2020). To address this issue, it is recommended that community health programme planners consider recruiting CHWs within education level that meet the requirements of the FIne-CHWs. This would ensure that CHWs have the necessary skills and experience while reducing the likelihood of turnover due to a lack of opportunities for professional growth.

The study found there was a perception that younger generations were less likely to assume the role without financial incentives. This change in expectations could jeopardize the programme's long-term viability. An ethnographic study on the position of CHWs in the current situation revealed that the values of "gotong royong" (mutual cooperation) were less appreciated by a society that has shifted to materialism in line with increasingly complex needs and daily life (Wicaksono, 2017). The study also explained how older CHWs with limited mobility persuaded their daughters to become CHWs. However, the younger CHWs often struggled with domestic jobs while being employed, resulting in absence from work because they were helping the community. However, this does not fully explain why young people are not interested in being volunteers. The lack of career advancement opportunities and inadequate incentives may make people less interested in becoming CHWs (Jaskiewicz and Deussom, 2013).

CHWs from poor socioeconomic backgrounds often felt that their remuneration did not reflect their efforts. CHWs did not always receive their allowance as per policy in Indonesia, despite often being only USD 5 per month (Ormel *et al.*, 2019). The

compensation provided to CHWs is inadequate to support their financial needs (certainly if considered as an occupational salary), and appropriate incentives should be considered to balance their efforts in helping the community.

This study also found that many CHWs are intrinsically motivated to serve their communities. They believed that community service will earn them intangible gifts from God, in line with Islamic religious values (Surjaningrum, Minas, *et al.*, 2018). Similarly, religious motivation is a common factor among those who volunteer to help others, as it is an ideological norm that ensures a place in heaven (Mattis *et al.*, 2009; WHO, 2020). Such faith doctrines and motivations are also observed in low-income public housing communities of the African diaspora in New York City, USA (Mattis *et al.*, 2009). Indonesia is renowned as the world's largest Muslim-majority country (Mboi *et al.*, 2018), where religion is positively linked to altruistic values and prosocial behaviour. Islam encourages giving and helping those in need, and this notion is deeply embedded in the culture.

Nevertheless, when a person volunteers, there is usually an expectation of receiving something in return, which does not necessarily have to be material. Intangible rewards associated with volunteer activities may include a sense of satisfaction, personal development, psychological comfort, or the feeling of contributing to the community (Bhattacharyya *et al.*, 2001). This study's findings are similar to other evidence concerning CHWs' motivation in Indonesia, whereby volunteering as a CHW is highly regarded across the country as it fosters satisfaction from social relationships, community recognition, and respect, which are considered non-financially intensive (Djuhaeni, Gondodiputro and Suparman, 2009; Mpembeni *et al.*, 2015). This is partly because the CHWPs in Indonesia emphasize the cultural and religious value of

"gotong royong", which promotes community service and volunteering for one's environment (Djuhaeni, Gondodiputro and Suparman, 2009; Gadsden *et al.*, 2022).

However, in selecting CHWs, their engagement, responsiveness, accountability, respect, and trustworthiness are more critical than their level of education; CHWs do not necessarily require high qualifications but must be willing to learn (Jaskiewicz and Deussom, 2013). This value might be identified as enthusiasm for the work which is often linked to CHW performance in Indonesia (Soeryaningrum, 2018). The prioritization of education level for undertaking the role of CHWs results in varying levels of capacity and capability among CHWs within the community. This raises concerns about how to ensure the competence of CHWs, as family members suggest the need for "real CHWs". In this study, CHWs expressed apprehension about their and their patients' ability to acquire new information. All study participants shared this concern. This finding contradicts the argument that a high level of education is not necessary to become a CHW since CHWs need the ability to learn, which is indirectly linked to educational achievements.

To address this issue, participants identified practical ways to teach both CHWs and patients, such as using illustrative pictures, interactive learning, and providing practice skills within a specified time frame while having support from family members. It is noteworthy that diabetic patients who have similar socioeconomic backgrounds as CHWs often have low literacy. Illiteracy in patients is a common issue in developing countries (Negarandeh *et al.*, 2013). A study in Indonesia reported that patients with lower educational backgrounds had significantly lower footcare behaviour than those with higher educational backgrounds. Less educated people tend to have less health knowledge and engage in unhealthy behaviours (Sari *et al.*, 2021). Patient education

and health literacy are closely related, and their definitions overlap. Health literacy pertains to individuals' capacity to access and understand essential lay health information and healthcare services, enabling them to make informed decisions regarding their health (Negarandeh et al., 2013).

When appropriate training, supervision, and materials are provided, successful programmes have demonstrated the effectiveness of illiterate or low-literacy CHWs. For instance, Female Community Health Volunteers in Nepal were found to be more effective when pictorial diagrams and appropriate forms are used to adapt to the situation (Jaskiewicz and Deussom, 2013). Research has shown that using pictorial images and teach-back educational strategies can increase knowledge and improve health literacy for patients with low literacy levels, particularly in older adults (Negarandeh *et al.*, 2013; Liu *et al.*, 2018; Sjattar *et al.*, 2019).

In a study by Tumbelaka *et al.* (2018) in East Java (Indonesia), counselling cards containing information and pictures were adapted to the local context and proved to be effective aids in promoting health and improving understanding among pregnant women. Similar experiences have been reported in Afghanistan, where pictures or photographs have helped demonstrate clinical signs without video. For more complex tasks, job aids with checklists for all the steps and packaged instructions for equipment have been developed (Aitken, 2013). In summary, the use of pictorial aids and appropriate training materials is effective in supporting illiterate or low-literacy CHWs in promoting health and improving patient outcomes.

The active participation of CHWs was vital to the learning process, and this can be achieved through discussions, role play, and interactive learning in small groups of participants, taking into account the duration of training (Tumbelaka *et al.*, 2018).

Therefore, more time should be allocated for processing information and asking questions, with hands-on activities included, while minimizing reading (Story, 2010). This finding is consistent with teaching footcare in Indonesia, where low-educated participants benefit from visual and auditory demonstration methods rather than written instructions (Sari, 2020). To address this issue, involving family members in patients' education in FIne-CHWs can help them deal with written material and serve as a reminder for patients' adherence to their footcare regimen. Family engagement has also improved diabetes care (Pamungkas, Chamroonsawasdi and Vatanasomboon, 2017)

Moreover, designing effective low-literacy educational materials requires attention to factors beyond reading level, as most of these materials are written at a lower reading level than average health education materials. Effective materials should focus on offering practical strategies for behaviour change, the "need to do", rather than on teaching facts, the "need to know" (Seligman *et al.*, 2007). Additionally, monitoring and observation conducted after training have been shown to help CHWs remember topics and achieve better health counselling (Tumbelaka *et al.*, 2018; Sjattar *et al.*, 2019). The training approach employed in this context diverges from the conventional CHW training conducted by PHC, which typically involves lengthy lectures delivered in a one-way manner to a larger group of participants without subsequent monitoring (MoH-RI, 2012; Tumbelaka *et al.*, 2018). Hence, there is a need to modify the training strategy to improve outcomes in enhancing CHWs' knowledge and skills.

To effectively teach both CHWs and patients, several methods should be employed, such as using pictorial images to illustrate clinical signs, followed by hands-on skill practice within a specific time duration, as recommended by scholars. Family members

should also be involved, and ongoing observation after training could be employed as a reminder system for those uncomfortable reading written materials.

The study's results suggest critical factors that could hinder or facilitate the development of FIne-CHWs. It is essential to acknowledge that CHWs must be accepted and respected by the community, and have strong connections with the PHC system. CHWs should be considered a vital tool for strengthening PHC programmes (Perry and Hodgins, 2021). Furthermore, before enlisting CHWs for community-based programmes, specific criteria or qualifications must be defined, including age and education level.

In Indonesia, CHWs are motivated by religious and cultural beliefs, often driving their willingness to volunteer. However, it is indicated that younger generations may need additional incentives, such as monetary rewards, to encourage participation as CHWs.

To implement FIne-CHWs successfully, several practical training strategies have been identified that are effective for patients with low levels literacy. These strategies differ from the conventional PHC methods used to train CHWs, patients, and the community. Thus, to ensure that the intervention is practical and acceptable within the Indonesian context, it is crucial to consider participants' perspectives and opinions and tailor support to address potential barriers.

6.3. Strengths

Several groups, including physicians, nurses, CHWs, patients, and family members, who are community actors in diabetes prevention, participated in this study. Key stakeholder perspectives provide the in-depth and rich interview data that may be

required to anticipate positive outcomes by predicting unforeseen obstacles that can cause an intervention to fail.

The study was analysed using reflexive thematic analysis, allowing for profound interpretations of datasets. This approach considers the context that would steer the interpretation (Braun and Clarke, 2022) to make sense of the situation and understand the health system policy and community culture. Moreover, the interpretation considered the "subjective" aspects within the interpretative lens. While it could have asserted a strong foundation for comprehending the data and refrained from disregarding uncomfortable realities, this approach renders the interpretation justifiable and supportable (Braun and Clarke, 2022).

The interview technique is an important prerequisite for a successful interview process and can influence the validity and reliability of findings. A pilot interview and preliminary interview discussions with the supervisory team and an ethnographer were conducted to improve the interview technique to obtain data-rich interviews. In addition, as part of the general community and a speaker of the same national and local languages, I was able to build good rapport with interviewees. This made the interviews more enjoyable and allowed participants to feel free to share their opinions based on the interview questions more freely. This allowed for the disclosure of more comprehensive information, and deeper insights into participants' perceptions and beliefs.

6.4. Limitations

The recruitment strategy for this study involved using different groups within the community. However, the absence of a village committee member, which is typically

responsible for CHW selection and funding, may have resulted in incomplete data. Selection bias may also exist if certain population groups are overlooked in the recruitment process. Despite these concerns, one of the family members who participated in the study was a former village head who had experienced managing the CHWP. Additionally, some CHW leaders actively participated in the programme, and had adequate knowledge of managing CHWs in the community. As community leaders, they were able to provide valuable information, ensuring that data was obtained from all stakeholders involved.

Before beginning the interview, I explained the interview guidelines to the gatekeeper to introduce the study in PHC via virtual meetings. However, this did not alleviate their concern that the interview would not encourage the participants to share sensitive information they wanted to keep private. Thus, the pilot interviews were conducted in PHC when a nurse sat close to the patients and CHWs; the participants may have been less open than they were because the nurse was present. The interviewer was not physically present as the interviews were conducted remotely it was difficult managing this situation. Fortunately, after three interviews, the gatekeeper permitted interview participants in a convenient location, such as their homes which made the interview process run smoothly and gained rich data from participants.

During the COVID-19 pandemic, these interviews were conducted remotely using WhatsApp video calls as an alternative method of data collection to circumvent restrictions on face-to-face meetings. Using the internet has its own set of challenges, such as noise when conducting interviews in public places; not all participants can afford gadgets, which limits their options for those who have cell phones. Furthermore, a poor internet connection can make the interviewer's ability to hear and see clearly

more difficult, resulting in data loss and repeated questions to be answered. To address this issue, several steps were taken, including offering participants payment to compensate for the cost of internet data.

6.5. Conclusion

The ISPs (Posyandu-Posbindu PTM), a community effort to empower community members participating in health services, has become a national initiative and is formally part of the MoHA community programme. Government control of the CHWP ensures recognition of CHWs as an essential part of the workforce. Notably, the community post is managed by CHWs, who have successfully managed the mother and child community (Posyandu) post for over three decades. The participants agreed that FIne-CHWs were adaptable in the Indonesian context as a preventive FCI in the community to address the low number of diabetic patients participating in the Prolanis programme.

In addition, the current resources of CHWs are a concern among community actors, which has led to the proposal of criteria for selecting CHWs who are suitable to deliver FIne-CHWs. Increasing the capacity and ability of CHWs through training should be prioritized before this intervention is implemented. Adequate supervision is necessary to foster community trust and ensure that the participants receive the intervention as required.

Although there are concerns regarding the adequacy of incentives for CHWs, altruistic motivations and religious values continue to drive their participation, even though young people may expect adequate monetary rewards. The issue of remuneration and incentives for CHWs, which is a hidden barrier that potentially hinders the expansion

of their role in delivering FIne-CHWs, arises from the position of CHWs between two authorities, namely MoHA and the MoH. While MoH supervises and shares the healthcare programme with CHWs through community posts; the funding for FIne-CHWs, including fixed CHW allowances, is provided by MoHA for all CHW tasks in the community. This raises the question of who is responsible for funding FIne-CHWs, an extended role of CHWs. This unintentionally limits the optimization of FIne-CHWs and affects the relationships among actors involved in foot problem prevention. Therefore, a coordinated approach and supportive relationships among community actors should be facilitated. Positive relationships between communities, health workers, and local health systems can increase the acceptability and practicality of FIne-CHWs

Findings from this chapter were synthesized with the mapping review results to inform the development of the FIne-CHWs using the Delphi consensus method, as described in the following chapter.

Chapter 7

Delphi Consensus

To refine and gain expert consensus on the core component of the FIne-CHWs, I employed the Delphi technique (Figure 14), involving a panel of Indonesian experts in diabetic care and policy. The Delphi survey statements were developed by triangulation of data from scoping review, mapping review and interview data to acquire the core component of intervention.

This chapter begins by outlining the utilization of a triangulation process to integrate data from the previous chapters to develop the core components of the intervention for the initial round of Delphi consensus. The selection of experts for the panel and the execution of the Delphi round are then described. The Delphi consensus analysis and a thematic analysis of the open-text data survey is presented in Chapter 8.

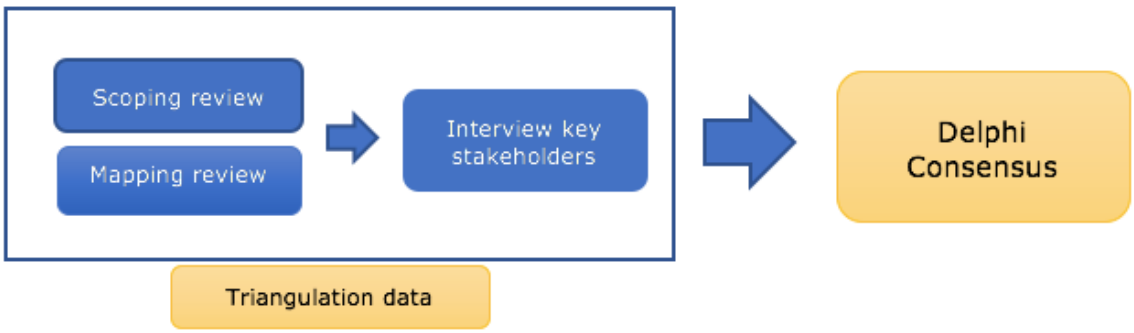


Figure 14: Organogram (Chapters 7 and 8)

Source: Author

7.1. Aims and Objectives

The overall aim of this chapter was to refine the core components of the footcare intervention to be delivered by CHWs (FIne-CHWs) for T2DM patients with low risk DFUs in Indonesia.

The specific research objectives were:

1. To integrate data from the scoping and mapping review and interview findings into the FIne-CHW intervention to develop core components of the Fine-CHW intervention.
2. To develop and select the expert panel of Delphi study.
3. To reach consensus on the FIne-CHWs core components through a three-stage Delphi study (Chapter 8).
4. To analyse Delphi panel member's opinions and perceptions regarding the core components of FIne-CHWs (Chapter 8).

7.2. Preparing a Delphi Questionnaire Through Data Triangulation

Mixed methods are applied for the design of the FIne-CHWs, whereby data integration occurs at various levels and stages (Figure 15). Triangulation was initially developed as a methodological approach to compare the findings obtained from two or more different research methods, to determine the accuracy of measuring an aspect of a phenomenon (Moran-Ellis *et al.*, 2006).

As expounded in the previous chapters, FIne-CHWs development used multiple methodological approaches, including scoping and mapping review, and key

stakeholder interviews data, involving multiple perspectives (from patients, family members, health workers and CHWs). The data from scoping and mapping review and interview participants were separately analysed before the process of triangulation was employed. A triangulation protocol was chosen to allow the evidence from these different sources to be assessed for differences and similarities and enabled them to be combined to develop core components of the FIne-CHWs. Convergence, inconsistency, and contradiction are three outcomes that arise from triangulation (Johnson and Onwuegbuzie, 2004). According to which of these outcomes prevail, the researcher can develop superior explanations of the observed social phenomena.

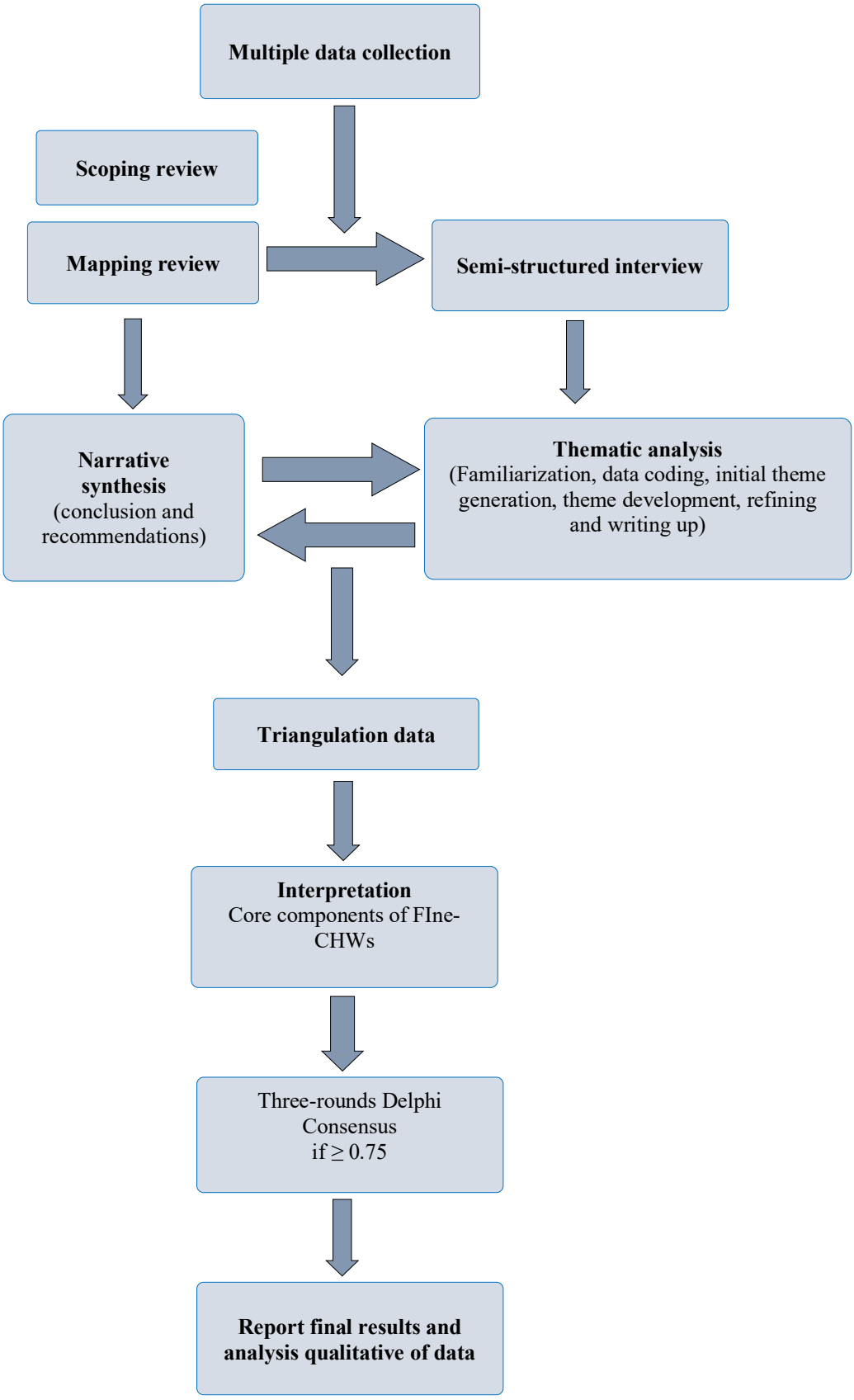


Figure 15: Data analysis

Source: Author

The comprehensive outline of the six-step triangulation process used in this study was adapted from Farmer *et al.* (2006) (see Table 11). The researchers must be clear about the process that generates the integrated relationship and the inevitable implications for subsequent analysis, interpretation and theorizing (Moran-Ellis *et al.*, 2006). The multiple data sets need to generate an integrated set of findings in order to test for convergence and dissonance alongside the complementarity of the outcome (Farmer *et al.*, 2006). Consistent findings from different data sources lend credibility to the interpretation while discrepant findings pave the way for further exploration of complex healthcare issues.

Table 11: Application of the triangulation protocol

Step	*Activity*
1. Sorting	Sort findings from each data source or method into similarly categorized segments that address the research question(s) of interest to determine areas of content overlap and divergence.
2. Convergence coding	Identify the themes from each data source. Compare the findings to determine the degree of convergence of (a) essence of the meaning and prominence of the themes presented and (b) provincial coverage and specific examples provided in relation to each theme. Characterize the degree and type of convergence using the following typifications of concurrence (or nonconcurrence) within theme areas.
Convergence coding scheme	
Agreement	There is full agreement between the sets of results on both elements of comparison (e.g., meaning and prominence are the same, provincial coverage and specific examples provided are the same).
Partial agreement	There is agreement on one but not both components (e.g., the meaning or prominence of themes is the same, provincial coverage or specific examples provided are the same).
Silence	One set of results covers the theme or example, whereas the other set of results is silent on the theme or example.
Dissonance	There is disagreement between the sets of results on both elements of comparison (e.g., meaning and prominence are different; provincial coverage and specific examples provided are different).
3. Convergence assessment	Review all compared segments to provide a global assessment of the level of convergence. Document when and where researchers have different perspectives on convergence or dissonance of findings.
4. Completeness assessment	Compare the nature and scope of the unique topic areas for each data source or method to enhance the completeness of the united set of findings and identify key differences in scope and/or coverage.
5. Researcher comparison	Compare the assessments of convergence or dissonance and completeness of the united set of findings among multiple researchers to (a) clarify interpretations of the findings and (b) determine degree of agreement among researchers on triangulated findings. Plan for how disagreements will be handled and how final decisions on interpretations will be made.
6. Feedback	Feedback of triangulated results to research team and/or stakeholders for review and clarification.

Source: Farmer *et al.* (2006)

The first step in data integration was to sort themes and categories from interview data into a coding matrix; in this study, selected quotations from themes were chosen to represent interview data which was subsequently merged with data from the scoping and mapping review. Contrasting the two files of findings concerning the themes' significance and interpretation, their prominence and frequency (such as the number of documents or interview subjects who mentioned a theme), and the precise instances used to support or explain a specific theme. Data in the matrix were then coded to

highlight if there was agreement, partial agreement, silence or dissonance between the groups of data. Based on this convergence coding, an overall evaluation of convergence between findings was conducted to develop statements for first round of the Delphi study (see Table 12).

Table 12: Example of data triangulation

Data sources	Method of delivery	Notes
Scoping review	Diabetes self-management of education delivered by CHWs reported that footcare as part of the intervention was conducted face to face, and primarily those education sessions were organized in small groups with a minimum of 5 person to maximum of 15 people (Spencer *et al.*, 2011; Islam *et al.*, 2013; Castillo *et al.*, 2014; Pacheco *et al.*, 2017; Schoenberg *et al.*, 2017). Most of the studies held multiple intervention sessions from 4 to 11 times meetings, as much educational knowledge and skill to be comprehended by diabetic patients. Two studies delivered the educational intervention to individual patients (Prezio *et al.*, 2014; Hughes *et al.*, 2016). In addition, family members and friends involved in a group of the intervention was reported by Castillo *et al*. (2010), with sessions led by a team of two CHWs (facilitator and assistant).	
Mapping review	**FCI by health workers** was delivered in various forms, individually or in small groups. Most studies reported that information provided face-to-face sessions (Ooi *et al*., 2007; Borges and Ostwald, 2008, Fujiwara *et al*., 2012; Fan *et al*., 2013; Fardazar, Tahari and Solhi, (2018); Nguyen *et al*., 2019), or individual sessions (Ooi *et al*., 2007; Borges and Ostwald, 2008; Fujiwara *et al*., 2012; Fan *et al*., 2013). Fardazar, Tahari and Solhi, (2018) applied the face-to-face method, individually or in small groups, depending on the patients' needs. Group intervention was administered in groups of 8 to 10 participants. One study reported using varied methods to convey the information through lectures, practically doing feet examination and special feet exercises, playing films, practicing, group discussion, question and answer, providing educational pamphlets and CDs, followed by individual counselling about footcare with a physician and diabetes expert, and psychological	

Table 12: Example of data triangulation

Data sources	Method of delivery	Notes
	counselling with a mental health professional (Fardazar, Tahari and Solhi, 2018). Patients were taught footcare practices to enhance their skills (Borges and Ostwald, 2008; Fan *et al*., 2013; Fardazar, Tahari and Solhi, 2018; Nguyen *et al*., 2019). Additionally, a foot self-care kit comprising a basin, a gallon of water, antibacterial non-deodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror was provided (Borges and Ostwald, 2008). Patients were equipped with essential educational materials, including a brochure, booklet, and waterproof tip sheet outlining footcare procedures (Nguyen *et al*., 2019). Two studies provided educational pamphlets to help patients remember details after being educated (Fardazar, Tahari and Solhi, 2018; Rahman *et al*., 2018). On the other side, two studies used SMS, mobile apps, and short audio-visuals as media to deliver information (Moradi *et al*., 2019; Dincer and Bahcecik, 2021).	
Interview data	There are two options for delivery methods – individually and in a group of patients. The majority of participants supported teaching patients in groups. Some patients held the belief that learning in the group would be fun, not stressful, and they would not feel embarrassed. One of the GPs held the view that teaching in groups would be more effective in community post since CHWs already get together to teach small groups of patients. *If you want to do it in groups, maybe you have to see the number of people. First, it's best not to have too many because it affects concentration. for example, a group of at least 5-6 people, enough with that amount. but if 1 group up to 10-15 I think it's less effective. But it also depends on whether or not kader is available, for example, there are many kader present, for example the number of kader is five people and the number of patients is 10 people. So, the activities are still being monitored, meaning that if we carry out detailed activities, it means whether the patient washes his feet properly or not, checks between his fingers or not, whether the nail method is correct or not. I feel like teaching that way is more personal, like the example above, for example, 1 kader supervises 2 patients, that's still okay.* **(GP2)** *….it will better in group because there are a lot of kader, so the kader can accompany, get closer and explain to them.* **(CHW4)**	

Table 12: Example of data triangulation

Data sources	Method of delivery	Notes
	Home visits have been done by CHWs when they delivered other health programme, I think it's possible. Because, there are some cases that... for example, one of patients who experienced dengue fever, the kader... visit to their house immediately... give health education individually. **(N4)** One general practitioner recommended family members be involved when CHWs provide footcare education, as some patients do not believe what family members suggest, by involving family members, patients will get support. *maybe it can be with their family member attend to look directly. According to his family, it's already warm, according to the patient, it's not like that yet, Patient (maybe) don't believe in this with family members (judgement), but if it's been practiced directly, yes, with many people, there are other kader, there may be other sufferers, maybe it can be more accepting.* **(GP2)** Embedded intervention using multimedia such as educational videos that diabetic patients can watch using their mobile phones was suggested by one of nurse to make the intervention easier to understand, she admitted that not all the community post have facilities to support presentations but she thought it could be possible as long as the head of the village or sub-district was allowed to use their devices. *If CHW has an educational brochure or video, they will quickly understand and demonstrate using the video (...) Most Posbindu PTM do not provide it, but if they ask, they can prepare it (head of sub-district or CHWs can bring their devices or laptops to share videos with patients (...) most Indonesians have mobile phones, they can view content using their mobile phones* **(N1)**	
Convergence	Two CHWs might be considered to conduct intervention sessions. Using multimedia device to enhance understanding of participants was revealed from multiple evidence sources.	Interventions should be conducted in small groups of no more than 15 people, and the evidence from FCI and interview data suggests a maximum of 10 participants per group.
Complementary	Patients were taught footcare practices to enhance their skills. a foot self-care kit comprising a basin, a gallon of water, antibacterial non-deodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror was provided.	
Dissonance	Multiple intervention sessions from 4 to 11 times meetings to delivered DSME by CHWs might be	

Table 12: Example of data triangulation

Data sources	Method of delivery	Notes
	ineffective, since there is the possibility of patient disengagement to attend.	
Silence	No interviewed participants supported multiple session of education.	
Number of Delphi statement	FIne-CHWs sessions should be in groups of up to 10 patients and family members. Family members should be actively encouraged to attend the FIne-CHW sessions with the patient. FIne-CHW sessions should always be delivered by two CHWs: one to deliver educational materials while the other monitors patients' understanding and provides further explanations. The educational sessions should consist of multiple teaching and learning methods such as lectures, group discussions, video presentations and hands on skill sessions. The FIne-CHWs sessions should include a video on diabetic footcare from a diabetes expert. All patients attending the FIne-CHWs sessions should be provided with educational printed materials (such as illustrated pamphlets) to take home. The CHWs should be provided with the foot self-care kit contained a basin (patients should bring their own basin), a gallon of water, antibacterial, nondeodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror.	

Source: Author (adapted from Farmer *et al.*, 2006)

7.3. Delphi Consensus

A three-round modified Delphi approach was used to gain consensus on the core components of FIne-CHWs. It is recommended to conclude the Delphi consensus process after two or three rounds of iterations (Diamond *et al.*, 2014). Delphi technique is a method pertaining to the utilization of expert opinions. The Delphi design is situational as it is guided by the research problem rather than the requirements of the method. This study utilized a modified Delphi method to mitigate the potential bias from the initial round. This involved presenting a set of statements to a panel of experts

for their agreement or disagreement. Subsequently, an open-ended free-text response was employed to collect expert insights and opinions related to these aforementioned statements.

However, there are some drawbacks to using the Delphi study, such as the fact that it is time-consuming, places a lot of demands on the panel members, and can directly affect the participant's motivation and choice identified, leading to high dropout rates in some studies. Furthermore, there is some criticism of participant selection or definitions, round wording, and many questions per round (Keeney, Hasson and McKenna, 2011). To mitigate this issue, I offered some solution such as, the steps for the Delphi method include formation of a team to execute and monitor Delphi, selection of panellists among experts, development of rounds, launching the survey to panellists, and preparation of reports with analysis (Diamond *et al.*, 2014; Yousuf, 2014) (Figure 16). This study was then conducted after an intensive discussion with the supervisory team who possess expertise in conducting Delphi studies for research; they monitored and engaged from the beginning of this study until the analysis was reported.

The 42 statements were generated from the triangulation protocol and posed to the Delphi panel in the first round of the process to gain panel consensus agreement or disagreement. The statements were grouped based on TIDieR guidelines (Hoffmann *et al.*, 2014), which encompass the core components of the intervention identified throughout the analysis and integration data, including items on intervention procedures (n = 3), intervention providers (n = 16), place of intervention (n = 2), delivery methods (n = 7), timing and duration (n = 3), educational content (n = 9), and tailored intervention (n = 2) (Table 13).

The statements were written in two languages: English and Indonesian to minimize loss of meaning, the questionnaire was not employed using a back-and-forth translation, since it is difficult to fully develop accurate and meaningful transcripts because the exact equivalence or meaning may not exist (Choi, Kushner, Mills *et al.*, 2012). A bilingual registered nurse and I worked together to translate the Delphi questionnaire into Indonesian. We first translated the Delphi questionnaire separately and then discussed the translations to develop accurate and meaningful transcripts that minimize potential threats to the validity of the data. A central issue for cross-language research, therefore, is ensuring translations that arrive at the same meaning and maintain relevance in the cultures of both the original language (non-English) and the study language (English) (Choi, Kushner, Mills *et al.*, 2012)

TIDieR is a checklist and guideline developed to help to improve completeness in the reporting of interventions in research studies (Hoffmann *et al.*, 2014). It was created to enhance the quality of intervention reporting and facilitate replication of interventions by providing a sufficiently detailed description of interventions. The TIDieR checklist is utilized not only by study authors but also by journal editors, peer reviewers, ethics committees, and funding agencies. By transparently and thoroughly describing the intervention, the checklist will help to minimize wasteful research and increase the potential impact of health (Hoffmann *et al.*, 2014).

Table 13: Questionnaire Delphi consensus, round one

Item no.	Procedure of Intervention
Intervention procedures	
1	Only patients without an active DFU are eligible for the FIne-CHW sessions.
2	A registered HCP (such as a nurse, physician or podiatrist) must screen all patients' feet for active DFUs before referring them to the FIne-CHWs educational sessions
3	All patients should have their blood glucose levels measured within one month before attending the first FIne-CHWs session
Intervention providers (CHWs)	
4	CHWs delivering the FIne-CHWs sessions must have passed senior high school
5	CHWs with the right personal specifications can be trained to competently deliver the FIne-CHWs education sessions.
6	CHWs delivering the sessions must not have any political affiliations.
7	CHWs delivering the FIne-CHWs sessions must have good communication skills and be motivated to deliver diabetic FCI.
8	Training on DFU care must be provided to CHWs before they can deliver the FIne-CHWs sessions.
9	The curriculum for training CHWs should also cover how to treat patients with dignity, compassion, and respect.
10	CHWs should be provided a course manual detailing how they should deliver the sessions.
11	The training of CHWs should use the teach-back method to emphasise practical skills.
12	The CHWs knowledge, skills and attitudes must be tested through an examination prior to them providing training to patients.
13	The CHWs providing the FIne-CHW sessions must be under the management of the community health centre or Posbindu PTM.
14	There must be a policy for referring patients to the FIne-CHWs.
15	CHWs must be reimbursed for their travel costs to the community centre, Posbindu PTM, or patients' homes.
Intervention providers (HCPs)	
16	CHWs providing the FIne-CHW sessions should be supervised by a GP or registered nurses.
17	A registered nurse should be present at the community centre or Posbindu PTM to supervise CHWs whilst they are delivering the sessions.
18	The nurse supervising the CHWs delivering the session should have previously received training in care of patients with DFUs.
19	Footcare training for nurses should also emphasize foot examination to categorize the risk of DFUs.

Table 13: Questionnaire Delphi consensus, round one

Item no.	Procedure of Intervention
Intervention place	
20	The FIne-CHWs intervention should be delivered in the community centre such as the Posbindu PTM or delivered at the community health centre unless the patients is assessed as needing a home visit.
21	Where patients are assessed as unable to visit the Posbindu PTM (for example, due to physical mobility issues), the CHWs should provide the intervention in the patient's own home, with booster sessions provided by telephone.
Intervention method of delivery	
22	FIne-CHWs sessions should be in groups of up to 10 patients and family members.
23	Family members should be actively encouraged to attend the FIne-CHW sessions with the patient.
24	FIne-CHW sessions should always be delivered by two CHWs: one to deliver educational materials while the other monitors patients' understanding and provides further explanations.
25	The educational sessions should consist of multiple teaching and learning methods such as lectures, group discussion, video presentations and hands on skill sessions.
26	The FIne-CHWs sessions should include a video on diabetic footcare from a diabetes expert.
27	All patients attending the FIne-CHWs sessions should be provided with educational printed materials (such as illustrated pamphlets) to take home.
28	The CHWs should be provided with the foot self-care kit contained a basin (patients should bring their own basin), a gallon of water, antibacterial, nondeodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror.
Intervention time and duration	
29	FIne-CHWs sessions should be provided in four sessions; two one-hour educational sessions and two 15-30-minute booster sessions
30	The booster sessions will reinforce the teaching and learning from the first two sessions and the need for patient to perform daily footcare.
31	The FIne-CHW sessions should be given over a six-month period.
Intervention content	
32	Educational content should cover knowledge on awareness about diabetes and foot complications: definition of the diabetic foot, its types, warning signs, footcare, etc.
33	Washing feet
34	Inspecting foot for problems
35	Moisturizing and massaging foot
36	Foot exercise (e.g., foot exercise using newspaper/ papers)
37	Toenail care
38	Wearing appropriate shoes and socks
39	Help seeking (when, where, how)
40	Stress management related to foot problem.

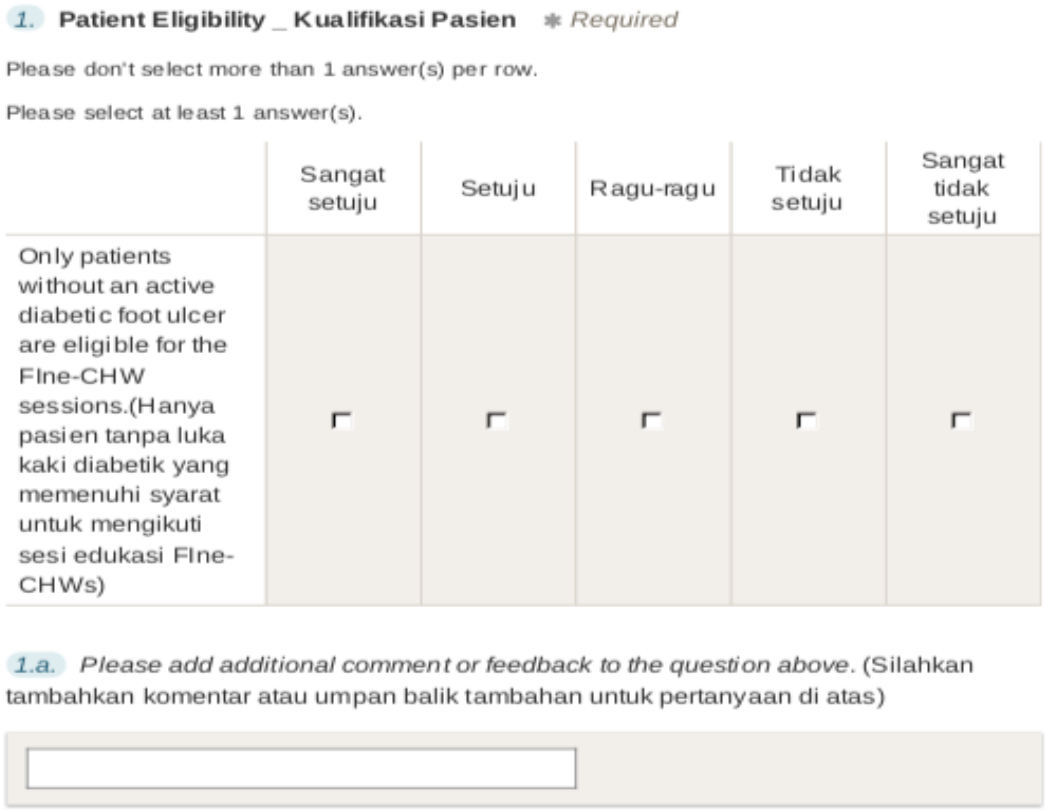
Table 13: Questionnaire Delphi consensus, round one

Item no.	Procedure of Intervention
Intervention tailoring	
41	Patients and family members who participate in the FIne-CHWs education sessions should be given healthy snacks if there is sufficient budget.
42	FIne-CHWs sessions should be delivered in the local language

Source: Author

Prior to the questionnaire being sent to panel, the supervisory team advised revisions to the wording and ordering of the Delphi statement, to ensure clarity of key terms, and the logical flow of statements. Revised statements were written in thematic sections to help participants understand the logic of the flow of statements, so that the new categories in the launched survey included patient eligibility; intervention providers (HCPs and CHWs); CHW management; content of educational sessions; FIne-CHW resources; place of intervention; time and duration of intervention and method of delivery (Appendix E)

The statements were then transferred to the online questionnaire platform. This study employed the Jisc Online Surveys (formerly the Bristol Online Survey - BOS) which was provided by the UoN, as this is an easy-to-use online tool for creating, distributing and analysing surveys (see Figure 16).



1. **Patient Eligibility _ Kualifikasi Pasien** * *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 1 answer(s).

	Sangat setuju	Setuju	Ragu-ragu	Tidak setuju	Sangat tidak setuju
Only patients without an active diabetic foot ulcer are eligible for the Flne-CHW sessions.(Hanya pasien tanpa luka kaki diabetik yang memenuhi syarat untuk mengikuti sesi edukasi Flne-CHWs)	☐	☐	☐	☐	☐

1.a. *Please add additional comment or feedback to the question above.* (Silahkan tambahkan komentar atau umpan balik tambahan untuk pertanyaan di atas)

Figure 16: Presents example statement and scoring

Source: Author

The questionnaire used statements rather than questions, because I was looking for a consensus on core components of the Flne-CHW intervention. However, respondents were also able to add additional information for each statement, enabling me to gain insight into the reasoning for the panel members scoring and information on diabetic footcare education that was not available in the currently published literature or through the semi-structured interviewers.

To ensure content and face validity, the questionnaire was piloted with three nurses in Indonesia who were not included in the panel before the survey was launched to all panellists. They were asked about the design, layout, clarity of information and content. In general, they agreed that the survey was well presented except for the

logical flow of the survey on grouping statements on the same topic. The final revision was then carried out in consultation with the supervisory team. An example of Delphi questionnaire can be found in Table 15.

7.4. Method of Determining Consensus

The study was planned to have three rounds of Delphi consensus. During each round participant were given two-weeks to respond, with reminder emails sent at 7, 10, and 14 days. However, this study experienced a technical problem where five participants who were supposed to receive the survey through the Jisc online platform did not receive it in their email. To address this issue, the duration of the Delphi study was extended by seven days, allowing the panel members additional time to complete the survey. Panel members were asked to score the 42 statements of diabetic footcare education using a five-point Likert scale ranging from 1 to 5 (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree). Five-point Likert scales are the most commonly used technique in survey research; they are usually familiar to participants, and are widely used in Delphi questionnaires (Bowling, 2014). They have the benefit of reducing forced answers by permitting the neutral midpoint answer, which also renders them germane to producing practical insights for evidence base practice via quantification of levels of agreement (Keeney, Hasson and McKenna, 2001).

7.5. Determining Consensus

To increase the validity and credibility of the Delphi findings, Diamond *et al.* (2014) recommend that *a priori* criteria for success should be described. Consensus is

typically determined by the percentage of agreement among participants, with the secondary factor being the proportion of participants who agreed within a particular rating range. They were as follows:

- A statement was included in FIne-CHWs if it reached a consensus level of ≥75% agreement after three rounds, indicated by a score of three or four (strongly agree or agree).
- Consensus agreement was determined by calculating the percentage of panel members combining the score of strongly agree and agree.
- Statements were removed from FIne-CHWs if ≥75% of panel members scored them disagree or strongly disagree.

7.5.1. Between-rounds analysis

The results of the first round inform the contents of the subsequent rounds. The following methods were used:

- A summary of the results of the first round was presented to participants.
- Consensus ≥75% was considered to indicate agreement with the statements, but where language or content were deemed to need improvement, or open-text comments indicated that additional modification was required, statements were refined through discussion with the supervisory team and then represented for panel to rescore.
- Statements that reached a consensus of ≥75% (disagree) were removed from the next round, following review and discussion with the supervisory team.

- For statements that did not reach consensus, the team reviewed and modified wording and then presented the revised statements to participants in the second round for assessment.

In the subsequent round, participants got the chance to rethink and reconsider their decisions for each of the previous questionnaire/surveys and return their responses. This cycle of rounds continued until a point of diminishing return has been achieved, with a maximum of three rounds, or no new information being forthcoming. The setting of the percentage level varies, but a 75% consensus rule-of-thumb is recommended to demonstrate the robustness of agreement (Diamond *et al.*, 2014).

7.5.2. Analysis data of the free-text responses.

The modified Delphi survey constructed using the process depicted in Figure 17, used closed questions followed by open-ended questions to encourage participants to make comments on the topic in question. Data was generated through free text responses from the first and second rounds to obtain information, opinions, experiences, or practices. These data produced participant-led rich qualitative data that provides more insight into responses (Braun, Clarke and Gray, 2017). The data in this study were analysed using a thematic analysis approach, to identify themes and pattern of data to address research question.

Free-text response data allows for in-depth engagement with some of the less obvious themes that cut cross participant responses (Braun, Clarke and Gray, 2017). The analysis was carried out using an inductive approach, whereby no attempt was made to incorporate data into existing theories (Smith, 2018). This analytical approach followed the thematic analysis methods detailed in Chapter 5.

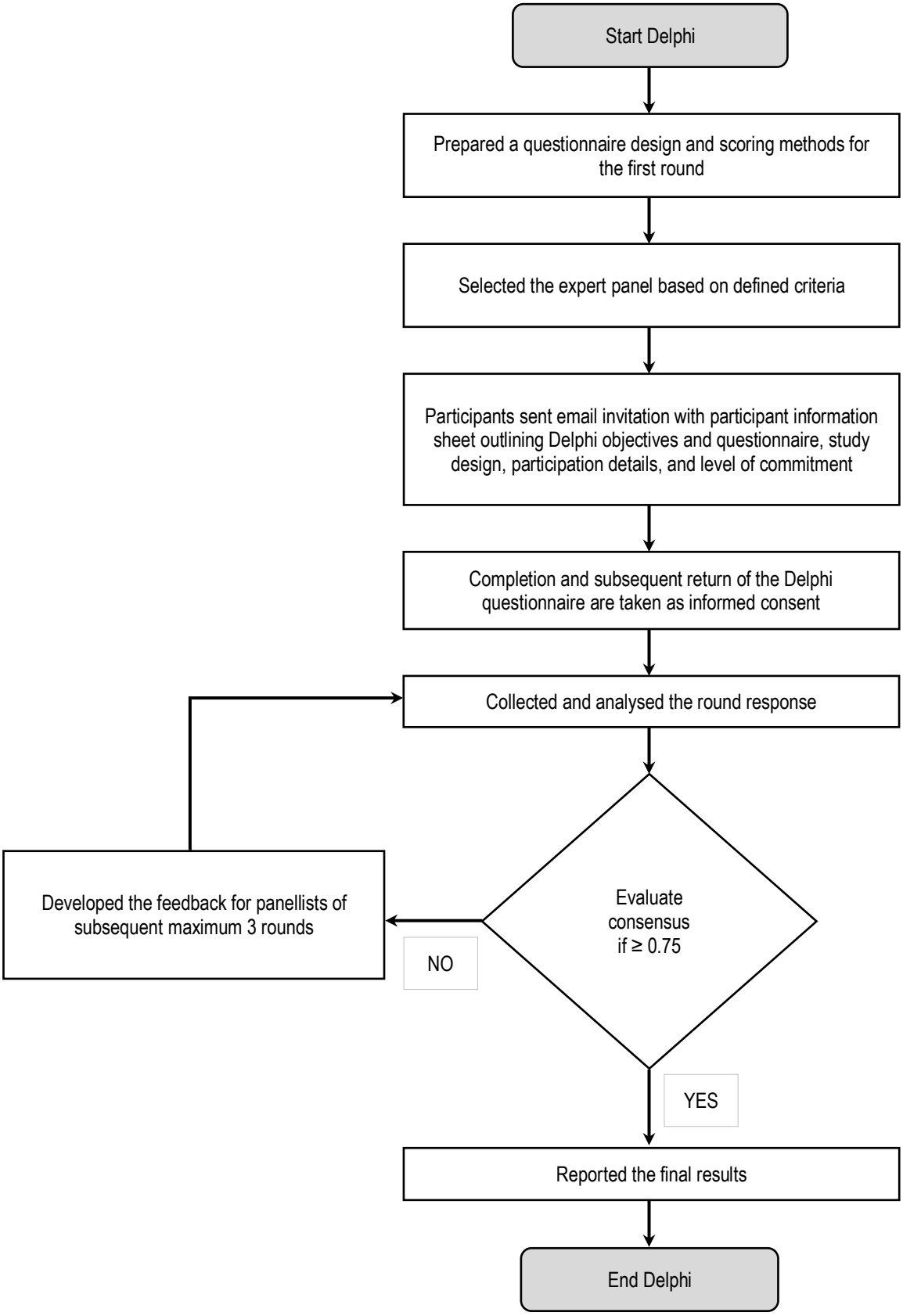


Figure 17: Modified Delphi study

Source: Author

7.6. Selecting Expert Panel Based on Defined Criteria

Purposive sampling was used to select 28 experts across Indonesia (a broad national scope was targeted). Purposive sampling is the best sampling strategy to gain a multi-professional consensus on FIne-CHWs. The range of panel sizes in studies varied significantly, from fewer than 15 participants to as many as 500, to gather representative information. Some scholars argue for a minimum of 10 participants with no upper limit. There are no specific guidelines on the number of individuals needed to constitute a representative sample. Generally, a larger number of participants is preferred, as it can improve reliability and minimize errors in the consensus process. However, there is limited empirical evidence regarding participant numbers' impact on the consensus process's reliability and validity (Keeney, Hasson and McKenna, 2011).

The minimum number of participants to ensure good group performance depends on the study design (Yousuf, 2014), and can vary according to research objectives, complexity and resources (Villiers and Kent, 2005; Keeney, Hasson and McKenna, 2011). The quality of the panellists represents the quality of the feedback from those who know a particular area of knowledge (Hasson and Keeney, 2011).

7.7. Inclusion and Exclusion Criteria

All experts had more than five years of experience in managing diabetic footcare in the community. Panel members were recruited through existing clinical (podiatrist, endocrinologist, medical rehabilitation specialist and nurse wound specialist), academic, and professional bodies across Indonesia, including: IPKKI (Association of Community Nurses Indonesia), InWOCNA (Indonesian Wound Ostomy Continence),

PERKENI (The Endocrinologist Society), PEDI (Diabetes Educator Society), P2PTM Kementerian Kesehatan (Division of Non-Communicable Disease, MoH), IDA/PERSADIA (Indonesia Diabetes Association) and PERDOSRI (Rehabilitation Physical Medicine Association). An invitation letter was sent to potential participants.

7.8. Recruitment Process

I emailed the professional organizations to identify panel members, asking them to recommend five panel experts. When the organizations did not reply, I sent up to two more follow-up emails requesting this information. Two professional organizations (PERKENI and PERDOSRI) subsequently agreed to participate and provided contact information for five experts.

The gatekeeper from the MoH's Division of Non-Communicable Disease (P2PTM) facilitated my contact with key individuals in the NCD programme, including the Director of P2PTM, the Head of the National Diabetes Programme, the former director of P2PTM and founder the ISP-NCD in Indonesia, and researchers from the National Research and Innovation Agency (BRIN). These researchers, who had previously evaluated the ISP-NCD and diabetes in Indonesia, agreed to participate as panel experts. One of the researchers could not participate due to not being involved in the diabetes project, but she referred me to her colleague who had evaluated CHWPs. Three civil servants from the MoH and two researchers affiliated with BRIN and the MoH agreed to participate. Additionally, the gatekeeper from the MoH provided contact information for the administrative group of another organizational body, but there was no response to my email. No further information was obtained regarding my request from other organizational groups.

As not all organizational bodies responded, I took the initiative to send private emails to experts from IPKKI (Association of Community Nurses Indonesia) and InWOCNA (Indonesian Wound Ostomy Continence). Some qualified experts from these associations agreed to join the expert panel. Additionally, researchers who had published work on diabetes in the community were invited via email and expressed their willingness to participate.

After contacting all participants through email or telephone, I inquired about their interest in participating. Those who expressed interest received a participant information sheet via email. This document provided details on the objectives of the Delphi study, the study design, participation requirements, and the expected level of commitment. Only those willing to complete all Delphi rounds were asked to participate. Completion and subsequent return of the Delphi survey was taken as informed consent.

7.9. Data Management

The Delphi study was conducted using a secure online questionnaire platform called Jisc Online Survey, an approved online survey tool for the UoN. The platform ensures minimal collection of personal data. Jisc, the organization operating the platform (Jisc Online Survey, 2023), follows an Information Security Management System (ISMS), and implements processes and policies aligned with the ISMS. Jisc is ISO 27001 certified, including its online survey operations.

Data collected during the study was stored within Amazon Web Services (AWS) servers in the Republic of Ireland, using an encrypted SSL (Secure Sockets Layer) or TLS (Transport Layer Security) connection, which is a secure communication protocol

between a web server and a browser. It ensures that the data transmitted between the server and the browser remains confidential and cannot be intercepted or tampered with by unauthorized parties. A participant number identification (ID) and email address were automatically generated to protect participants' privacy. This ensures individuals remain anonymous and their data is anonymized.

Once all the data was collected, it was transferred to an Excel spreadsheet and kept anonymized for further analysis using the unique study identification number. Data sharing for analysis purposes is limited to the principal investigator and co-investigator, maintaining confidentiality. The summary findings derived from the data are determined based on the agreement of the researcher members.

If the third-party request access to the data, the team would apply regulations from the University Information Compliance Office to ensure compliance with proper procedure and permissions. All data processing and sharing will adhere to the UoN's Data Protection Policy:
https://www.nottingham.ac.uk/governance/records- and-information-management/data-protection/data-protection-policy.aspx

The core components of Fine-CHWs were compiled by employing a triangulation approach, which combined evidence from scoping and mapping review and interview data. The 42 statements of FIne-CHWs were organized according to the TIDieR guideline before undergoing refinement in the Delphi exercise to obtain consensus from experts. The results of the Delphi exercise, along with the analysis of the free-text responses from the Delphi questionnaire, are detailed in the subsequent chapter, Chapter 8.

Chapter 8

Delphi Consensus Findings

The results of the Delphi exercise are presented in this chapter, which can be divided into two main parts. The first part presents the results of the Delphi consensus process. The second part presents the thematic analysis of the open-text comments collected from the survey. The discussion section considers the outcomes of expert agreement and the identified themes derived from the open-text data. Additionally, this chapter discusses the strengths and limitations of the Delphi study, and provides a conclusion based on the findings.

8.1. Delphi Results: Round One

8.1.1. Procedure and Participant Profiles

The initial round of the Delphi survey commenced on 18th May and concluded on 7th June 2022. Responses were received from 22 out of 28 panellists, which translates to a response rate of 78%. Four panellists did not reply to emails, and two panellists failed to respond even after the final reminder email and subsequent private texts were sent. Characteristics of panellists are displayed in Table 14.

Table 14: Demographic data of panellists

Variable	N (%)
Profession	
Physician	11 (50%)
Nurse	9 (41%)
Pharmacist	1 (5%)
Epidemiologist	1 (5%)
Current job responsibilities	
Lecturer and published author in diabetes and community	7 (32%)
Lecturer and clinicians	6 (27%)
Health policy maker and analysis	5 (23%)
Clinicians	4 (18%)
Highest qualification	
Professor	1 (5%)
Doctorate	14 (64%)
Master	6 (27%)
Undergraduate	1 (5%)
Time qualified working as a health professional/job (year)	
Mean ± SD	22.7 ± 6.1
Median	22
Range	16-40

Source: Author

Half of the participants (50%) were physicians working in academia as clinical lecturers, clinicians, or policymakers in the MoH, followed by 41% nurses who were lecturers in a community nursing department or nurse practitioners specialising in wound care. One pharmacist (5%) worked with research projects on diabetes, and one epidemiologist (5%) was a researcher affiliated with the MoH and was experienced in the evaluation of ISPs and CHWPs.

All participants had considerable experience in managing diabetes in the community, with a mean of 22.7 years (± 6.1). Most of them graduated with a doctorate degree,

and one professor is the founder of the ISP-NCD having 40 years of experience in policymaking in MoH and research institutes.

8.1.2. Consensus Results

A total of 35 out of 42 statements reached a consensus agreement level of ≥75% in round one, as displayed in Table 15.

Table 15: Percentage level of agreement results for Delphi round one

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
Patient eligibility							
1	Only patients without an active DFU are eligible for the FIne-CHW sessions.	18.2	0	9.1	36.4	36.4	18.2
2	A registered HCP (such as a nurse, physician or podiatrist) must screen all patients' feet for active DFUs before referring them to the FIne-CHWs educational sessions	54.5	36.4	0	4.5	4.5	90.1
3	All patients should have their blood glucose levels measured within one month before attending the first FIne-CHWs session.	27.3	50	4.5	18.2	0	77.3
CHW person specification							
4	CHWs with the right personal specifications can be trained to competently deliver the FIne-CHWs education sessions.	45.5	45.5	4.5	0	4.5	90.1
5	CHWs delivering the FIne-CHWs sessions must have passed senior high school	31.8	27.3	4.5	27.3	9.1	59.1
6	The CHW delivering the sessions must not have any political affiliations.	50	27.3	13.6	4.5	4.5	77.3
7	CHWs delivering the FIne-CHWs sessions must have good communication skills and be motivated to deliver diabetic FCI.	81.8	18.2	0	0	0	100

Table 15: Percentage level of agreement results for Delphi round one

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
Training of CHWs							
8	Training on DFU care must be provided to CHWs before they can deliver the FIne-CHWs sessions.	81.8	13.6	0	0	4.5	95.4
9	The curriculum for training CHWs should also cover how to treat patients with dignity, compassion, and respect.	81.8	13.6	0	0	4.5	95.4
10	The CHW should be provided a course manual detailing how they should deliver the sessions.	77.3	13.6	0	0	9.1	90.9
11	The training of CHWs should use the teach-back method to emphasise practical skills.	72.7	22.7	0	0	4.5	95.5
12	The CHWs knowledge, skills and attitudes must be tested through an examination prior to them providing training to patients.	72.7	18.2	4.5	0	4.5	90.9
Intervention provider (HCPs)							
13	CHWs providing the FIne-CHW sessions should be supervised by a GP or registered nurses.	36.4	45.5	0	18.2	0	81.8
14	A registered nurse should be present at the community centre or Posbindu PTM to supervise CHWs whilst they are delivering the sessions.	36.4	40.9	0	22.7	0	77
Training health workers							
15	The nurse supervising the CHWs delivering the session should have previously received training in care of patients with DFUs.	72.7	22.7	0	4.5	0	95.5
16	Footcare training for nurses should also emphasize foot examination to categorize the risk of DFUs.	77.3	22.7	0	0	0	100

Table 15: Percentage level of agreement results for Delphi round one

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
Management of CHWs							
17	The CHWs providing the FIne-CHW sessions must be under the management of the community health centre or Posbindu PTM.	59.1	27.3	9.1	4.5	0	87.2
18	There must be a policy for referring patients to the FIne-CHWs.	50	36.4	4.5	4.5	4.5	86.4
19	The CHW must be reimbursed for their travel costs to the community centre, Posbindu PTM, or patients' homes.	57.9	13.6	9.5	9.5	9.5	70.7
Content of education sessions							
20	The content of education should cover knowledge on awareness about diabetes and foot complications: definition of the diabetic foot, its types, warning signs, footcare, etc.	77.3	18.2	4.5	0	0	95.4
21	Washing feet.	86.4	9.1	4.5	0	0	95.4
22	Inspecting foot for problems.	86.4	9.1	4.5	0	0	95.4
23	Moisturizing and massaging foot.	77.3	13.6	4.5	4.5	0	90.9
24	foot exercise (for example foot exercise using newspaper/ papers).	63.6	27.3	4.5	4.5	0	90.9
25	Toenail care.	77.3	13.6	9.1	0	0	90.9
26	Wearing appropriate shoes and socks.	68.2	27.3	4.5	0	0	95.4
27	Help seeking (when, where, how).	72.7	22.7	4.5	0	0	95.4
28	Stress management related to foot problem.	59.1	22.7	9.1	9.1	0	81.8

Table 15: Percentage level of agreement results for Delphi round one

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
FIne-CHW resources							
29	The FIne-CHWs sessions should include a video on diabetic footcare from a diabetes expert.	63.6	27.3	4.5	4.5	0	90.1
30	All patients attending the FIne-CHWs sessions should be provided with educational printed materials (such as illustrated pamphlets) to take home.	59.1	27.3	9.1	4.5	0	86.3
31	The CHWs should be provided with the foot self-care kit contained a basin (patients should bring their own basin), a gallon of water, antibacterial, nondeodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror.	45.5	31.8	18.2	4.5	0	77.2
32	Patients and family members who participate in the FIne-CHW education sessions should be given healthy snacks.	18.2	31.8	36.4	9.1	4.5	50
Place of intervention							
33	The FIne-CHWs should be delivered in a community centre such as the Posbindu PTM.	36.4	27.3	13.6	22.7	0	63.7
34	Where patients are assessed as unable to visit the Posbindu PTM (for example, due to physical mobility issues), the CHWs should provide the intervention in the patient's own home, with booster sessions provided by telephone.	22.7	54.5	0	13.6	9.1	77.2

Table 15: Percentage level of agreement results for Delphi round one

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
Time and duration of intervention							
35	FIne-CHWs sessions should be provided in four sessions: two one-hour educational sessions and two 15–30-minute booster sessions.	27.3	50	18.2	4.5	0	77.2
36	The booster sessions will reinforce the teaching and learning from the first two sessions and the need for patient to perform daily footcare.	45.5	40.9	4.5	4.5	4.5	86.3
37	The FIne-CHW sessions should be given over a six-month period.	22.7	36.4	27.3	4.5	9.1	59.1
Method of delivery							
38	FIne-CHWs sessions should be in groups of up to 10 patients and family members.	36.4	36.4	13.6	9.1	4.5	72.8
39	Family members should be actively encouraged to attend the FIne-CHW sessions with the patient.	59.1	31.8	9.1	0	0	90.9
40	FIne-CHW sessions should always be delivered by two CHWs: one to deliver educational materials while the other monitors patients' understanding and provides further explanations.	31.8	54.5	0	13.6	0	86.3
41	The educational sessions should consist of multiple teaching and learning methods such as lectures, group discussion, video presentations and hands on skill sessions.	63.6	31.8	0	4.5	0	95.4
42	FIne-CHWs sessions should be delivered in the local language.	54.5	22.7	18.2	4.5	0	77.2

Source: Author

8.1.3. Revising items

8.1.3.1. Overview

One statement (item 1): Only patients without an active DFU are eligible for the FIne-CHW sessions reached consensus agreement (18.2%) and was consequently removed for the next round.

The six statements that did not reach a consensus level of ≥75% agreement in round one were reviewed and refined by considering related open-text comments.

The six statements were modified and reframed using input from panellists, to be reconsidered by them in the second round. The free text comments were analysed to consider if the statements that were not agreed needed rephrasing and, if so, the required changes. These rephrased statements were re-presented to the panel in round two.

8.1.3.2. Item 5: CHWs delivering the FIne-CHWs sessions must have passed senior high school

There was disagreement between panel members on whether the CHWs must have passed senior high school to be Fine-CHW educators. Some panel members believed that CHWs with less education could effectively implement the FIne-CHW intervention, since communication skills and motivation, which are crucial qualities for educators, are not necessarily tied to higher education. However, statement number 7 included the requirement for good communication skills and motivation. In contrast, one member believed that CHWs would need an education level higher than senior high school.

the main thing is understanding and communication skills which are not always determined by the level of higher education. **(Panellist 6, Physician rehabilitation physical medicine)**

High school education is not enough for diabetics. **(Panellist 5, Nurse educator in community nursing)**

Considering these rationales, the statement was not changed and represented for consideration by the panellists in the second round.

8.1.3.3. Item 6: FIne-CHWs sessions should be in groups of up to 10 patients and family members

Several panellists stated that giving FIne-CHWs sessions in small groups is better for achieving the intervention goals. I revised the statement by placing "Patient and family members" in brackets to clarify the number of intervention participants.

The group should not be too big; a maximum of 10 people per 1 kader is sufficient. **(Panellist 6, Physician rehabilitation physical medicine)**

Don't do too much [participants], so the teacher can focus more. **(Panellist 16, Physician rehabilitation physical medicine)**

The revised statement is presented below:

FIne-CHWs sessions should be in groups of up to 10 participants (patients and family members)

8.1.3.4. Item 32: Patients and family members who participate in the FIne-CHW education sessions should be given healthy snacks

Most panellists partially agreed with this statement, pointing out that the provision of snacks is dependent on the available funds to support the FIne-CHWs sessions. If this was a requirement, the educational programme might not be sustainable.

> *depending on the availability of funds to support activities.* **(Panellist 19, Nurse educator in community nursing)**

> *increasing the financing burden will make the programme difficult to sustainable.* **(Panellist 14, Physician, Lecturer community medicine)**

The revised statement is presented below:

Patients and family members participating in Fine-CHW educational sessions should be provided with healthy snacks if there is a sufficient budget.

8.1.3.5. Item 33: The FIne-CHWs should be delivered in a community centre such as the Posbindu PTM

This statement did reach consensus, but some participants believed that the educational session could be carried out in many places convenient for patients, including patients' homes and the PHC or Puskesmas.

> *flexible implementation places can be anywhere, such as mosques, under croft [traditional] houses, terraces, etc.* **(Panellist 2, Nurse educator, wound care specialist nurse)**

Educational activities can be carried out in several settings, not necessarily Posbindu PTM/posyandu. can be done in the Puskesmas [PHC] or family settings. **(Panellist 22, Physician, MoH)**

Home visits had already been included as an alternative place for intervention delivery if the patient is assessed as unable to visit the community centre. The statement was revised to include PHC as another place to deliver the intervention.

The revised statement is presented below:

The FIne-CHWs intervention should be delivered in the community centre such as the Posbindu PTM or delivered at the community health centre unless the patient is assessed as needing a home visit.

8.1.3.6. Item 37: The FIne-CHW sessions should be given over a six-month period

One panellist argued that six months is sufficient time to have a positive effect of intervention, while other panellists considered that three or four months would suffice for footcare education intervention.

In behavioural theory, it takes 6 months to expect a change in behaviour, the important thing is the frequency of training and the results of the evaluation. **(Panellist 11, Researcher, MoH)**

3 months is enough. **(Panellist 16, Physician rehabilitation physical medicine)**

To clarify the duration of the FIne-CHWs, more detail about the timings of the FIne-CHWs sessions were explained in the second-round statement:

The FIne-CHW sessions should be given over a six-month period, but the first two educational sessions should be given in two consecutive months and cover all topics followed by the two boosters' sessions provided between one and three months after completion of the two educational sessions.

8.1.3.7. Item 38: The CHW must be reimbursed for their travel costs to the community centre, Posbindu PTM, or patients' homes

Some panellists were concerned about the availability of the budget because the CHWs involved were voluntary and would not expect payment.

> *(...) Kader are liaisons; kader work is done voluntarily; reimbursement of transportation is not a must.* **(Panellist 22, Physician, MoH)**

However, other panellists argued that the provision of transportation costs needed to be considered to support CHWs to reach the referral area.

> *A good referral flow is important to reduce disability in patients with diabetic foot who are screened, and for optimal results, kader need to be given money to reach referral areas and centres.* **(Panellist 16, Physician rehabilitation physical medicine)**

The statement was consequently not revised.

8.2. Delphi Results: Round Two

The second round of the Delphi Survey took place over two weeks, from 17th June to 4th July 2022. To ensure that all panellists received the questionnaire, it was sent through two channels simultaneously: the Jisc Online survey platform and email. This approach aimed to anticipate any issues where panellists may not have received the

questionnaire through one of the channels. Of the 22 participants, 18 completed the survey, resulting in a response rate of 81%. Table 16 displays the results of Delphi round 2.

Table 16: Percentage level of agreement results for Delphi round two

No	Statements	1	2	3	4	5	LA
1 = strongly agree, 2 = agree, 3 = neither agree or disagree, 4 = disagree, 5 = strongly disagree. LA: Level of agreement (%)							
5	CHWs delivering the FIne-CHWs sessions must have passed senior high school	38.9	44.4	0	16.7	0	83.3
19	The CHW must be reimbursed for their travel costs to the community centre, Posbindu PTM, or patients' homes	61.1	27.8	0	5.6	5.6	88.9
32	Patients and family members who participate in the FIne-CHWs education sessions should be given healthy snacks if there is sufficient budget.	16.7	66.7	0	16.7	0	83.4
33	The FIne-CHWs intervention should be delivered in the community centre such as the Posbindu or delivered at the community health centre unless the patients are assessed as needing a home visit.	50	27.8	0	22.2	0	77.8
37	The FIne-CHWs sessions should be given over a six-month period. The first two educational sessions should be given in two consecutive months and cover all the topics followed by the two boosters' sessions provided between one and three months after completion of the two educational sessions.	50	38.9	5.6	5.6	0	88.9
38	FIne-CHWs sessions should be in groups of up to 10 participants (patients and family members)	44.4	44.4	0	11.1	0	88.8

Source: Author

All of the six statements reached the consensus level. These items were subsequently added to core components of intervention FIne-CHWs.

8.3. Outcome of Delphi Consensus on FIne-CHWs

Following two rounds of Delphi exercise, the consensus agreement was achieved on 41 out of 42 statements on core FIne-CHWs components, and consensus disagreement was achieved for 1 out of 42 statements. Intervention components were defined and reported following TIDieR, divided into themes of intervention: procedures, provider (CHWs or HCPs), place, method of delivery, time and duration, content, and tailoring (Table 17).

Table 17: The core components of FIne-CHWs

No item	Procedure of Intervention
Intervention procedures	
2	A registered HCP (such as a nurse, physician or podiatrist) must screen all patients' feet for active DFUs before referring them to the FIne-CHWs educational sessions
3	All patients should have their blood glucose levels measured within one month before attending the first FIne-CHWs session
Intervention provider (CHWs)	
4	CHWs delivering the FIne-CHWs sessions must have passed senior high school
5	CHWs with the right personal specifications can be trained to competently deliver the FIne-CHWs education sessions.
6	The CHW delivering the sessions must not have any political affiliations.
7	CHWs delivering the FIne-CHWs sessions must have good communication skills and be motivated to deliver diabetic FCI.
8	Training on DFU care must be provided to CHWs before they can deliver the FIne-CHWs sessions.
9	The curriculum for training CHWs should also cover how to treat patients with dignity, compassion, and respect.
10	The CHW should be provided a course manual detailing how they should deliver the sessions.
11	The training of CHWs should use the teach-back method to emphasise practical skills.
12	The CHWs knowledge, skills and attitudes must be tested through an examination prior to them providing training to patients.
13	The CHWs providing the FIne-CHW sessions must be under the management of the community health centre or Posbindu PTM.
14	There must be a policy for referring patients to the FIne-CHWs.
15	The CHW must be reimbursed for their travel costs to the community centre, Posbindu PTM, or patients' homes.
Intervention provider (HCPs)	
16	CHWs providing the FIne-CHW sessions should be supervised by a GP or registered nurses.
17	A registered nurse should be present at the community centre or Posbindu PTM to supervise CHWs whilst they are delivering the sessions.
18	The nurse supervising the CHWs delivering the session should have previously received training in care of patients with DFUs.
19	Footcare training for nurses should also emphasize foot examination to categorize the risk of DFUs.

Table 17: The core components of FIne-CHWs

No item	Procedure of Intervention
Intervention place	
20	The FIne-CHWs intervention should be delivered in the community centre such as the Posbindu PTM or delivered at the community health centre unless the patients is assessed as needing a home visit.
21	Where patients are assessed as unable to visit the Posbindu PTM (for example, due to physical mobility issues), the CHWs should provide the intervention in the patient's own home, with booster sessions provided by telephone.
Intervention method of delivery	
22	Family members should be actively encouraged to attend the FIne-CHW sessions with the patient.
23	FIne-CHW sessions should always be delivered by two CHWs: one to deliver educational materials while the other monitors patients' understanding and provides further explanations.
24	The educational sessions should consist of multiple teaching and learning methods such as lectures, group discussion, video presentations and hands on skill sessions.
25	FIne-CHWs Sessions should be delivered in the local language
Intervention time and duration	
26	FIne-CHWs sessions should be provided in four sessions: two one-hour educational sessions and two 15–30-minute booster sessions.
27	The booster sessions will reinforce the teaching and learning from the first two sessions and the need for patient to perform daily footcare.
28	The FIne-CHWs sessions should be given over a six-month period. The first two educational sessions should be given in two consecutive months and cover all the topics followed by the two boosters' sessions provided between one and three months after completion of the two educational sessions.
Intervention content	
29	The content of education should cover knowledge on awareness about diabetes and foot complications: definition of the diabetic foot, its types, warning signs, footcare, etc.
30	Washing feet
31	Inspecting foot for problems
32	Moisturizing and massaging foot
33	foot exercise (for example foot exercise using newspaper/ papers)
34	Toenail care
35	Wearing appropriate shoes and socks
36	Help seeking (when, where, how)
37	Stress management related to foot problem.

Table 17: The core components of FIne-CHWs

No item	Procedure of Intervention
Intervention tailoring	
38	Patients and family members who participate in the FIne-CHWs education sessions should be given healthy snacks if there is sufficient budget.
39	The FIne-CHWs sessions should include a video on diabetic footcare from a diabetes expert.
40	All patients attending the FIne-CHWs sessions should be provided with educational printed materials (such as illustrated pamphlets) to take home.
41	The CHWs should be provided with the foot self-care kit contained a basin (patients should bring their own basin), a gallon of water, antibacterial, nondeodorant soap, a hand towel, a washcloth, an emery board, hypoallergenic lotion, and a mirror.

Source: Author

8.4. Thematic Analysis

The one overarching theme across the experts' panel on consensus CHWs delivered FCI is:

"CHWs Are Only Volunteers": Lack of Policy for Connectivity and Integration of CHWs in Healthcare Service Delivery

Three themes are discussed in detail: (I) CHWs deliver footcare education for all diabetic patients (role CHW clarity); (II) Remuneration and incentives; (III) Flexibility of community FCIs (community-based intervention).

Most participants emphasized that the position of CHWs as volunteers who serve the community by encouraging them to participate actively in health programmes (MoH-RI, 2012). This view is in line with the WHO definition of CHW as members of the communities in which they work as they are selected by the community to be answerable for their activities to the community (Lehmann and Sanders, 2007). In Indonesia's health system, CHWs are known as kader, also community members who

manage the operations of ISP (Posyandu-Posbindu PTM) to be a forum to mobilize community participation for the success of community health programmes (MoH-RI, 2012).

Some panellists narrated the position of CHWs in healthcare service delivery as volunteer and partner in empowerment of the community participants to support health programme.

> *what is meant by health centre management? because the kader are not subordinates/employees of the Puskesmas (PHC), but are partners and under supervision of the Puskesmas ; referrals are made to Puskesmas, not to Posbindu PTM/posyandu (because) kader are not professional, kader are liaisons; kader work is done voluntarily, transportation replacement is not a must.* **(Panellist 22, Physician, MoH)**

The accounts highlight several limitations to the position of CHWs: CHWs are not PHC employees; as a volunteer, incentives for their contribution in the community is not a must and referring patients to CHWs is unacceptable because CHWs are not the HCPs. The position of CHWs in terms of the relationship with the health system was also explained in the WHO reports that the CHWs should be supported by the health system but not necessarily a part of its organization (Lehmann and Sanders, 2007). Further arguments were narrated by several panellists who determined the CHW relationship with patients or members of the public.

> *Health kader are extra pair hand of HCPs who are primarily driving the Community-Based Health (UKBM) programme. [Health*

education] should be given by HCPs. **(Panellist 15, Nurse educator in community nursing)**

Kader are known laymen with being trained, not professionals, so their relationship is with clients, not patients. **(Panellist 22, Physician, MoH)**

One panellist held the belief that CHWs are not in a position to educate the community, as the CHWs main function is as a catalyst for social change. CHWs act as intermediaries between communities and health services, and that at least part of their work consists of health education or health promotion, encouraging behavioural change. This role as change agent (as health promoter) is often undervalued by both governments and communities (Hodgins *et al.*, 2021).

One of the panellists argued that the typical person who might benefit from CHWs' services is in a non-severe condition or moderately controlled condition.

Because the session is indeed conducted by kader, ideally the participants have a fairly controlled condition. **(Panellist 14, Physician, lecturer community medicine)**

Clinicians are open to innovation and know enough about CHWs to find them widely accepted for diabetes prevention but have concerns about whether CHWs will fully benefit patients (Gore *et al.*, 2020). In addition, one of the panellists, a policy maker at the MoH, explained the role of CHWs and how PHC (Puskesmas) are involved in supervising ISP (Posyandu-Posbindu PTM).

> *Posbindu PTM/posyandu (ISP) is a form of community-based health effort that should be able to be carried out independently but is still within reach of the supervision of Puskesmas(PHC)/health workers, therefore in its implementation kader need to be trained and ensured that they are ready to carry out their roles as kader.* **(Panellist 22, Physician, MoH)**

In Indonesia, the decentralization governance system makes ISP-NCDs (Posbindu PTM) activities highly dependent on the capacity and commitment of local governments where impact on differences in the programme settings of CHWs (MoHA-RI, 2007). On the other hand, the position of CHWs is functionally related to the delegation of tasks from HCPs. The activities of CHWs are under the management of the PHC, while funding to support CHWs financially comes from the municipal council. The nearest PHC provides technical guidance and support, the real accountability of the CHWs is to the village committee that appointed and supports them in their work (Oendari and Rohde, 2021). This is evident in the following accounts.

> *There are several villages currently that have paid their kader with village funds. Kader are volunteers, so yes, they do everything sincerely. If you pay for every trip, who will pay for it? Puskesmas (PHC) does not have a budget for kader.* **(Panellist 18, Nurse educator, wound care specialist nurse)**

One of the panellists was concerned about the sustainability of the programme if the PHC was to finance the CHWP.

> *What is needed is not a policy but a POB [community empowerment programme]. Posbindu PTM is basically a community empowerment activity, if the financing is charged to the health facilities (PHC), then sustainability is difficult to maintain.* **(Panellist 14, Physician, Lecturer community medicine)**

Moreover, the idea of referring patients from PHC to CHWs seems unfamiliar some panellist as CHWs were identified as non-professional health workers.

> *not relevant for health workers in health facilities (PHCs) refer DM patient with diabetic feet to Posbindu PTM.* **(Panellist 12, Physician, MoH)**

Conversely, other panellists advised what the referral pathways that might look like to address with absence current patient referrals to FIne-CHWs.

> *(...) indications and referral lines must be clear (for patients with) BPJS (national insurance) or not BPJS.* **(Panellist 6, Physician rehabilitation physical medicine)**

> *(...) Can be referred to Prolanis programme at their respective Puskesmas (PHC)* **(Panellist 18, Nurse educator, wound care specialist nurse)**

Overall, panellist's responses were situated within the milieu of a lack of clear regulations on how CHWs ought to be involved in care service delivery. This is despite FIne-CHWs being part of national health initiatives, including components of CHW training integrated into MoH strategy. Clearly all CHW programmes need further

embeddedness, connectivity, and integration into the larger system of healthcare service delivery. Often the context and systems of which CHWs are a part—in particular, peripheral PHC services—are relatively neglected, providing a decontextualized picture of the role and function of CHWs (Hodgins *et al.*, 2021). No clear alignment of CHW to healthcare system has potentially impacted on optimization of FIne-CHWs on broad aspect including clarity of CHW role, remuneration and effect of implementation of programme in the community. Across the three themes, this analysis extends this discussion of how this affects FIne-CHWs in various aspects of footcare education and its implications.

8.4.1. Theme I: CHWs Deliver Footcare Education for All Diabetic Patients (CHW Role Clarity)

The role and position of CHWs is known as a bridge between HCPs and community member and helping communities identify and address their health needs independently (MoH-RI, 2012). Regarding footcare education, most of the panellists agreed that CHWs should be able to provide footcare education for diabetic patients in all conditions.

> *All patients with DM are at risk for the incidence of the diabetic foot so all need to be educated.* **(Panellist 6, Physician rehabilitation physical medicine)**

> *In fact, what really needs to be related to this education are patients who have foot injuries or have had one.* **(Panellist 19, Nurse educator in community nursing)**

The panellist underlined how important footcare education is to reduce the risk and incidence of DFUs.

> *Because the pre-ulcer condition is an important target in prevention programmes, prevention programmes can reduce the risk of amputation by up to 85%, in the form of early detection of risk factors and education on acquired disorders.* **(Panellist 8, Physician internal medicine)**

Several panellists raised concerns about CHW's authority in managing NCDs in Indonesia, especially DFPs, due to the lack of regulations in the area.

> *The limits of the kader's authority must be determined, so that if there are difficult topics, they just refer to the health workers.* **(Panellist 18, Nurse educator, wound care specialist nurse)**

> *adjusted to the limits of their authority.* **(Panellist 18, Nurse educator, wound care specialist nurse)**

In line with the explanation of CHW authority, some panellists were concerned about CHW workload if more tasks are added such as to deliver footcare education. The panellists connected CHW' current jobs to the possibility of remuneration to cover transportation costs.

> *Kader will have too many tasks and responsibilities, just modify the session in Posbindu PTM.* **(Panellist 1, Nurse educator in community nursing)**

> *Consideration of kader workload.* **(Panellist 3, Physician rehabilitation physical medicine)**

The authority and responsibilities of CHWs were a concern for some panellists. Further consideration is needed to determine how FIne-CHWs fit with existing workloads.

8.4.2. Theme II: Remuneration and Incentives

Some concerns regarding remuneration or incentives were raised whereby CHWs were asked to conduct specific interventions outside of current duties; in such contexts, financial support to cover transportation costs were considered a minimum level of remuneration. One of the panellists narrated that the barrier faced by CHWs in serving the community is financial, she thought remunerating travel cost could be a reward for their hard work.

> *Experience showed that motivated kader are quite constrained by transportation financing problems and work hard and try to be rewarded at least with transportation costs.* **(Panellist 6, Physician rehabilitation physical medicine)**

> *A good referral flow is important to reduce disability in patients with diabetic foot who are screened, and for optimal results, kader need to be given money to reach referral areas and centres.* **(Panellist 16, Physician rehabilitation physical medicine)**

In addition, one of the panellists said that usually a CHW is someone who needs financial support because they come from disadvantages group and cannot afford to incur additional costs to serve the community.

> *Those willing to become kader are usually/often someone who does not have a formal job, and may belong to a low-income family group. If the kader is willing to bear the cost of their own trip or the destination is within walking distance, it's okay not to reimburse.* **(Panellist 3, Physician rehabilitation physical medicine)**

Some panellists stated that the CHWs should be reimbursed for transportation costs if they perform footcare education, to motivate them. Satisfaction (or dissatisfaction) with incentives was closely linked to CHW motivation and performance (WHO, 2020).

> *Kader have many tasks from the Puskesmas and village, it is better to add this activity so that they can get reward in the form of transportation costs.* **(Panellist 11, Researcher, MoH)**

> *The reward given is more to appreciate programme participation, and also as a volunteer.* **(Panellist 9, wound care specialist nurse)**

One panellist argued that covering transportation costs would decrease CHWs motivation, and that non-monetary support such us providing lunch or having new uniforms, provide a better appreciate of their effort.

> *The existence of kader is part of the active and voluntary participation of the community in health development. If they are required to provide transportation money, this will disrupt the motivation of the community to play an active role, because when there is money the kader will be active, but if there is no money, the kader will not be active. Giving money can be replaced by eating lunch or giving uniforms or other*

incentives, according to the ability of the region. **(Panellist 5, Nurse educator in community nursing)**

One panellist identified that there are no regulations currently in place regarding provision of transportation costs, and advised that policymakers should develop a policy on this matter (and funding).

[CHWs] Need support from policy holders related to the home visit patients (transportation costs) **(Panellist 6, Physician rehabilitation physical medicine)**

Commensurate with this argument, another suggestion from some panellists for addressing this issue is that the financial support is provided by the municipal council.

In exchange for transportation and rewards. Currently, several villages have used village funds for kader activities. **(Panellist 18, Nurse educator, wound care specialist nurse)**

current funds can be obtained from the village fund, BOK. The MoH and the Ministry of Home Affairs (MoHA) are working on transport kader for all posyandu/Posbindu PTM in administrative blocks, hamlet, and village/ urban village that will become LKD Posyandu (Prime posyandu) in the transformation of primary services. **(Panellist 12, Physician, MoH)**

Several participants provided further advice on how much money CHWs should receive if they were to provide an FCI.

To sustain [the program}, pay transportation cost according to general cost standards, and kader services need to be respected. **(Panellist 20, Physician and researcher, Founder Posbindu PTM)**

To substitute for the transportation cost, equivalent to what they have spent. **(Panellist 1, Nurse educator in nursing)**

Furthermore, in terms of budget allocation for provision of snacks to increase community participation in the community post, some panellists argued that it is not mandatory, because this intervention is a community-based intervention that should be carried out independently by the community.

Sometimes the health education provided is not in formal education conditions, such as home visits, Posyandu, and other community activities. So, snacks are not something that must be provided. **(Panellist 18, Nurse educator, wound care specialist nurse)**

the activity is carried out voluntarily; if [food is] provided it is good, but if it cannot be done, in the following session they can be told that it is necessary to bring their own lunch. **(Panellist 22, Physician, MoH)**

In summary, as noted by multiple panellists, the CHWP's optimization requires some kind of financial support, ranging from direct remuneration for transport costs they incur, or the form of gifts or food. Nonetheless, a crucial issue remains as to who bears responsibility for funding expenses related to the CHWP, including transportation costs.

8.4.3. Theme III: Flexibility of Community FCIs (Community-Based Intervention)

The problem of where interventions can be carried out was a concern among some panellists. One of the panellists narrated that multiple barriers were faced by patients to reach ISP-NCDs (Posbindu PTM).

> *It doesn't have to be, because the problem that will also be faced is the community's challenge to reach Posbindu PTM (ISP-NCD), not just motivation. Limited time, long distances, and an unsupportive economy are only some of the obstacles to the education programme, so implementation should not be rigid, and this is one of the reasons why it is important to educate kader in the same neighbourhood.* **(Panellist 6, Physician rehabilitation physical medicine)**

In line with this argument, several panellists argued that the place of intervention should be more flexible to increase community participation.

> *more flexible, in order to achieve goals.* **(Panellist 4, Physician rehabilitation physical medicine)**

> *flexible implementation places can be anywhere, such as mosques, under croft (traditional) houses, terraces, etc.* **(Panellist 2, Nurse educator, wound care specialist nurse)**

Aside from the place of intervention, panellists also considered the flexibility of the education level of CHWs with regard to their potential role as intervention providers. Several panellists would accommodate CHWs below high school to deliver footcare

education, as they thought that communication skills were more important than the level of formal education.

> *The main thing is the ability to communicate and communicate with the community. The level of education is often correlated with this ability. At least high school, because in some areas it may be difficult to find kader who graduate higher than high school.* **(Panellist 13, Pharmacist, lecturer)**

> *Many kader graduated from junior high school in rural areas and are more communicative and active.* **(Panellist 18, Nurse educator, wound care specialist nurse)**

The presence of HCPs as supervisors of CHWs when providing FCIs was not though necessary by some panellists based on the assumption that CHWs are qualified volunteers who are sufficiently educated to deliver the education.

> *[The CHW/kader is] the extended hand of health workers [HCPs] who are more educated, not only at Posyandu, but also in daily activities. So, there is no need for strict supervision.* **(Panellist 18, Nurse educator, wound care specialist nurse)**

> *The aim of the delegation is the division of labour so that by evaluating kader/CHWs from the training [and they are being] the competent kader, monitoring is no longer needed.* **(Panellist 6, Physician rehabilitation physical medicine)**

Panellists reported that footcare education delivered by CHWs should be community-based and appropriate to community needs and resources. Health programmes involving CHWs are community empowerment involving community participants (WHO, 2020). The intervention must be flexible to the context in which the intervention is implemented (Skivington *et al.*, 2021).

8.5. Discussion

The consensus agreement on 41 out of 42 the statements of core components of the FIne-CHWs; there was one consensus disagreement on the criteria of patients eligible to receive FIne-CHWs educational sessions (concerning diabetic patients without DFUs). Most participants argued that all patients with all conditions should receive information regarding DFUs. Furthermore, from analysis of the free text response of the Delphi questionnaire emerged overarching theme: "CHWs Are Only Volunteers": Lack of Policy for Connectivity and Integration of CHWs in Healthcare Service Delivery. This was explained through the three themes adumbrated above: (I) CHWs deliver footcare education for all diabetic patients (CHW role's clarity); (II) remuneration and incentives; and (III) flexibility of community FCIs (community-based intervention).

In line with what the limitation of task sharing should be given to CHWs, this leads to further questions. What kind of actor is a CHW? The definition of CHWs as community volunteers were narrated by the panellists to respond to the statements that the CHWs should be under the management of PHC or particularly under Posbindu PTM management. This statement was made with the consideration that CHWs in Indonesia are involved in many ISPs with a wide range of roles, from the management

of mothers and children to mental health posts (Oendari and Rohde, 2021). However, panellists also noted that HCPs are not line managers of CHWs, and they may unintentionally impact the introduction of new specific interventions, such as FIne-CHWs which had significant implications for involvement in CHW management.

This statement reached consensus agreement. However, some panellists from the MoH argued that volunteers are not part of the health system organization, and have limitations regarding their role to serve the community; referring patients to the FIne-CHWs was not feasible due to their non-health professional status and low-level positions within the healthcare system. Lehmann and Sanders (2007) stated that HCPs often perceive CHWs to be lowly aides, to be placed as assistants in health facilities, often misunderstanding their role in promoting and empowering health in society. In contrast, in many countries CHWs have been set up to become agents of change in society; they function as extensions of formal healthcare – as auxiliaries rather than independent agents. This dilemma leads to the question about who owns and manages the CHWP and to whom the CHW is accountable (Lehmann and Sanders, 2007).

In Indonesia, a high cultural value is placed on doing something for one's neighbour without financial compensation except for a small reimbursement for expenses such as transportation costs. Volunteering as a CHW is greatly appreciated in the community. The roles of the MoH at the national level and its provincial agencies are largely responsible for setting norms and providing guidance to the lower-level administrators (PHC) (Oendari and Rohde, 2021). The PHC has no authority over financial and hiring/firing decisions related to CHWs, which are the responsibility of the village committees under the MoHA. The management of the CHWs by two authorities (MoH and MoHA) impacts the CHWs' position, and unintentionally

hinders optimising FIne-CHWs. Moreover, the absence of a direct hierarchy from the PHC influences the roles and functions of CHWs, which impacts FIne-CHWs's implementation. This issued lack of policies was reported in FIne-CHWs in Indonesia (Oendary and Rohde, 2021), and can lead to inadequate support for CHWs and CHWs not being recognized by health authorities, limiting how they operate in the community (Kok, Kane *et al.*, 2015). Moreover, it impacts the integration of CHWs into the broader healthcare system, the range of tasks which they perform, including referral, and collaborative relationships with other HCPs in primary care teams (WHO,2018). Therefore, clear referral pathways are needed to ensure patients receive appropriate education and treatment where needed.

The statement that reached consensus disagreement concerned the criteria for patients receiving footcare education sessions: "Only patients without active DFUs were eligible for FIne-CHW sessions". Most panellists thought that all diabetic patients with or without DFU should be eligible to be taught by CHW. All patients diagnosed with diabetes should be given clear information and explanation about DFUs (Diabetic Foot Australia, 2016; NICE, 2020), and early detection and treatment is one strategy to reduce the burden of diabetes (RNAO, 2007; IDF, 2017). Moreover, several studies have shown that CHW interventions in footcare education hold promise for improving foot self-care in diabetic patients (Culica, Walton and Prezio, 2007; Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Hughes *et al.*, 2016; Vaughan *et al.*, 2017).

However, the risk to patient safety of referring all diabetic patients without prerequisites to be managed by CHWs needs further consideration. CHWs are community volunteers with limited training and authority to perform specific tasks.

The delegation of roles from HCPs to CHWs can have a detrimental effect, because the quality of care provided by CHWs can become less than optimal if CHWs are given complex tasks. Task sharing is an essential strategy for addressing shortages based on need, but quality and safety issues may arise, as well as professional and institutional resistance (WHO, 2020). Protocols and guidelines can improve CHW performance because they help facilitate and coordinate CHW-related programmes such as role delegation. CHWs are unregistered healthcare workers with shorter training than HCPs; therefore, clear job descriptions should be defined in standard protocols to ensure the highest levels of CHW productivity (WHO, 2020).

Furthermore, one of the essential elements of a successful CHWP is CHW differentiation and role clarity, to maintain a clear scope of work and accountability (Lehmann, Twum-Danso and Nyoni, 2019). The lack of a well-defined and comprehensive definition for the position of CHWs within the healthcare system has resulted in a vague understanding of their role and responsibilities. This ambiguity poses a challenge when implementing new interventions such as FIne-CHWs and hampers the optimization of CHWPs.

Several panellists also highlighted the limited authority of CHWs and their existing workloads. CHWs are expected to perform a variety of functions, including home visits, health education involving referrals, and recording and collection of specific community case data (Lehmann and Sanders, 2007; Oendari and Rohde, 2021). The workload affects CHW productivity (WHO, 2020), while no ideal work environment is known, nor is there a maximum number or mix of CHW tasks that will ensure the highest levels of CHW productivity, optimized programmes could be achieved if CHWs have clear job descriptions (WHO, 2020). Therefore, a clear policy is needed

to regulate the work assignment of CHWs to ensure that FIne-CHWs is optimized and the contribution of CHWs is assessed to address specific health problems.

WHO (2021) released guidelines that follow a health systems approach, and specifically identify the policy and system advocates needed to optimize the design and performance of CHW initiatives. The primary target audience for this guide is policymakers, planners, and managers responsible for health workforce policy and planning at national and local levels. These guidelines suggested using the following criteria for selecting CHWs for pre-service training including the minimum level of education that must meet the task under consideration. The panellists concluded that the CHWs who provide footcare education should graduate from high school to be able to convey information to patients accurately. This requirement meets the manual for CHWs to run ISP-NCD (MoH-RI, 2012).

Personal attributes, capacities, values, and professional life and experiences of the candidates (e.g. cognitive abilities, integrity, motivation, interpersonal skills, demonstrated commitment to community service, and public service ethos) (WHO, 2018) are also included in the Delphi statements, as well as some prerequisites for CHWs such as CHWs are not to bring their personal political affiliation with them when they serve in the community. This was considered a necessary precautionary measure to ensure acceptance by the wider community. CHWs need good interpersonal communication skills, good community engagement skills, and the opportunity to participate in community-based organizations (LeBan, Kok and Perry, 2021).

Furthermore, CHWs must undergo footcare training, followed by assessment of their knowledge, skills, and attitudes before they provide training to people; this

requirement meets the recommendations of WHO on formal competency-based certification for CHWs who have successfully completed pre-service training and with priority emphasis on supervised practical experience in training CHWs (WHO, 2018)

Furthermore, supervision is essential for optimizing the performance and motivation of CHWs, to maintain the CHWP's effectiveness, productivity, and respect of CHWs in the community (WHO, 2020; Westgate *et al.*, 2021). In addition, HCPs should receive training to coach and mentor CHWs (WHO, 2018). Additionally, nurses should undergo refresher training sessions for managing DFUs, with an emphasis on how to conduct screening risk of DFUs, since patients should have a footcare examination prior to the educational sessions (Borges and Ostwald, 2008; Fan *et al.*, 2013; Nguyen *et al.*, 2019). This statement achieved consensus among panellists, who agreed that the HCPs should have adequate knowledge prior to supervising FIne-CHWs educational sessions. In addition, the HCPs (primarily nurses) should attend when CHWs deliver footcare education in the ISP-NCD to enhance community trust and respect for CHWs.

The panellists also raised the issue of budget constraints to support the CHWP. There was little disagreement among the panellists about whether CHWs should be paid for their contributions to deliver FIne-CHWs. However, there are no regulations or budget resources available from the PHC, and only a little funding from the village committee in exchange for CHWs' role in managing community posts. This situation was identified when the government recognized CHWs, but the health system was still not equipped to monitor, support, and incentivize all the work of CHWs (WHO, 2018). Provision of transportation costs for CHWs making patient home visits reached consensus. This statement is in line with WHO (2021) recommendations for

remuneration of CHWs for their work, with a financial package commensurate with the demands of the work, complexity, number of hours, training, and the role they perform.

Whether CHWs should become community volunteers without incentives, or be paid through community or government funds, was widely debated among panellists. Most of the literature tends to imply that volunteering is the ideal desired by most CHW schemes, and assumes there is sufficient will to undertake voluntary social services in rural areas and informal settlements (WHO, 2020). However, most of the CHWs are part of disadvantaged groups living in poor communities in need of income (Ormel *et al.*, 2019; WHO, 2020). Several panellists raised the issue that CHWs are people with non-formal jobs from low-income families and need to be compensated for transportation costs to serve areas that cannot be reached on foot, or reaching distant referral areas to educate patients with disabilities. Some panellist suggested providing non-monetary awards to CHWs (e.g., clothing gifts).

Motivation is sustained when CHWs feel they are valued members of the health system, and have a clear role and set of responsibilities within it (Colvin, Hodgins and Perry, 2021). Providing multiple incentives over time has been shown to motivate CHWs in many successful programmes and can build a sense of satisfaction and ongoing satisfaction for CHWs (WHO, 2020), increasing their ability to work effectively (Zulu *et al.*, 2014).

Panellists raised concerns regarding the potential burden placed on eager and dependable volunteers who may become overwhelmed with additional tasks from PHC (Puskesmas). This is due to the lack of alignment between the reimbursement and incentives provided by the village or local government, as well as the fact that

CHWs are under the management of two authorities, namely the MoH and the MoHA. The effect of inadequate support can be that CHWs feel discredited by health authorities, which limits their ability to operate in the community (WHO, 2020).

Learning from successful community health posts for mothers and children to provide or cook nutritious meals together (Oendari and Rohde, 2021), the FIne-CHWs also added a statement on providing healthy food for visitors to NCD posts as an incentive. Providing food would increase the interest of community members to come and be involved in educational sessions; since it is a community-based intervention, providing food is not mandatory, but will depend on the available budget.

The panellists argued that the CHWP should be run flexibly through local adaptation and take considerations of the available financial and human resources and physical facilities. The new MRC Framework recommends that developing complex interventions should be flexible and allow for variations in how, where, and by whom interventions are administered and received (Skivington *et al.*, 2021). The performance of CHWs is influenced by the community and socio-cultural values, practices, and beliefs (Kok, Kane *et al.*, 2015; WHO, 2020), and is shaped by effective community management (Lehmann, Twum-Danso and Nyoni, 2019). It is widely recognized that there is a considerable gap between the ideals of community-driven and owned programmes and the reality of the programme with which CHW can make a valuable contribution to community development (Lehmann, Twum-Danso and Nyoni, 2019).

Several panellists suggested holding footcare education sessions in the ISP-NCD (Posbindu PTM) and other community venues agreed upon by the people involved. Geographic factors and distance to households are also key factors influencing the performance of CHWs, including health system and human resources policies. Local

geography (including proximity of households, distance to clinic and population density (WHO, 2018) needs to be considered when choosing the site for the implementation Fine-CHW intervention. The panellist agreed that the sessions should be held in ISPs as they are places for community gatherings, close to an area neighbourhood so that the patients and CHWs do not require transportation costs to attend the education session. Holding the sessions in the ISPs will also facilitate the supervision of CHWs, as the HCPs also attend the community post monthly.

Solid consensus was reached on the educational content, as it meets international guidelines for the prevention of diabetic foot issues (RNAO, 2007; ADA, 2020; Bus *et al.*, 2020; NICE, 2020). Educational content also includes managing stress-related foot problems; this statement was supported by WHO (2021), which suggests that CHWs provide psychosocial support for the community.

CHWPs can achieve better integration into national initiatives when policymakers and community actors participate in CHWPs and view the programme positively (Zulu *et al.*, 2014). A stronger CHW position in health system is needed by defining clearly role and remuneration, as well as essential attributes, to support the CHWs position in health service care delivery and the community. These contextual factors could challenge the feasibility of the FIne-CHWs as a new structured educational intervention which has specific requirements to enhance CHWs capacity to undertake this role.

The lack of policies on cohesiveness, connectivity, and integration into the wider healthcare delivery system can have impacts on the success of the CHWP (Lehmann, Twum-Danso and Nyoni, 2019), and it requires a functional system that allows the CHW to play a constructive role (Hodgins *et al.*, 2021).

8.6. Strengths

Details of each component in a complex intervention are needed to increase the transparency of the approach and assist in the appraisal, replication and implementation of the intervention. The development of the core intervention components in this study used TIDieR (Hoffmann *et al.*, 2014), thereby ensuring that all intervention components were included. In addition, triangulation protocol data synthesis (Farmer *et al.*, 2006; O'Cathain, Murphy and Nicholl, 2007) was used to integrate data from the reviewed literature with interviews, to develop the core components of the intervention. This approach increases researchers' confidence in the outcomes thickening and enriching data, synthesizing and integrating theories, uncovering contradictions, and obtaining completeness.

The Delphi study was used to gain consensus from experts throughout Indonesia. The Delphi approach has been widely used to gain opinion and consensus from experts in the design of complex interventions for diabetes (Abrar *et al.*, 2020; Ryan *et al.*, 2021; Othman *et al.*, 2022). The expert panel consisted of representatives of diabetes experts including policy makers from the MoH who are responsible for diabetes prevention policies. It is also involved the founder of the ISP-NCD (Posbindu PTM), and researchers from academia and the National Research and Development Agency. A heterogeneous sample was use to ensure that a spectrum of opinion was determined (Keeney, Hasson and McKenna, 2001, 2011). This robust Delphi panel improved transferability and validity of findings.

With varying degrees of agreement, most panellists accepted that FIne-CHWs could be implemented in the Indonesian context. Most components of the intervention also reached consensus agreement, although this does not necessarily mean the correct

answers have been found. It merely means that, to a specific level, the participants have agreed on an issue or set of issues (Keeney, Hasson and McKenna, 2011; Diamond *et al.*, 2014). A set of Delphi research quality criteria were also identified, which were adhered to throughout the study to maintain the rigours of reported data. In addition, the core components of intervention have captured most of WHO recommendations to optimize the CHWP, but one crucial statement still needs to be added to the curriculum for pre-service training: personal safety, to protect CHWs from malpractice risks (WHO, 2018).

A common criticism levelled at Delphi methods is the tendency for panellist dropout between rounds. This study achieved at response rate of 87% between rounds one and two (i.e., attrition of 13%), surpassing the recommended 70% response rate required between rounds to maintain rigour (Keeney, Hasson and McKenna, 2001).

8.7. Limitations

Surveys are usually part of large-scale research that presents participants' short or not in-depth answers. The panel was relatively small; however, the quality of the panellists represents the quality of the feedback from those who know a particular area of knowledge (Keeney, Hasson and McKenna, 2011) also, reliable results can be achieved with a small sample of similarly trained experts, so dependence can be achieved by including diverse sample of experts (Hasson and Keeney, 2011). Furthermore, the qualitative data was analysed using thematic analysis to understand and find patterns across the corpus data to better understand the panellists' opinions on FIne-CHWs.

Delphi studies often collect qualitative and quantitative data, yet little guidance exists concerning the balance of data collected and how to manage the generated data (Green *et al.*, 1999). The lack of guidance leads to a variety of approaches and can result in different interpreting and reporting, this could affect the integrity of the method (Keeney, Hasson and McKenna, 2001). The lack of precise definition of the technique places the purist of reliability and validity at a distinct disadvantage (Hasson and Keeney, 2011). This study employed a modified two-step Delphi approach. Scholars believe that a modified two-step Delphi (close-ended) is an ideal approach to verify the content and face validity compared to a traditional first round which may create unambiguous, broad statements which could lead to bias from the outset (Hasson and Keeney, 2011).

The thematic analysis tried to probe below the surface data to glean underlying assumptions or structures from initially semantic data to more latent orientation (Braun and Clarke, 2022). This allowed the author and team to identify, describe, and interpret patterns (themes) within data (Braun and Clarke, 2022). The analysis identified semantic meaning across all the data set, not merely focusing on participants' responses to the closed question of questionnaires. Although the survey often presents "straightforward" data, it can be difficult for researchers to look beyond the "answer questions" to see patterns across dataset (Braun *et al.*, 2021). Data were collected from panellists' responses to specific statement in closed-ended questions as part of a corpus of data, which was then used to understand the position of CHWs in the health system when delivering footcare education.

Furthermore, to gain trustworthiness in this Delphi study, since panel experts change their minds and tend to move toward the consensus in line with majority of panellists,

this situation can challenge the validity and reliability of Delphi outcome. Therefore, the integration of additional research methods can increase credibility (Hasson and Keeney, 2011), validity, and reliability in Delphi studies (Keeney, Hasson and McKenna, 2001). The Delphi study statements were developed through scoping and mapping review of the core components of FCIs, followed by interviews with key stakeholders to obtain their opinions on the acceptability and practicality of the intervention. Thus, triangulated data was used to generate the questionnaire statements. A detailed description of the analysis process can increase certainty and several steps were followed to gain consensus, using a two-round strategy with continuous iteration and feedback given to the panellists, thereby manifesting member-checking.

8.8. Conclusion

Designing and developing the FIne-CHWs used a multi-method approach to increase the validity and reliability of the Delphi study findings. This included gathering current evidence through scoping and mapping review, engaging with key stakeholders by conducting interviews to understand the practicality and acceptability of the intervention, followed by seeking consensus from a panel of experts recruited from throughout Indonesia. This intervention was developed to adapt to the local context to ensure that it has the potential to be cost-effective, transferable and scalable in the Indonesian context.

The Delphi technique proved helpful in systematically obtaining consensus on 41 out of 42 core components of intervention FIne-CHWs, which means that the panellists agreed on specific core components of the intervention to be implemented in

Indonesian contexts. However, some considerations should be considered to implement this intervention across the country. Healthcare services authorities need to clarify the definition of CHWs' function and role, including their position in health service delivery. Another issue to implementing FIne-CHWs in the real world is whether it can be standardized, or whether it should maintain flexibility to be tailored according to specific local contexts. Furthermore, health system to provide the needed support, including training and supervision of CHWs, provision of competency-based certification, effective management of the CHWP, protection of CHWs from malpractice risks, remuneration in a timely and adequate manner, creation of appropriate channels for linkages and referrals, and procurement of commodities and essential supplies. These are areas considered in the discussion, chapter 9.

Chapter 9

Discussion and Conclusion

This study aimed to develop an FCI delivered by CHWs for patients with T2DM with LR-DFUs in Indonesia, referred to as the FIne-CHWs. The FIne-CHWs was guided by the new MRC Framework for developing and evaluating complex interventions, to develop an evidence-based, acceptable, and practical intervention. To achieve this, the study used mixed method approach by applying triangulation protocol, combining data from scoping and mapping review and interviews to develop statements of the core components of intervention. These statements were then refined through two rounds of a Delphi consensus which involved a panel of diabetes care experts from Indonesia.

The objective of this chapter is to discuss the study's outcomes and the likely challenges and support needed to implement the FIne-CHWs. The findings are viewed through Indonesia's healthcare policy lens to comprehensively understand the intervention's viability within the Indonesian context. Additionally, the core components of the FIne-CHWs are presented and considered regarding its specific findings, advantages, drawbacks, research implications, and suggestions for future development.

9.1. Summary of Key Findings

The first step of the MRC Framework is to understand the Indonesian context, in order to ensure that FIne-CHWs will be acceptable and practical to deliver in the national context. This required early and meaningful engagement with patients, practitioners, and policymakers associated with the intervention context and the local system (Skivington *et al.*, 2021), to support the success and sustainability of the intervention

(Hodgins *et al.*, 2021). This is the first attempt to use this framework to develop a diabetes FCI for Indonesia.

A quasi-experimental study by Sttajar (2019) involving 23 CHWs and seven nurses from a PHC in Makassar, Indonesia, showed that training in footcare significantly improved the participants' ability to perform footcare for diabetic patients (p=0.000). This study provided insights into the training of CHWs in footcare in Indonesia, but it did not fully capture the intricate nature of the CHWP within the current health policy landscape, given the existential differences between nurses (and other HCPs) and CHWs in Indonesian care delivery. Furthermore, there was a lack of information from key stakeholders, hindering a deep understanding of how to tailor this intervention to the specific context. Therefore, the current study deployed the MRC complex interventions framework in order to provide a robust and validated approach to the development of such an intervention, as outlined in Figure 18. This approach aimed to prevent potential failures by enhancing the intervention's appropriateness for the target population and healthcare system.

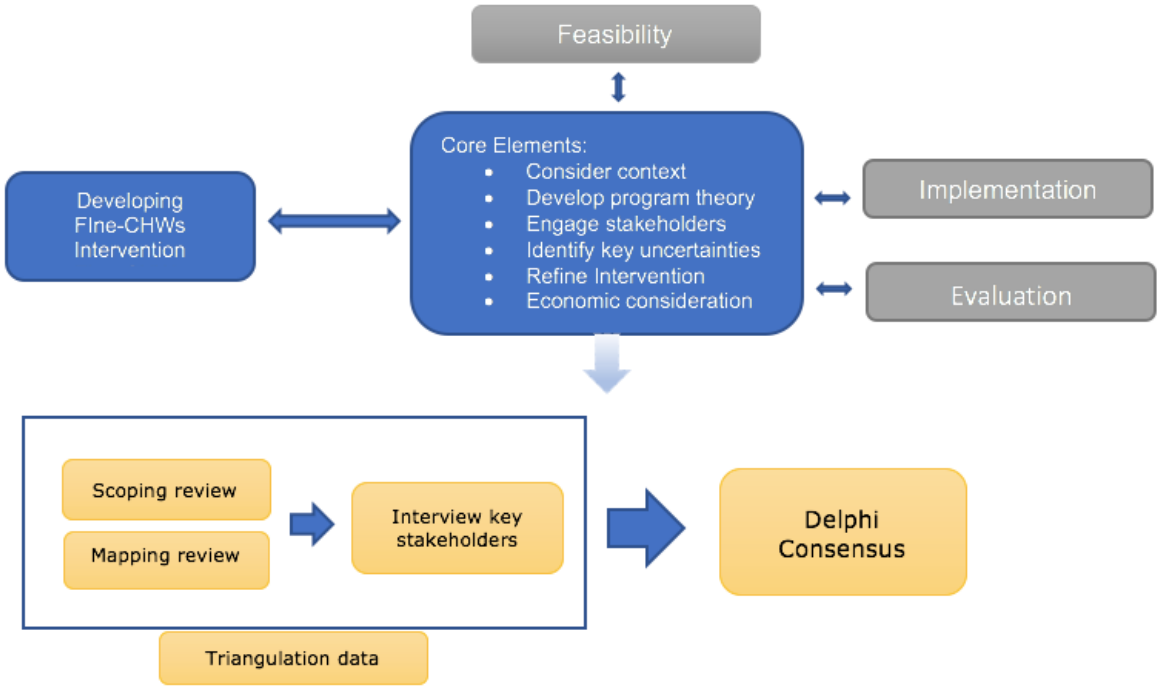


Figure 18: Study diagram

Source: adapted from Skivington *et al.* (2021)

A preliminary scoping review of FCIs delivered by CHWs reported that most studies conducted in the US that considered health disparities and underserved communities revealed a significant improvement in diabetic patients' preventive footcare behaviour after CHW intervention (Culica, Walton and Prezio, 2007; Castillo *et al.*, 2010; Spencer *et al.*, 2011; Islam *et al.*, 2013; Prezio *et al.*, 2014; Rothschild *et al.*, 2014; Hughes *et al.*, 2016; Vaughan *et al.*, 2017). However, there has been limited research conducted on comparable interventions in developing countries that share similar contextual characteristics as Indonesia (Paz-Pacheco *et al.*, 2017).

Moreover, existing studies have not specifically addressed FCIs, as footcare education is often integrated into general diabetes education. The location and method in which the intervention is administered, as well as how it is customized to suit the specific needs of underserved communities, offer valuable insights into the core components

of FCI. These studies have also shown the potential of CHWs delivering FCIs in encouraging positive behaviour and reducing the occurrence of DFUs. Nevertheless, further in-depth information was required concerning other intervention components, including the educational materials used, the amount administered, the duration, and the procedural details.

Given the paucity of information regarding the core components of FCIs, a further mapping review was carried out to collect evidence from HCPs concerning interventions for low-risk patients and guidelines for managing footcare. Broader searching was employed, since there was limited evidence investigating LR-DFUs. Therefore, this review aimed to map the intervention components for patients without DFUs, including method of delivery, procedure, intervention provider, intervention location, place and duration, and intervention content, as per TIDieR (Hoffmann *et al.*, 2014). Nonetheless, there is a need for more in-depth investigation into the ability and competence of CHWs to effectively deliver the intervention, as perceived by community actors participating in the FCI.

Since the intervention was intended to be implemented in Indonesia, it was essential to understand the perceptions and experiences of diabetic patients in Indonesia when developing the intervention (Widayanti *et al.*, 2020). Semi-structured interviews were undertaken to understand the barriers and support required for the FIne-CHWs, and to ascertain the perceptions and opinions of key stakeholders of footcare in the community, including patients and their families, HCPs, and CHWs, on the acceptability and practicality of the developed intervention. The five salient themes that emerged from the interview data were:

1. Community Knowledge and Experience of DFU Prevention

2. Enhance Healthcare Uptake by Expanding CHW's Role
3. Community Embeddedness
4. Recruitment and Selection of CHWs
5. Community Training Approach

Overall, the study findings supported the acceptability of FIne-CHWs, albeit some barriers were identified related to the practical aspects of implementing this intervention around the community actors and healthcare policy in the community settings.

The next step in this study was to synthesise scoping and mapping review and interview data through the data triangulation approach, which combines different methods and datasets to converge findings and enhance the validity of research outcomes (Moran-Ellis *et al.*, 2006). Using triangulation, the core components of the intervention were identified and formulated as statements for the Delphi consensus. These statements encompassed the essential aspects of CHWs management and healthcare policy specific to the Indonesian context.

The Delphi technique was then employed to seek the opinions of Indonesian experts in diabetic footcare on the importance of these aspects for inclusion in FIne-CHWs. The aim was to achieve consensus on how the intervention could be made acceptable, implementable, cost-effective, scalable, and transferable across Indonesian contexts. After two rounds of the Delphi exercise, consensus agreement was reached on 41 out of 42 statements regarding the core components of FIne-CHWs, with consensus disagreement for one statement. Furthermore, from analysis of the free text response of the Delphi questionnaire emerged overarching theme: *"CHWs Are Only*

Volunteers": Lack of Policy for Connectivity and Integration of CHWs in Healthcare Service Delivery.

This was explained through three subthemes, namely: CHWs deliver footcare education for all people with diabetes (CHW role's clarity); remuneration and incentives; and flexibility of community FCIs (community-based intervention).

In summary, this study employed the new MRC Framework to develop FIne-CHWs, utilizing various methods to identify key uncertainties and engaging with key stakeholders to refine the intervention in the Indonesian context.

9.2. Barriers and Facilitators of FIne-CHWs Implementation

The study is the first attempt to introduce a specific structured intervention to be delivered by CHWs in Indonesia. The transition phase from current CHW practices, with short training to manage maternal and children health, to the structured FIne-CHWs, raises concerns about CHWs' resources and management, including supervision, remuneration, evaluation of the CHWs' programme, and community acceptance of extending this specific intervention. CHWPs are complex interventions, that involve both the community and the formal health system (Lewin, Lehmann and Perry, 2021). Programme success is dependent on the local context, including the health system and culture, as well as the programme context, which includes factors such as supervision, training, and incentives (Gergen, Crigler and Perry, 2013; Kok, Broerse *et al.*, 2017). The prominent barriers found in relation to FIne-CHWs pertain to the role and position of CHWs, their resources, and remuneration. Understanding the barriers and supports of the intervention is critical to successfully implementing the FIne-CHWs programme in the Indonesian context.

9.3. CHWs' Position in the Indonesian Context

This study identified that the success of the FIne-CHWs programme may be influenced by the ambiguous position of CHWs in relation to healthcare system delivery, notwithstanding the crucial role CHWs can play within the healthcare system when deployed appropriately, in relation to their responsibilities, powers, and potential contributions to health programmes (Gergen, Crigler and Perry, 2013). This study showed that the governance and implementation of FIne-CHWs are complex and relational, involving a wide range of stakeholders, and may be shaped by existing laws and regulations. The NCD programme embedded in the ISP-NCD (Posbindu PTM), which determines the role of CHWs in enhancing community health awareness, has been a key national initiative of the MoH (MoH-RI, 2012); this acknowledgement of the potential contribution of CHWs nationally bolsters the case for CHW-led programmes in Indonesia.

However, FIne-CHWs management is a shared responsibility between the MoH and the MoHA in operational ISP-NCD (Posbindu PTM) at the village level. This leads to challenges in implementing FIne-CHWs. While CHWs are responsible for health programmes delivered via PHCs (under the MoH), they are formally financed by and accountable to the village committee under the MoHA, who are responsible for organizing CHWs (Surjaningrum, Minas, *et al.*, 2018; Oendari and Rohde, 2021). Despite the fact that CHWs are accountable to village committees, which have a direct line to the MoHA, some studies in Indonesia have identified that the PHC (Puskesmas) plays the primary practical role in the deployment of CHWs in the community, because they are responsible for providing guidance and support to CHWs, whereas CHWs are tasked by HCPs (Soedirham, 2012; Yandrizal *et al.*, 2016).

However, this coordination between two authorities raises the challenge of who is responsible for holding CHWs accountable, supervising them, and funding the implementation of FIne-CHWs as a new specific intervention. Based on previous research on optimising ISP-NCD in Indonesia (Yandrizal *et al.*, 2016), this has been a source of concern: the PHC, represented by HCPs, provides directions to CHWs without recourse to the heads of sub-districts or districts (part of village committees) in monitoring and evaluating community health programmes, leaving the village committee unfamiliar with the progression of CHWPs in ISP-NCD (Posbindu PTM). This condition often happens globally when CHWPs fall outside the governance structures of the formal health system, leading to poor integration and challenges in governing and implementing these programmes (Surjaningrum, Minas, *et al.*, 2018; WHO, 2020).

Nevertheless, the responsibility for recruiting and funding CHWs within a local community, specifically within a district or sub-district area, lies with the village committee. This responsibility is expected to align with the deployment of CHWs from PHCs to deliver FIne-CHWs, as well as other factors related to remuneration after CHWs deployment. However, the feasibility of this arrangement is challenged by gaps between policy and practice, as highlighted in a study on expanding the role of CHWs in managing perinatal depression in Surabaya, Indonesia, by Surjaningrum *et al.* (2018). The current study affirms their findings, as although some expert panellists appreciate the CHWs' position, and place high expectations on them to combat the incidence of DFUs, some panellists perceived barriers to delegating this task-sharing to CHWs, as CHWs are not officially recognized as part of the health system. At the same time, HCPs, as supervisors of CHWs, are not responsible for hiring and firing CHWs, as the CHWs are known as volunteers, and the HCPs are expected to work

with the current CHWs' resources, which might not meet the requirements to deliver task sharing. The unclear position of CHWs in the health system potentially hinders the optimization of FIne-CHWs.

This study indicated that the management and governance of CHWPs may overlap and present challenges. Cases of successful CHWPs attributed their effectiveness to CHWs having a direct line to HCPs, and being accountable to the Healthcare Centre, as observed by Culica, Walton and Prezio (2007). They found that CHWs could provide a comprehensive approach to footcare when trained to perform a complete foot examination, including visual inspection, pedal pulses assessment, and monofilament testing. The examination results were documented in patients' charts and clinical medical records, and any foot abnormalities were reported immediately to the responsible physician. CHWs also provided education on appropriate footwear and daily home footcare (Culica, Walton and Prezio, 2007). Furthermore, tailored clinical management through community-to-clinic navigation in T2DM self-management holds promise for hard-to-reach rural populations in Appalachian, Kentucky (US). (Schoenberg, Ciciurkaite and Greenwood, 2017). These evidences can inform the governance and implementation of FIne-CHWs.

The successful execution of various CHWPs necessitates coordinated efforts and collaboration among multiple sectors and stakeholders. This includes various government entities, such as the MoH, other government departments, regional and local authorities, professional associations, NGOs, and local communities. To achieve this effectively, it is essential to establish an intense coordination process and an appropriate mechanism that can unite these stakeholders around a shared platform and agenda, ensuring that their actions are synchronized (Afzal *et al.*, 2021). Drawing

lessons from numerous countries, the MoH, as the primary stakeholder, assumes a central role and offers guidance for the coordination process. It takes the initiative to engage and harmonize various sectors at critical stages, including planning, resource mobilization, programme implementation, and monitoring of programme efficacy. This coordination platform can also serve as a means to address the financial and technical assistance required for the successful execution of CHWPs (Afzal *et al.*, 2021). Different governing models for CHWPs have far-reaching implications, including their financing and funding, selection and training of CHWs, support and supervision, payment, and community involvement, among other issues (Lewin and Lehmann, 2013).

9.4. CHWs' Resources

The community actors interviewed in this study perceived the implementation of FIne-CHWs to be feasible and acceptable in Indonesia; this is supported by consensus agreement on core components of FIne-CHWs from panellists in the Delphi study. However, the decision to extend the role of CHWs in providing FIne-CHWs in Indonesia has practical implications for the health system. Currently, most CHWs in this study are generalists, responsible for a full range of services delivered by the PHC system (Hodgins *et al.*, 2021), but they can also train in technical programmes such as supervising medication adherence for tuberculosis patients (Oendari and Rohde, 2021), which are known as specialized CHWs as definition. However, expanding their role to include FIne-CHWs raises concerns about their capability to learn and potential high workload to undertake new tasks.

Some participants in this study (as discussed in Chapter 6) expressed concerns regarding the capability of current CHWs to effectively implement the FIne-CHWs, particularly senior CHWs who were anticipated to encounter potential difficulties in learning new skills. This data was supported by another study evaluating the effectiveness of ISP-NCD (Posbindu PTM) in Bogor, Indonesia, which reported that older CHWs with relatively lower levels of education were not able to deliver health education in ISP-NCD (Posbindu PTM) contexts (Alfiyah and Pujiyanto, 2019), and such findings raise doubts about the quality and safety of care provided. Task sharing is essential for addressing skill imbalances, and complete delegation to CHWs can produce adverse effects, including resistance from HCPs and institutions, in addition to service users (WHO, 2020).

In this regard, it is crucial to identify CHWs capable of undertaking the expanded role of FIne-CHWs educators. This study showed that participants perceived that level of education and age need to be considered when choosing CHWs to deliver FIne-CHWs; this requirement links to how the current CHWs are selected by the village committee or by the FWM (the women's agency of the MoHA). New CHW positions are often offered to individuals by the head of FWM with no formal recruitment process, as found in this study; in some cases, the CHWs were asked by their mothers to help manage ISPs (Posyandu-Posbindu PTM) (Wicaksono, 2017; Oendari and Rohde, 2021). The requirements for becoming a CHW are limited to basic literacy skills and a willingness to participate in voluntary community service. Despite the MoH (2012) setting a minimum education level of year 12 schooling for managing Posbindu PTM, most CHWs participating in this study did not meet this standard. Moreover, the majority of CHWs are housewives (Oendari and Rohde, 2021) and elderly people or

pensioners (Alfiyah and Pujiyanto, 2019), who are available during weekdays when ISP-NCD operates.

Introducing more complex responsibilities may lead programmes to show a preference for CHWs with higher levels of education (Glenton, Javadi and Perry, 2021). This could also drive efforts to professionalize and better integrate CHWs into the healthcare system (Schleiff *et al.*, 2021). Conversely, lower-level CHWs typically operate within neighbourhood settings, managing a more limited scope of tasks. They maintain direct connections, enjoy trust within, and possess first-hand knowledge of the most economically disadvantaged and underserved communities with significant challenges in accessing essential services (Schleiff *et al.*, 2021). An emphasis on higher qualifications may pose a potential obstacle to local recruitment, and potentially exacerbate barriers to accessing scarce resources for disadvantaged communities (Glenton, Javadi and Perry, 2021). This emphasizes the need to recognize and leverage the distinctive advantages that local CHWs can bring to community healthcare interventions.

Variation of capacity and capability of current CHWs was indicated by HCPs in this study, who perceived that not all CHWs have the capability to take on more work with regard to an educational role for FIne-CHWs, and some might not be capable of learning new skills. However, this study identified that potential CHWs educators could be identified based on their ability to perform specific interventions while considering their educational level. CHW *leaders* are deemed capable of taking on an expanded role in FIne-CHWs, while CHW *assistants* can be assigned primary tasks such as taking measurements of visitors to a community post. Given the current availability of CHWs, the role of FIne-CHWs educators could potentially be extended

to some CHW leaders, who can be trained for specific interventions based on their capacity, including their educational level. This study was supported by evidence from various CHWPs in countries such as Bangladesh, Ethiopia, Ghana, Nepal, and Nigeria, showing the effectiveness of dual-tier CHWs (Westgate *et al.*, 2021). This model involves professional and salaried CHWs who act as intermediaries between the community and formal health services, along with village volunteers who serve fewer households. The dual cadre model was developed for multiple purposes in the CHW programme (Schleiff *et al.*, 2021). The higher-level CHWs supervise the lower-level volunteer CHWs, working together in the community (Westgate *et al.*, 2021). This dual-tier CHWs might work to extend CHW's role in FIne-CHWs in Indonesia.

However, in situations where CHW roles are implemented through different programmes, funding and logistical support differences can negatively affect programmes with limited resources and their CHWs. This can ultimately impact the motivation and retention of CHWs (Hodgins *et al.*, 2021). A further finding is that the CHWs manage ISP-Maternal and Children (Posyandu) and ISP-NCD (Posbindu PTM) deploy the same CHWs, and both ISPs are held on the same day. Separating CHWs for deployment differently in the two ISPs should be considered necessary, because the same CHWs engaging with multiple tasks simultaneously might cause work overload. CHWs may find it more manageable to split work between them, focus on and become skilled at a small number of tasks, or have tasks introduced gradually (Glenton and Javadi, 2013; Glenton, Javadi and Perry, 2021).

WHO (2020) guidelines note that high workloads reduce the motivation, satisfaction, efficacy, and retention of CHWs, albeit there is no known ideal work environment nor a known maximum number or mix of CHW job tasks to ensure the highest CHW

productivity level. They observe that success is more likely when CHWs have a clear job description, a limited number of tasks, standardized protocols, and job aids that match their training. Therefore, focusing on some CHWs generalists to manage the ISP-NCD (Posbindu PTM) separate from ISP-maternal and children (Posyandu) is more practical than recruiting new CHWs to undertake this role; as long as they meet the prerequisite criteria, it may be more efficient to train, supervise, and support fewer "generalist" CHWs than to have the same number of tasks delivered by a more significant number of "specialist" CHWs. Decisions regarding the number of functions a CHWs should also be based on consultation and analysis of when and where each task will be performed, and the workload each job entails (Glenton, Javadi and Perry, 2021).

9.5. CHWs' Remuneration

The experts on the panel in the Delphi study, as discussed in Chapter 8, reached a consensus that CHWs should receive compensation for their transportation expenses when travelling to the referral area. They also concluded that volunteers travelling to visit patients at their homes might be discouraged more if they were not reimbursed for their travel, rather than not being paid for their services *per se*. CHWs tend to be from low socioeconomic background, and will not necessarily be able to afford transportation cost associated with their responsibilities themselves (Ormel *et al.*, 2019; WHO, 2020). The panellists acknowledged that CHWs are typically poor people, living in poor communities, and require material support, but they differed concerning the forms this should take, with some participants thinking direct financial remuneration might be counterproductive.

Nevertheless, Henry and Hodgins (2013) argued that the reliable delivery of even simple community-based services by volunteers or minimally compensated CHWs requires functional support systems. In current regulation, CHWs managing ISPs (Posyandu-Posbindu PTM) may receive a small monthly transportation cost allowance (Ormel *et al.*, 2019; Gadsden *et al.*, 2022). However, the policy of providing an allowance to CHWs is not consistently implemented in Indonesia, as the decentralized government rules allow local governments to implement different regulations on CHWPs. Some studies reported that Indonesian CHWs typically receive a monthly financial gift at the discretion of the village government, which typically ranges between USD 2-5 (Ormel *et al.*, 2019; Gadsden *et al.*, 2022). This is a trifling sum even in comparison to other developing country contexts; for instance, CHWs in Bangladesh typically receive a monthly salary ranging from USD 190-362, and they operate some of the most successful CHWPs in the developing world (Colvin, Hodgins and Perry, 2021).

However, some panellist in this study suggested that increasing the financial incentives for CHWs would reduce the altruistic motivation and impact the sustainability of the programme in question if voluntary jobs were always linked with incentives. Notably, expecting low-income countries' governments to provide regular payments to CHWs is deemed unrealistic, as it is unsustainable and may raise unsustainable expectations, causing tension in the health system and weakening intrinsic motivation (Greenspan *et al.*, 2013).

This study found that none of the CHW participants considered the financial incentives a motivator for them to be active in the community. Religious values were identified as strong encouragement for people to serve the community. However, there still is a

concern about who would be responsible for paying CHWs' costs, since the PHC needed an allocation budget for the CHW programme to reach long-distance home visits. Learning from the CHW programme in Zambia, in which CHWs work on an entirely voluntary basis, attrition rates are high, and the few enthusiastic and reliable volunteers become overloaded with tasks from other agencies and sectors (Ormel *et al.*, 2019). A shift in motivation needs to be anticipated to maintain FIne-CHWs' sustainability; several participants (as explained in Chapter 6) considered that the young people are less interested to be CHWs due to inadequate incentives received. During the 1997 monetary crisis in Indonesia, up to 70% of Posyandu stopped functioning because many CHWs had to prioritize earning money for the survival of their families, so they could no longer serve the community on a voluntary basis (Oendari and Rohde, 2021).

The findings from this study found that various viewpoints exist regarding the efficacy and desirability of providing financial incentives to CHWs. While some argue that such incentives may prove counterproductive by undermining the intrinsic motivation of CHWs, and creating doubt about their intentions among clients, the opposite appears to hold for volunteer CHWs. CHWs in this study possessed intrinsic motivators that mitigate the negative impact of modest financial allowances. Although some voluntary CHWs may acknowledge the value of financial incentives, they typically regard them as secondary to the intrinsic drivers of their volunteering spirit. CHW participants indicated that they acknowledged their volunteer status, resulting in them not being disheartened by the limited incentives they received. However, the HCPs and family members expressed concerns about the low incentives for CHWs, especially if additional tasks were added to their responsibilities in delivering FIne-CHWs.

A discrete choice experiment conducted with 471 CHWs from 28 villages in the Malang district of Indonesia, involving senior and experienced CHWs, found that they opposed increasing the number of incentives, expressing a preference for a small monthly financial benefit. They feared that higher incentives could lead to increased work hours and responsibilities, possibly weakening their altruistic motivation (Gadsden *et al.*, 2022). This result was unexpected, and contrasts with previous studies of CHW preferences elsewhere (Ormel *et al.*, 2019; Gadsden *et al.*, 2022). However, young CHWs in discrete choice experiment expected longer shifts and higher incomes (Gadsden *et al.*, 2022). Recruiting trained and young CHWs was also suggested to increase health coverage in the study evaluation programme in the ISP-NCD in Bogor, Indonesia (Alfiyah and Pujiyanto, 2019).

Ormel *et al.* (2019) reported that one of the planners of CHWPs in Indonesia stated that introducing financial incentives for volunteers who previously did not receive an allowance weakened intrinsic motivation. This statement contrasted with an ethnographic study about CHWs in ISP maternal and children, and their role as housewives; this study found a lack of CHWs involved in managing ISP (Posyandu), and one senior CHW interviewee aged 63 years old who had been a CHW for over 20 years stated that she could not retire, since it was challenging to find new CHWs. This study also explained there was a shift in motivation in the community, from pure volunteering to being formalised by receiving a certification as well as a small incentive. The study found it was difficult to retain CHWs as the complexity of ISP (Posbindu) tasks, along with the writing of 31 monthly reports that had to be completed by two or three CHWs, led to the resignation of the CHWs (Wicaksono, 2017); the altruistic motivation of most CHWs to volunteer in health services cannot be expected to sustain such an onerous bureaucratic load without compensation. This is likely an

essential issue in poor socio-economic contexts. Lower-than-expected incentives lead to demotivation and hinder performance (Ormel *et al.*, 2019).

The subsequent inquiry pertains to the origins of the incentives, as there is no financial allocation from PHC to support the extended role of CHWs. This matter was deemed insignificant in Surjaningrum *et al.*'s (2018) feasibility study examining the expanded role of CHWs in the management of perinatal depression, as the task was located within walking distance, but support was required for communication equipment. However, in my study, some expert panel members proposed utilizing village funding (BOK) to cover transportation costs equivalent to the standard transportation cost. To enable PHCs to oversee the task-sharing extension of FIne-CHWs, they should be capable of communicating and collaborating with the village committees at the district and sub-district levels to provide CHWs with remuneration for transportation allowance.

Financial support from the government is necessary to ensure a CHW can be held accountable; incentives may serve to establish and strengthen accountability, and financing mechanisms for CHWPs are more than just a means of generating resources. They can be a means for incentivizing good performance, assuring sustainability, and fairly distributing the burden of healthcare costs (Ormel *et al.*, 2019). To address this issue, applying a dual-tier CHWs system might work to reduce the financial costs of FIne-CHWs. CHW leaders can be trained and get more direct remuneration, and they can with other ancillary village CHWs who can be rewarded with other forms of appreciation, such as lunches and uniforms; this would address the issue that providing financial rewards to all tiers of CHWs may jeopardize the sustainability of the community programme. Nevertheless, it is important to note that the variations in

skills, services, and training among different CHW cohort operating within the same community can be perplexing for patients, and can erode their trust and result in reduced healthcare service demand (Afzal *et al.*, 2021).

The panellists in the Delphi study agreed that CHWs should be reimbursed for their travel costs incurred when going to the community centre, Posbindu PTM, or patients' homes. This statement is also in line with the new WHO (2018) programme support guideline, which also recommends that CHWs receive a financial package commensurate with the job demands, complexity, number of hours, training and roles that they undertake.

9.6. Current *MoH Technical Guidelines* for Managing Community-Based Diabetic Foot CHWs

The results of this study indicated that diabetic foot education was not prioritized for delivery at PHC facilities. Consequently, HCPs are not trained in this area and may lack the knowledge and skills to offer patients preventive advice. Without proper training, HCPs may lack the confidence to supervise CHWs delivering the intervention. It is worth noting that the MoH-RI (2015) has developed *the MoH Technical Guidelines* for managing community-based diabetic foot. However, this is not available online, and during the interviews conducted for this study, none of the HCPs mentioned it, indicating that it has not been widely disseminated and implemented nationally.

The *MoH Technical Guidelines* provide an outline of how FCI can be conducted in the community setting to integrate footcare to the ISP-NCD programme. It also provides details the procedures, providers, place of intervention, and educational content for

CHWs training, referral system, and patient criteria. However, no details of these aspects are included in the *MoH Technical Guidelines* concerning patient needs and the specific competencies required of CHWs to provide the intervention safely. Interestingly, considering the flow of referred patients, some expert panellists indicated that it might not be acceptable for patients to be referred to FIne-CHWs due to CHWs not being part of PHC system. In contrast, this guideline explains how patient referral should be organized. The absence of regulations on CHWs position in health delivery system will affect CHW deployment.

Commensurate with the information provided in the *MoH Technical Guidelines*, consideration is needed to expand the roles of existing CHWs. Programme planners must consider various factors to ensure the acceptability, appropriateness, effectiveness, safety, and feasibility of the recommended tasks for the target population, the CHWs themselves, and the community actors involved. This can be achieved through a situational analysis that draws on various sources of information, including the peer-reviewed and grey literature, stakeholder meetings, visits to local communities, identification of gaps and assets, and formative research (Gergen, Crigler and Perry, 2013).

The lack of evidence used to develop the *MoH Technical Guidelines*, which is supposed to scale-up programme nationally, could cause potential failure of the intervention. Although the guidelines mention that HCPs and trained CHWs would conduct the intervention together, there is no delineation of task boundaries for these intervention providers. HCPs are more likely to accept tasks from CHWs if clear boundaries are established, and if CHWs are perceived to be contextually appropriate for the care setting (Glenton, Javadi and Perry, 2021). Moreover, when planning new

CHW roles or expanding existing ones, programme planners must analyse current research evidence and evidence-based guidelines on the effectiveness and safety of relevant tasks performed by CHWs (Glenton, Javadi and Perry, 2021).

The *MoH Technical Guidelines* identified the barrier of a lack of knowledge among community actors, lack of resources, and lack of supervision. Nevertheless, the *MoH Technical Guidelines* does not report sources of evidence regarding barriers and support which should be mitigated before the intervention is scaled up, or what key stakeholders can expect from the intervention.

The FIne-CHWs presents a comprehensive analysis of barriers and support for the lack of knowledge and skill among HCPs, CHWs, and patients, with further concerns related to the capability of CHWs' resources, which can cause community distrust toward CHWs. This provides preliminary evidence for improvements in the recruitment and training of CHWs. Different from concerns raised by panellists in the Delphi study regarding footcare task-sharing in the community, given that CHWs are not formally part of the health system delivery, the *MoH Technical Guidelines* describes the referral flow for those LR-DFUs to CHWs intervention. In contrast to the *MoH Technical Guidelines*, the FIne-CHWs programme aims to provide interventions to a wider range of diabetic patients, encompassing not only those at low risk but also individuals at various levels of risk, as long as those who do not have active DFUs.

The FIne-CHWs also includes guidance on handling stress associated with foot issues, along with instructions on how, when, and where to seek assistance when encountering foot problems. A shared aspect between both the *MoH Technical Guidelines* and FIne-CHWs is incorporating foot exercises using newspapers/papers as an educational

component, considering Indonesia's distinct context. Table 18 compares the *MoH Technical Guidelines* and the FIne-CHWs.

Table 18: Comparison of MoH Technical Guidelines and FIne-CHWs

MoH Technical Guidelines (MoH-RI, 2015)	**FIne-CHWs**	**Comparison**
Barriers		
Lack of knowledge among HCPs and CHWs Lack of skill among patients and CHWs Lack of resources Lack of supervision of monitoring diabetes complications	Lack of knowledge and skills among HCPs, CHWs, and patients CHWs' resources Community distrust FIne-CHWs funding CHWs' motivation	FIne-CHWs presents in-depth understanding of barriers in addition to lack of knowledge and supervision
Intervention core components		
Intervention provider		
HCPs and CHWs (no clear task boundaries) Early DFU screening, counselling, and community education.	CHWs as patient educators without DFUs HCPs screening DFU risk categories and supervising CHWs	FIne-CHWs has division of roles for CHWs and HCPs
Intervention place		
Various community places	NCD community post and PHC	FIne-CHWs has flexible community locations and CHW supervision
Intervention procedure		
Set foot care on five desks service flow into ISP-NCD, including monitoring blood glucose, foot screening and counselling	Embedded in ISP-NCD service, allowing for blood glucose test, foot screening and small group of education session by CHWs	FIne-CHWs do not set footcare education at specific desks as per the *MoH Technical Guidelines* in the ISP-NCD service flow.
Intervention method of delivery		
CHW classroom training (max. 30 CHWs), followed by hands-on skills sessions	Multiple teaching and learning methods, including lectures, group discussions, video presentations, and hands-on skill sessions in small group sessions	*MoH Technical Guidelines* focus on training CHWs; no information on delivery to patients
Intervention time and duration		
CHWs training over 3 days No reported time to intervene with patients	More specific for education of patients, with set, specific times for face-to-face intervention, telephone contact boosters, and home visits	*MoH Technical Guidelines* do not specify specific times or durations for patients

Table 18: Comparison of MoH Technical Guidelines and FIne-CHWs

MoH Technical Guidelines (MoH-RI, 2015)	**FIne-CHWs**	**Comparison**
Intervention educational content		
Focus education material for CHWs training (no explanation of content for patients) Introduction to diabetes and diabetic foot complications Early detection, classification of diabetic foot risk levels Diabetic footcare Recording and reporting	Content education for CHWs and patients Introduction to diabetes and diabetic foot complications Diabetic footcare Help seeking Stress management	The *MoH Technical Guidelines* emphasize content of education for CHWs training, not specifically for patients

Source: Author

Interestingly, the *MoH Technical Guidelines* characterize CHWs as executive officers within the ISP-NCD, which diverges from the former understanding of CHWs articulated by Posbindu (2012, 2020) employing the term "kader" to denote CHWs. This shift in terminology might distinguish CHWs based on their skills and abilities, potentially arising from disparities in the extent of training CHWs undergo. While the community might perceive all CHWs uniformly, unintended distinctions might emerge for programme planners within the MoH, possibly recognizing various types of CHWs, including those who have undergone more extensive training, as highlighted in this study, albeit without explicit definition. Consequently, those responsible for formulating CHWPs in Indonesia should acknowledge the diversity in CHWs' capacities and capabilities, which could relate to the CHWs' recruitment process. This aspect is also critical for fostering community trust in the competency of individuals designated as CHWs.

It is also essential to assess the acceptability and practicality of the intervention, conduct a rigorous assessment of its effectiveness, and consider its contextual appropriateness. In this regard, the FIne-CHWs study, which utilized the new MRC

Framework and multiple methods to understand the acceptability and practicality of FCI, provides valuable insights and informs the development of the intervention in the Indonesian context. By considering the various factors discussed above, planners can ensure the success and sustainability of CHWPs and improve access to healthcare uptakes.

While the *MoH Technical Guidelines* offers technical guidance on implementing footcare education in the community, it needs to address issues of acceptability and practicality that could hinder the scalability and effectiveness of the intervention. To bridge this gap, this study found several potential barriers that should be considered by programme planners and policy makers before scaling-up FIne-CHWs, such us the ambiguous position of CHWs in Indonesian healthcare policy (which potentially hinders expanding CHWs' role), patients' eligibility, requirements of CHW selection, CHW management, and specific methods and times for the intervention itself. This study also provides comprehensive educational content alongside community training approach tailored to the intended patients and CHWs.

The first phase of new MRC Framework explores the practicality and acceptability of complex interventions, to ensure that the FIne-CHWs is appropriate for the Indonesian context, and to avoid potential failure when implemented at scale.

9.7. Core Components of Intervention

Issues regarding the core components of FIne-CHWs are explained in detail following TIDieR (Hoffmann *et al.*, 2014) in the following subsections.

9.7.1. Procedure of Intervention

"Procedure" can refer to the sequence of steps to be followed, such as processes or activities including referral, screening, case finding, and assessment (Hoffmann *et al.*, 2014). The mapping review found that numerous studies have examined and implemented footcare programmes that classify patients based on their diabetic foot risk level (Harwell *et al.*, 2001; Pollock, Unwin and Connolly, 2004; Fujiwara *et al.*, 2011; Kishore, Upadhyay and Jyotsna, 2015; Wu *et al.*, 2015; Wei *et al.*, 2019), with interventions delivered after HCPs assess the feet and determine the risk of foot ulcers (Borges and Ostwald, 2008; Fan *et al.*, 2013; Nguyen *et al.*, 2019). This classification is directly linked to a strategy that refers patients for treatment (van Netten *et al.*, 2016).

This study found that HCPs are responsible for preliminary foot screening before referring the patients to FIne-CHWs. This referral flow is suggested by the *MoH Technical Guidelines* (MoH-RI, 2015) whereby patients with no symptoms of DFUs ought to consult trained CHWs in the ISP-NCD. However, the expert panel disagreed with the statement that FIne-CHWs should only provide educational sessions to patients *without* DFUs; this may be because there is no clear definition of CHWs' role in diabetes management, including diabetic foot prevention, nor are there criteria in previous studies of diabetes management that determine which patients should receive footcare education delivered by CHWs.

However, two studies have reported that CHWs in the US performed a complete foot examination, including visual inspection, pedal pulses assessment, and monofilament testing (Prezio *et al.*, 2017; Vaughan *et al.*, 2017), which may call for consideration if

adopted in low-resource countries where CHWs do not currently perform these skilled procedures.

9.7.2. Content of Education

This study summarizes the basic footcare information conveyed to patients diagnosed with diabetes, including: awareness about diabetes and foot complications; definition of the diabetic foot (its types and aetiology); identification of at-risk foot (risk factors and warning signs); daily self-footcare (including daily washing, inspecting foot for problems, moisturizing, and massaging); wearing proper shoes and socks; toenail care; and help-seeking (when, where, and how). The recommendations for basic footcare align with international guidelines from RNAO (2007), Bus *et al.* (2020), and NICE (2020). Non-biomechanical foot issues like stress management related to footcare and foot exercise is increasingly acknowledged to be important (Fardazar, Tahari and Solhi, 2018), and the promotion of foot exercises via newspapers is also included as part of unique educational material in Indonesia, as it has been widely implemented in the community.

This study found that the community requires information on diabetes in general, in addition to minor signs of DFUs, and how to take proper action to prevent the latter. Many diabetics are unaware of their condition until serious complications arise, and there is a high rate of undiagnosed diabetes in Indonesia (Widayanti *et al.*, 2020). For instance, in this study (Chapter 6) patients described “kutu air” (tinea pedis) in their leg as a result of laundry detergent, causing them to be less aware of further potential infection in their leg. Effective treatment of tinea pedis is critical for diabetic patients, because these infections can cause foot ulcers and secondary bacterial infections, leading to lower limb amputation (Matricciani and Jones, 2015). The position of

CHWs as part of their community can be an advantage to explain diabetes and address misconceptions among community members using lay terminology and language.

9.7.3. Healthcare Providers

The expert panel reached consensus regarding the resources available to CHWs and the requirements necessary to fulfil to deliver FIne-CHWs. The study findings are in line with the WHO recommendation that to deliver interventions successfully, CHWs require an adequate level of education, communication skills, and high motivation to deliver the intervention (WHO, 2018).

According to several studies, CHWs have been enlisted to effectively deliver footcare education as part of diabetes care in diverse contexts (Spencer *et al.*, 2011; Islam *et al.*, 2013; Castillo *et al.*, 2014; Prezio *et al.*, 2014; Hughes *et al.*, 2016; Pacheco *et al.*, 2017; Schoenberg *et al.*, 2017). Nevertheless, the effectiveness of CHWs in providing these interventions was contingent on them being adequately and supportively supervised. Consistent supervision enhanced CHWs' motivation, clarified their roles and responsibilities, ensured the availability of necessary tools, supplies, knowledge, and skills, and promoted a secure working environment (Westgate *et al.*, 2021; Zulu and Perry, 2021).

This study also revealed that community members expressed doubts about the current capacity and ability of CHWs, which necessitated on-site supervision from HCPs while delivering FIne-CHWs. However, planning for leadership must consider the existing staff's ability to assume additional responsibilities (Gergen, Crigler and Perry, 2013; Westgate *et al.*, 2021). Consequently, involving HCPs in planning CHWPs should be initiated early, to prevent overburdening the already strained health facility

staff with new supervisory and mentoring duties, as well as paperwork, meetings, and field visits (Lewin, Lehmann and Perry, 2021).

The limited time available to HCPs for teaching DFPs in PHC, coupled with the lack of focus from health offices, has caused this initiative to be deprioritized in current primary healthcare services. This study found that HCPs prioritized glucose control over other diabetes management practices, consistent with another study conducted in Indonesia, indicating that patients may not view footcare as critical as glycaemic control and may not prioritize it (Sari *et al.*, 2021).

Even though the PHC programme does not allocate time for teaching diabetic prevention, HCPs do not object to supervising CHWs if the supervision schedule is aligned with their monthly schedule for supervising the ISP-NCD (Posbindu PTM). However, the expansion of the CHWs' role should be anticipated by providing supervisors with refresher training before they undertake supervision of FIne-CHWs, given this study's finding of a lack of knowledge and skills among community actors in diabetes footcare prevention.

To ensure the effectiveness of the CHW programme, CHWs, the community, supervisors of CHWs, and others within the health system require training (Schleiff *et al.*, 2021). Currently, GPs, nurses, or midwives are the HCPs resources available to supervise the ISP-NCD. However, a qualitative study evaluating the effectiveness of the ISP-NCD in Malang, Indonesia, reported that midwives expressed a burden in the expanded task in NCD prevention, along with a lack of competency in this specific area of DFU prevention (Pratono and Maharani, 2018).

> *"Being a midwife in the village is quite challenging. I am an expert in maternal healthcare by training, but local people expect me to provide all kind of medical treatments, including for health problems of elderly people…"* (Pratono and Maharani, 2018, page 1569)

This study identified that one nurse held a wound care specialist certificate after one week of training and demonstrated sufficient knowledge and skill in footcare. However, there was no evidence of midwives being involved in footcare education interventions elsewhere, and physicians, nurses, mental health professionals, or podiatrists are typically enlisted as intervention providers (Harwell *et al.*, 2001; Pollock, Unwin and Connolly, 2004; Fujiwara *et al.*, 2011; Kishore, Upadhyay and Jyotsna, 2015; Wu *et al.*, 2015; Wei *et al.*, 2019). Although the nurses participating in this study needed to become more familiar with the screening risk of DFUs, wound care nurses latently possess the right level of expertise and confidence to supervise FIne-CHWs by default, and they are reported to already exercise a *de facto* role in teaching DFU prevention (Sari *et al.*, 2021).

CHWs are known as volunteers, who do not require specific recruitment standards except their willingness to help the community. The panel of experts questioned CHW's willingness to take an exam to confirm their competence, and some considered that setting such high standards would be impractical, given the CHW's current resources. However, building public trust in CHW's capabilities and increasing the confidence of the CHW is an important step to increasing the effectiveness of their role in modern healthcare systems (Lewin and Lehmann, 2013, WHO, 2020). Therefore, it is recommended to use "formative evaluation" for CHW evaluation in training, through an emphasis process that checks performance progress throughout

the training, not just at the end (Aitken, 2013); it is hoped that this will reduce the stress of the CHW during the summative evaluation to ensure their competence.

9.7.4. Method of Delivery

This section of TIDieR describes the delivery medium of the intervention, considering whether it might take place physically (in person), over the phone, by email, the internet, DVD, a large-scale media campaign, or a combination of these modalities (Hoffmann *et al.*, 2014). The recommendations of the current study are to develop a programme that contains three methods of delivery: face-to-face intervention in small groups with not more than 10 participants, plus telephone contact booster sessions, and home visits for those unable to visit ISP-NCD. Group-based education for T2DM patients is more cost-effective and efficient than individual education (Monami *et al.*, 2015), allowing for detailed information in less time, reducing demands on HCPs, and facilitating patient discussion and support from others in similar situations (Odgers-Jewell *et al.*, 2017).

A telephone contact booster lasting 10-15 minutes was included in this study to ensure that patients fully comprehended foot self-care. This allowed for any lingering concerns to be addressed and the essential elements of daily self-care practices reviewed (Fan *et al.*, 2014). This study included home visits for people who could not visit ISP-NCD (Posbindu PTM) during the FIne-CHWs sessions. The belief is that CHWs contribute to communities by making their services accessible and available to their clients (Lehmann and Sanders, 2007; WHO, 2007; Silverman *et al.*, 2018). Additionally, reminders and recall systems are necessary for diabetes control and risk assessment to ensure the success of the diabetes programme (RNAO, 2007).

This study identified a viable method of training of CHWs and patients. Teaching problem-solving skills and other complex tasks requires training beyond basic classroom lectures and memorization (Schleiff *et al.*, 2021). Visual and multimedia materials are highly beneficial in presenting necessary information, and pictorial job aids outlining activity protocols or offering audio-visual support for health promotion are essential (Negarandeh *et al.*, 2013; Liu *et al.*, 2018; Sjattar *et al.*, 2019). This approach differs from conventional classroom training as this method is used to train current CHWs in Indonesia (MoH-RI, 2012). Aitken (2013) recommends that CHW training programmes focus on competency-based approaches, rather than relying solely on traditional knowledge-based methods (i.e., increased focus on hands-on skills).

9.7.5. Time and Duration

FIne-CHWs recommends two one-hour education sessions, and two 15-30-minute booster sessions. Previous interventions delivered by HCPs have varied, ranging from 20 to 120 minutes for the main session (Fujiwara *et al.*, 2011; Fan *et al.*, 2014; Fardazar, Tahari and Solhi, 2018; Nguyen *et al.*, 2019), and with some disparity in the length and number of sessions. A scoping and mapping review and formative interviews suggest that two-hour sessions provide ample time for group participants to engage in in-depth discussions. Telephone contact booster sessions are after the two one-hour sessions. This recommendation aligns with two studies that utilized telephone contact booster sessions two to three times after the main sessions, each lasting 10 to 15 minutes (Fan *et al.*, 2014; Nguyen *et al.*, 2019). Short reinforcement sessions are recommended to aid participants in retaining the newly acquired information and adhering to foot self-care practices.

9.7.6. Place of Intervention

The interventions delivered by CHWs are mainly implemented in community settings such as the village health centre, an urban faith clinic, and a community self-care centre (Spencer *et al.*, 2011; Islam *et al.*, 2013; Castillo *et al.*, 2014; Prezio *et al.*, 2014; Pacheco *et al.*, 2017; Schoenberg *et al.*, 2017). Additionally, some interventions were conducted in patients' homes (Islam *et al.*, 2013; Hughes *et al.*, 2016; Schoenberg *et al.*, 2017). In this study, the FIne-CHWs session will be held at the ISP-NCD (selected due to its proximity to patients' homes and the potential cost savings on transportation. Furthermore, this monthly activity at ISP-NCD was designed to align with the schedule of HCPs for supervision of CHWs.

However, another place that was suggested by the panellists from the MoH was the PHC, as these villages were under the catchment service. This venue was supported by evidence that learning settings should be as similar and as close as possible to work settings; the clinical setting for practicing clinical skills is not the same as a village home, but ensures that enough cases are available, and help CHWs feel comfortable with the clinic and how things are done there (Glenton and Javadi, 2013).

Considering the factors above, the main place to implement this intervention is at the ISP-NCD. However, as long as the programme has been evaluated and is functioning properly, the CHW has the necessary competence to ensure safety, and patient confidence has developed in the CHW, flexibility in the venue for interventions can be considered as these interventions become embedded in communities.

9.7.7. Tailoring of Intervention

Variations in how, where, and by whom interventions are given and received are made possible by flexibility in intervention delivery (Skivington *et al.*, 2021). CHWPs

should be designed to be adaptable to local community contexts. The panellists reached consensus that FIne-CHWs sessions should be delivered in the local language. Delivering the intervention in the participants' language was considered more practical for most studies on interventions conducted in the US by deploying bilingual CHWs (Islam *et al.*, 2013; Castillo *et al.*, 2014; Prezio *et al.*, 2014; Rothchild, 2014; Vaughan, 2017). Materials should also be tailored according to patient literacy levels, and be culturally appropriate (Schoenberg *et al.*, 2017).

The participants in this study perceived CHWs role in community empowerment as more valuable for people from low socioeconomic backgrounds who live in the same neighbourhood as the CHWs. Several strategies to teach people with low literacy are identified relevant to teaching both CHWs and patients, such as providing food or souvenirs for patients who attend FIne-CHWs in ISP-NCD (this recommendation was requested by all group participants, as it was considered likely to increase patients' participation. It is also suggested that giving door prizes to active participants will draw the public's attention to the ISP-NCD (Nugraheni *et al.*, 2018). Providing healthy food reached consensus agreement from panellists, with the note that sufficient budget allocations would have to be available to facilitate this.

9.8. Programme Theory

Programme theory is presented as part of the core element as the first step to developing an intervention using the MRC framework. Programme theory explains how an intervention works, including its components, mechanisms, and expected impacts in the target context. It also helps diverse stakeholders understand the intervention and identify research questions. Before evaluating an intervention,

researchers must first develop a programme theory that involves diverse stakeholders, incorporates evidence and theory from relevant fields, and is refined throughout successive phases. This theory should be created at the beginning of the research project, and enhancing programme theory can inform intervention transferability and aid decision-makers in obtaining evidence and comprehension (Skivington *et al.*, 2021).

Programme theory can be visually represented through a logic model, realist matrix, or system map, depending on the research perspective and questions (Skivington *et al.*, 2021). The FIne-CHWs used a logic model to simplified visual representation that shows the relationship between different programme components. A logic model is used to assess the programme's feasibility, clarify goals and conceptual gaps, monitor implementation progress and changing needs, develop evaluation measures, and disseminate knowledge (Ebenso *et al.*, 2019).

The structure and terminology of logic models can differ, but they typically encompass elements that condense the input/resources invested in an intervention, its implementation/outputs, the outcomes/impact it achieves, as well as the contextual connections between these components. Logic models serve to pinpoint, elaborate upon, and organize these vital facets of an intervention, illustrating how it brings about change, often employing arrows to signify causal links between these elements (Public Health England, 2018).

Theoretically, contextual or implementation-related factors may impact the acceptability and efficacy of FIne-CHWs, such as patient's eligibility and criteria for patient referral to the programme, and prerequisite training for CHWs and HCPs prior to commencement. All these issues need to be addressed appropriately before the FIne-

CHWs undergoes testing through a feasibility study, to evaluate specific criteria regarding the intervention's design, recruitment, data collection, retention, outcomes, and analysis.

The logic model generated as a result of my current research is shown in Figure 19. It aimed at assessing the feasibility of the FIne-CHWs programme reveals that the input components involve CHWs' resources, HCP availability for supervision, diabetes patient data from PHCs, and the village fund designated for CHWs' compensation. Additionally, it encompasses the recognized CHWP integration into ISP-NCDs. The process continues to use various actions, including coordinating intervention planning among community stakeholders, developing a training protocol, and providing training for both HCPs and patients.

The subsequent output involves the delivery of training sessions to patients, and HCPs supervising the FIne-CHWs session. The outcomes to be measured encompass improvements in patient knowledge, behaviour, and skills, as well as a reduction in the incidence of minor DFUs. Ultimately, the end goal is to decrease the occurrence of DFUs and amputations while simultaneously enhancing patients' QoL, and reducing the overall healthcare cost burden.

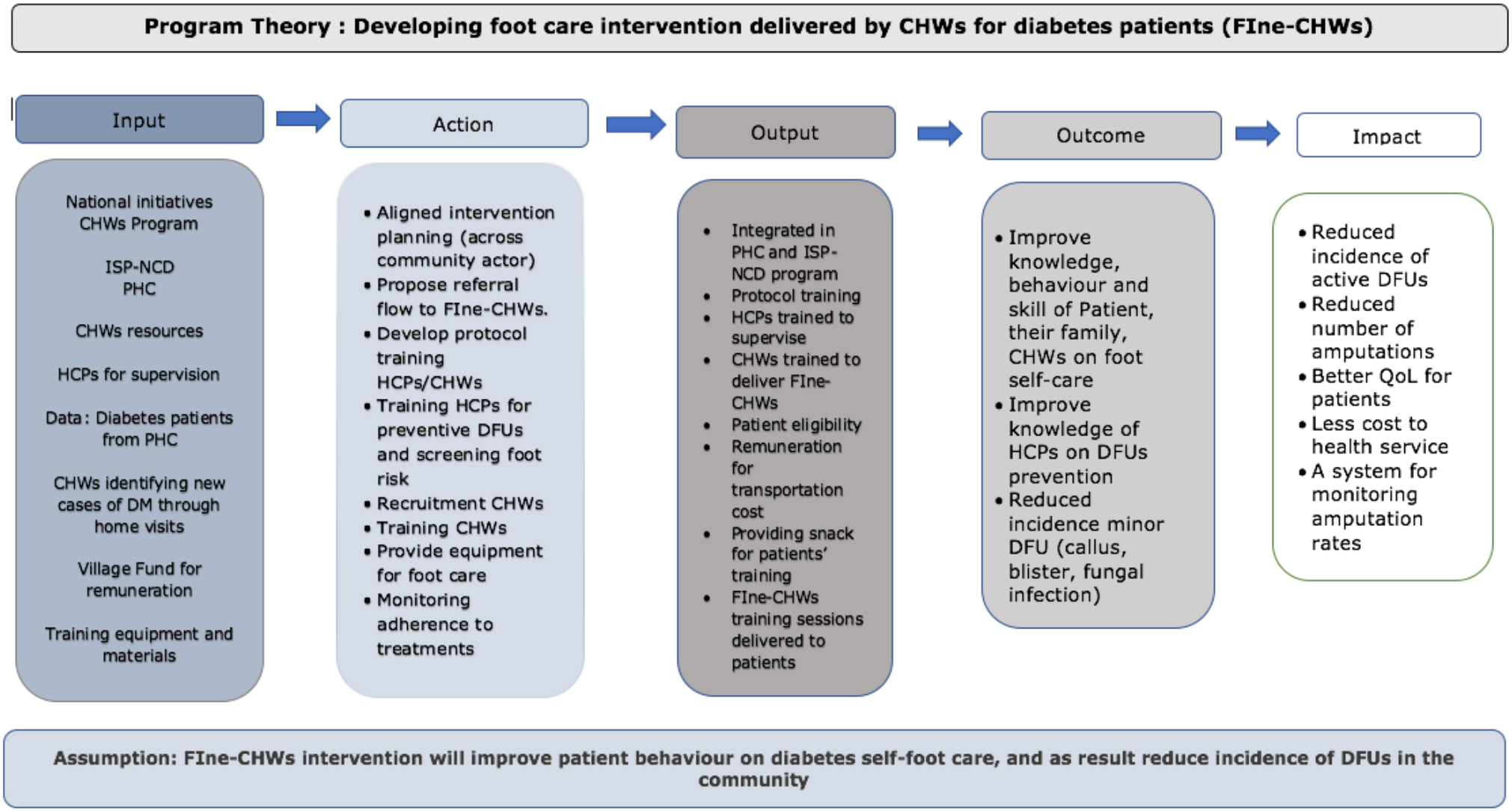


Figure 19: Logic model of FIne-CHWs

Source: Author

In practical terms, pre-determining all these factors can be challenging, so the logic model might only encompass some elements that account for the results. Conversely, an excessively intricate logic model can become cumbersome and unmanageable. To some degree, logic models can be adjusted to accommodate certain complexities within an intervention, like incorporating feedback loops, as seen in the MRC process evaluation framework. Nevertheless, logic models will continue to be relatively simplistic, sequential depictions of change processes that only partially capture the intricate nature of the real world, but which offer a roadmap for HCPs and policymakers to implement evidence base practice (Public Health England, 2018).

9.9. Summary of Contributions to Knowledge

The FIne-CHWs is a new specific FCI delivered by CHWs; this intervention identified strategic priorities to scale-up CHWPs, and whether FIne-CHWs should standardized or tailored to particular contexts. Through a rigorous methodology using the MRC Framework, which emphasizes consideration of the context of intervention in addition to its effectiveness, this study presents core components of intervention as an effort to standardise intervention yet tailored to the Indonesian context. By combining these two elements, the risk of failure of intervention can be reduced.

This study has generated new knowledge on the role of the CHWs in Indonesia, including their relationships with the community and the health service, capacity and capability to deliver new healthcare interventions, and needs in the changing paradigm of modern healthcare service delivery. This new knowledge can be used to support the development of other services delivered by CHWs.

The lack of proper coordination and harmonization of actions between the two main public authorities concerned with CHW activities (i.e., the MoH and MoHA) leads to the fragmentation of CHW initiatives, which in turn poses a challenge to the expansion of CHW roles. This study has brought to light the issue of weak coordination among national partnerships that have hitherto remained largely hidden.

9.10. Future Recommendations and Future Research

9.10.1. Recommendations for Practice

This study present core components of FIne-CHWs; the next step according to the MRC Framework is feasibility testing, to assess the predefined progression criteria that relate to recruitment, data collection, retention, outcomes, and analysis of core components of the intervention. Before a feasibility study, researchers should conduct an evaluability assessment. This involves working with stakeholders to establish expected outcomes, identifying data for assessment, and determining the best evaluation approach. The assessment recommends feasibility, cost, and methods for the evaluation (Skivington *et al.*, 2021). The FIne-CHWs needs additional assessment before it can be put into practice. It is essential to focus on specific actions that must be considered, including:

- The consensus disagreement about the criteria of patients for referring to FIne-CHWs might be resolved using FGDs with expert panels, *before* the feasibility study of FIne-CHWs in full-scale practice.
- Prior to commencing the feasibility study, it is imperative to establish a recruitment manual for CHWs, which should take into account the existing resources within the community. Furthermore, seeking the input and

viewpoints of experienced CHWs and newly qualified CHWs is needed to gain insight into their community volunteering motivations and requirements.

- Training of HCPs and CHWs should be conducted prior to the feasibility study of FIne-CHWs. Public sector institutions, including academics and researchers, should engage in multi-sectoral coordination to optimize the CHW programme (Afzal *et al.*, 2021). This study discovered that nursing interns and university researchers in particular can effectively enhance community knowledge in footcare.
- Investigation is necessary to collect the viewpoints of community stakeholders regarding the transportation allowance rate; it is needed to explore potential funding sources from both the community and healthcare services. Furthermore, a more profound comprehension of community resources is essential to support FIne-CHWs financially.

9.10.2. Recommendations for Policy

- Optimizing and scaling-up the FIne-CHWs necessitates fundamentally re-evaluating the role of CHWs within Indonesia's healthcare system policy, particularly in relation to ISP-NCD posts. This requires better coordination between MoHA and MoH, and a revision and formalization of health policy regarding CHW activities and initiatives. Secondly, there should be a clear division of task from both authorities (MoH and MoHA), by giving more authority to MoH to coordinate FIne-CHWs in community health programmes, whilst welfare tasks not relate to health programmes can still be administered by the MoHA. This study identified barriers related to CHW's role and position in healthcare system delivery. Understanding the CHWPs from diverse groups

of key stakeholders, including programme planners, is needed to comprehend how the programme can be made more sustainable within existing resources.

- Coordinating the FIne-CHWs's strategy with local community stakeholders and programme planners (MoH), and utilizing the existing manual for community-based footcare programmes can streamline the integration of FIne-CHWs into ISP-NCD's programme for DFUs prevention. This approach will also establish a well-defined process for referring patients to the FIne-CHWs.
- Programme planners and policymakers should consider the integration of FIne-CHWs into the Prime ISP-NCDs, especially in cases where the ISP has existing CHW resources and funding to support FIne-CHWs.

9.11. Strengths

The discussion sections of each chapter have outlined the specific strengths and limitations of the various components of the study. However, it is essential to note that several additional factors must be considered when evaluating this thesis as a whole.

This study was designed using the UK's new MRC Framework (Skivington *et al.*, 2021), which focuses on determining the acceptability, applicability, cost-effectiveness, scalability, and transferability of interventions, rather than just their effectiveness *per se*. The outcomes of intervention are multifaceted and extend beyond determining whether or not the intervention achieves its objectives. These responses help determine whether the research should proceed to the next phase, return to a previous stage, repeat a step, or stop completely (Skivington *et al.*, 2021).

When designing a new CHWP, it is critical to consider the intervention's context because it involves a wide range of stakeholders at the local and national levels, and

the governance is complex and relational (Lewin and Lehmann, 2013). The interaction between the intervention and its context can result in complexity. To address this issue, the new MRC Framework allows for community engagement to assess the intervention's practicability and acceptability, while refining the core components of FIne-CHWs to ensure implementation feasibility, cost-effectiveness, and scalability in Indonesia contexts.

The core components of the intervention use the TIDieR guideline (Hoffman *et al.*, 2013) to facilitate reporting and replication of the intervention, ensuring that core components are included and can be replicated. The study also takes into account the Indonesian context, with a particular emphasis on intervention providers. The study provides a nuanced understanding of the core components of the FIne-CHWs by understanding the context in which it will be implemented.

The current study used a mixed methods approach to ensure a rigorous design process. Mixed methods research combines qualitative and quantitative approaches to comprehensively understand and corroborate the findings of in-depth and broad studies (Johnson *et al.*, 2007). To accomplish this, the study used various data collection methods, including a qualitative approach that included scoping and mapping review and interview data, refined core components FIne-CHWs using the Delphi technique. Utilising multiple procedures for data collection and analysis in a single study to address the research problem provides a more comprehensive understanding of the research problem than using single approaches in isolation (Zhang and Watanabe, 2013).

This is the first study to develop a structured FCI specifically delivered by CHWs in Indonesia. The structured intervention is distinguished by clearly defined intervention

components that allow for easy replication by multiple group facilitators (Odgers-Jewell *et al.*, 2017). Using the structured FIne-CHWs educational intervention, it should be possible to achieve specific outcome measures that evaluate the effectiveness of patient education in preventing DFUs. These outcome measures include the footcare knowledge score or the patient behaviour assessment score (Dorresteijn, Kriegsman and Valk, 2010), or more long-term outcomes related to FCI, such as the incidence of foot ulceration and amputation, clinical outcomes like callus development, the number of fungal infections, and the incidence or duration of hospitalization for DFPs (Dorresteijn, Kriegsman and Valk, 2010).

Furthermore, one of the benefits of implementing FIne-CHWs in Indonesia was the MoH initiative to publish the *MoH Technical Guideline* for community-based FCI (MoH-RI, 2015) which demonstrates how national initiatives are attempting to broaden the role of the CHW in the NCD programme beyond its traditional role in managing ISP in the context of maternal and child health. In this case, the study provided core intervention components while also elucidating barriers to be addressed and other issues arising from health policy and CHW management, to develop a successful community based FCI to support and complete aspects of the intervention not provided in the current *MoH Technical Guideline*.

CHWs are expected to have broader roles in preventing NCDs (Perry and Hodgins, 2021). There are no recommendations for CHWs' roles and competencies for managing NCDs comparable to the "Recommendations Concerning the Deployment of CHWs for Maternal and Newborn" (WHO, 2012). This study provides evidence for expanding CHW's role in managing NCDs to strengthen and optimize healthcare resource deployment in resource-constrained settings.

9.12. Limitations

Using the New MRC Framework, this study is the first step towards developing new interventions (Skivington *et al.*, 2021) for diabetic footcare in low-resource countries. It should be noted that, in order to account for the contextual factors influencing this intervention, developing countries' circumstances differ significantly from those of developed countries in terms of setting, population, and healthcare policies. It is also noted that the MRC Framework requires considerable time and resources dedicated to intervention development which can lead to an outdated intervention that is no longer feasible or relevant due to significant changes in the context or shifting priorities. This investment in intervention development can also be prohibitively expensive for low-resource countries. Another major obstacle to designing evidence-based policies to improve diabetes outcomes in resource-constrained countries is the scarce availability of nationally representative data on the current patterns of treatment coverage. Higher-income countries tend to have greater coverage (Flood *et al.*, 2021).

Furthermore, the research community in Indonesia is less familiar with the dominant scientific language of English (Horton, 2016). For example, Indonesian endocrinologists conform to international guidelines for developing manuals for diabetic patients due to the absence of locally derived research evidence-based recommendations in Indonesia, resulting in a disconnect between the contextual understandings of illness and management and policy-driven initiatives (Soelistijo *et al.*, 2021).

Drawing insights from a study on developing a treatment support intervention using the MRC Framework, which involved delivering SMS text messages to improve BP control in low-resource settings, funders and policymakers must allocate adequate

time and resources for intervention development. It is also important to encourage the evaluation of the entire design and testing process (Bobrow *et al.*, 2018). In low-resource countries, where there are limitations in terms of time and resources, the need for extensive intervention development should be considered.

To establish comprehensive and thriving community health services on a large scale, it is essential to employ various research and evaluation techniques. This includes conducting rigorous and practical implementation research on expansive programmes to gather the necessary evidence (Hodgins *et al.*, 2021). The WHO (2018) guideline stated it may not be feasible to expect extensive RCTs to comprehensively address all the existing evidence gaps, especially concerning the support of the system required for effective programmes, solely from an effectiveness standpoint. Additionally, RCTs are not well-suited for gaining insights into the intricacies of complex programmes. Instead, a more valuable approach would involve conducting in-depth, critical case studies of programmes. This statement implies that pilot intervention can be implemented widely so that the programme's experience can be used to scale-up CHWPs (Schleiff *et al.*, 2021), without automatically depending on RCTs as the otherwise recommended further step in the MRC Framework.

However, the new MRC Framework strongly emphasises considering the context of the intervention. This emphasis aligns with the recommendations of scholars who advocate for optimizing community programmes by utilizing CHWs as educators in healthcare initiatives (Lewin, Lehmann and Perry, 2021).

The FIne-CHWs is designed for a specific context; while learning from CHWPs around the world is valuable, they pertain to many different features and contexts, posing limitations for study comparison and generalizability. This study primarily

focuses on people living in densely populated residential areas in urban areas, located in the capital of one of Indonesia's major cities, which is considered to have relatively robust health service performance (especially compared to smaller islands and remote areas throughout the Indonesian Archipelago) (Oendari and Rohde, 2021). As a consequence of the COVID-19 pandemic, I was unable to conduct research in rural areas and had to limit my study to urban areas that I was familiar with. Due to this limitation, the number of participants interviewed was restricted, which may have affected the generalisability of the study's findings.

It is indisputable that the varied culture of Indonesia will have an impact on the implementation of FIne-CHWs. As a necessary consequence, to scale FIne-CHWs, this intervention should initiate in urban areas with conditions similar to the study's planned performance. Despite the need for flexibility in implementation in Indonesia's diverse areas, this study provides the core components necessary and incorporates potential adjustments to local communities.

9.13. Conclusion

The primary aim of this study was to create an FCI delivered by CHWs, named FIne-CHWs. Despite CHW-delivered FCI being recognized as a part of diabetes self-management interventions in the US, there is a lack of data regarding similar intervention in low-resource countries, particularly in Indonesia. Additionally, specific core components of FCIs have not been extensively detailed, as they are typically embedded within broader diabetes interventions. This study represents an initial effort to develop a novel intervention using the UK's new MRC Framework, specifically tailored to the Indonesian context.

The expanded role of CHWs in FIne-CHWs education intervention should be considered as a potential source of reducing amputations while also improving the QoL of diabetic patients. This study has identified that CHWs have the latent potential to extend healthcare services to vulnerable populations, primarily to assist people in meeting unmet health needs in a culturally appropriate manner, as not all people are covered by national health insurance.

Community actors have acknowledged the acceptability of the FIne-CHWs to be implemented in the Indonesian context, and the majority of the core components of the FIne-CHWs have received strong consensus from a panel of experts. However, several obstacles must be overcome before this CHWP can be scaled-up into a large-scale community programme.

The mapping review represented the first review to map the evidence for FCIs and determine which types of patients can potentially be educated by CHWs. The importance of comprehensive self-footcare education for all diabetic patients, excluding those with active DFUs, is needed, particularly in Indonesia, where data indicated delayed people with DFUs visited referral hospitals.

Religious motivation is acknowledged as a fundamental driver of altruistic behaviour, serving as a prominent factor contributing to the resilience and advancement of FIne-CHWs in Indonesia. Notably, a distinctive characteristic of the Indonesian CHWs is their non-emphasis on incentives for community service, which is perceived as diminishing their altruistic motivation and discouraging increased voluntary contributions. Consequently, this limitation hinders the expansion of FIne-CHWs. To address this challenge, programme planners must reassess their recruitment strategy, seeking to attract individuals with diverse profiles and motivations.

Despite positive national initiatives which involved the MoHA and MoH in supporting CHWPs, there is less integration of FIne-CHWs into health system hierarchy, largely due to the perceived ancillary nature of preventive footcare. This represents a barrier to optimizing FIne-CHWs education interventions since fragmented programmes can lead to challenges including lack of adequate funding, inadequate supervision, lack of continuous performance assessments and improvements. These challenges might affect the quality and sustainability of services delivered by CHWs.

Notably, this necessitates national to local health sector leadership, local government support, and community organization partnerships. Large-scale CHWPs should be designed to allow for local flexibility in adjusting to the local community context, as unequal distribution of health facilities and personnel, as well as a leadership gap between well-performing and underperforming areas, has always been a significant challenge for Indonesia's health system. As a result, the FIne-CHWs may be appropriate for areas where the healthcare system can expand the specific role of CHWs.

Therefore, FIne-CHWs was developed as an initial step to provide resources for developing manuals that can improve CHW performance, covering essential practical aspects such as facilitating and coordinating CHW-related programmes and delegating roles and responsibilities. Based on the analysis, it calls for bolstering and formalizing the role of CHWs in empowering the communities they serve in the promotion of NCD programmes. CHW-led programmes are recognized as one of the most valuable assets globally, wherein the role of CHWs can be enhanced to become primary caregivers where appropriate, and to facilitate access to healthcare resources and care escalation

where necessary, thereby improving QoC, patient satisfaction, and health system effectiveness (WHO, 2018; Perry and Hodgins, 2021).

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Appendix A: Table Data of Mapping Review

(Overleaf)

Footcare Intervention Part of DSME in General						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Ghavami *et al.* (2018)	Iran	RCT with a pre– post-test design	74 (37/37)	Adults (≥18 years and older) with diabetic neuropathy, without any ulcer on their foot,	Footcare as part of DSME Four educational sessions on lifestyle that emphasize strategies for lowering blood glucose, increasing PA, promoting weight loss, prudent diet, and foot caring. Each session was lasted for 1.5 hour. Then patients followed for 12 weeks. During this period, they received counselling on mentioned lifestyle interventions.	Comparing differences of mean of Diabetic peripheral neuropathy (DNP) severity before and after lifestyle intervention between two groups of study, there was a significant difference ($p<0.001$).
Yang *et al.* (2020)	China	Quasi experimental Single-blinded	109 (55/54)	Exclusion criteria: patients were at the IV stage of nephropathy or had a diabetic foot above grade 1,	Footcare as part of DSME Each group visit session lasted approximately 2 h, and included a 15 min warm-up and feedback period, a 40-minute presentation of diabetes-related education, a brief 10-minute break, and a 15-minute interaction period, followed by 40 min of one-on-one consultations with the interdisciplinary expertise as needed.	At the 6-month follow-up, intervention for diabetes prevention covering all topics; diabetes knowledge, self-efficacy and self-management scores were higher in patients in the intervention group than that in the control group ($p < 0.05$). For self-efficacy score, there was no significant interaction effect of group by time ($F = 2.353$, $p = 0.072$), but a significant main effect of group ($F = 7.430$, $p = 0.007$)

Footcare Intervention Part of DSME in General						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Eroglu (2021)	Turkey	RCT	80 (40/40)	Exclusion criteria: Having severe retinopathy, nephropathy, neuropathy, or foot wound	Footcare as part of DSME The average duration of the education is 45 min. After the education, a diabetes education booklet was given. Edu- cations are carried out in line with the patient education booklet. The content of the education was repeated completely or partially by the researcher according to the needs of each patient. Methods such as direct instruction, question-answer, and demonstration were used as teaching methods. In order to test that he gained the right skill, the instructions were repeated and applied.	There was no statistically significant difference in the sub-dimensions of the self-efficacy scale in patients with type 2 diabetes ($p > 0.05$). In the experimental group, the difference in the mean scores of diets + foot care, medical treatment, physical exercise in the post-test at the 6th month was statistically significant compared to the pre-test ($p < 0.01$). In the control group, there was no statistical significance in the post-test compared to the pre-test ($p > 0.05$). The difference between the experimental and control groups at 6 months was statistically significant ($p < 0.01$).

Cross-Sectional Design and Retrospective Study						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Pollock *et al.* (2004)	UK	Cross sectional study	550	All patients were eligible for sampling on the population-based diabetes register in Middlesbrough, UK consisting of patients managed in primary or secondary care	The aim of this study was to determine knowledge about foot care and its practice in people with diabetes. The study was conducted using a self-administered postal questionnaire. The content of the questionnaire was based on the most recent guidelines for care of the feet in people with diabetes.	Those with high risk feet showed a higher (6.8) but not significant knowledge score compared to those at low risk (6.5) and their foot care practise was better
Kishore, Upadhyay and Jyotsna (2015)	India	Cross sectional study	100	Patients of diabetes mellitus who have not yet developed foot ulcer	Aim of this study was to determine the distribution of categories of foot at risk in patients with diabetes, attending a tertiary care hospital and factors that affect it Detail history and examination including neurological and vascular assessment were performed in 100 patients. Foot at risk was classified according to the task force of the ADA Foot Care Interest Group. Category of foot at risk was correlated with demographic and clinical features	Foot at risk was present in 52% patients of diabetes attending the tertiary care centre. Increasing duration of diabetes, lower educational, lower socioeconomic status and level of health care have significant correlation with foot at risk

Cross-Sectional Design and Retrospective Study						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Harwell *et al.* (2001)	US	Cross sectional study	537	Medicare inpatient and outpatient billing data from 1993 and 1994 were used to identify Montana Medicare beneficiaries with diagnosed diabetes	This report describes the results of a telephone survey conducted among Medicare beneficiaries with diagnosed diabetes in Montana and compares self-reported foot care practices and perceptions of risk with the actual risks for LEA as determined through Medicare claims data. A telephone survey of a random sample from this cohort was conducted to assess their foot care practices, barriers, and perceptions of risk.	Eight percent of respondents reported a history of foot ulcers and 7% a history of lower extremity amputation. Based on claims data, 30% of respondents were at high risk for future foot complications. Compared to those at low risk, those at high risk were more likely to report having an annual foot exam, using protective footwear, and perceiving themselves to be high risk for future foot complications

Cross-Sectional Design and Retrospective Study						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Wu *et al.* (2015)	China	Retrospectives study	296	Diabetes hospitalized in a tertiary hospital	Aim of this study was to determine the prevalence of risk factors for diabetic foot complications in diabetic patients free of active ulceration in a hospital setting and to investigate the knowledge of foot care of the patients. A convenience sampling was adopted to recruit subjects during 2012/2013. All completed an interviewer-administered questionnaire and underwent medical assessment including foot examination and assessment of presence of peripheral sensory neuropathy (PSN) and peripheral arterial disease (PVD). The patients were assigned to a foot risk category which was developed by the IWGDF.	According to the classification system of the IWGDF, 35.1% of patients were considered as having low risk by the modified IWGDF classification (group 0), and 49% of the study population were at high risk for pedal ulceration (group 2 and 3). The mean knowledge score of foot care was 21.21/35 ±3.84 95% of patients knew about foot disorder risks, but most (88.14%) were unaware of therapeutic insert benefits. 78% initially lacked knowledge about foot issues like corns, calluses, redness, or lesions, opting for self-treatment methods, such as using special ointment or sharp instruments to treat corns and disinfectants or dressing for wounds. 68% of patients did not connect plantar calluses to high pressure, and 71% did not know pressure reduction could prevent diabetic foot problems. Regarding foot care, 64% did not realize the importance of drying feet post-washing, and 65% were unaware of using emollients for foot health, especially preventing heel cracks.

Cross-Sectional Design and Retrospective Study						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Heggie *et al.* (2020) Also available at: People with diabetes with a low risk of developing foot ulcers can be screened less often, study suggest https://evidence.nihr.ac.uk/alert/people-with-diabetes-with-a-low-risk-of-developing-foot-ulcers-can-be-screened-less-often-study-suggests/	Fife, Scotland	Observational study	10 421	The study analysed data on 10 421 people diagnosed with diabetes who had their first visit to screening clinics in Fife, Scotland between 2009 and 2017	To estimate the rate at which people with diabetes and a low risk of foot ulceration change diabetic foot ulceration risk status over time, and to estimate the rate of ulceration, amputation and death among this population.	The results showed: People with diabetes changed from low to moderate risk slowly One in twenty (5.1%) low-risk patients became moderate-risk after two years Around one in ten changed from low to moderate risk after five years (9.9%) and eight years (11.3%) Most changes in risk status (94%) were down to nerve damage in the feet (peripheral neuropathy) One in 250 (0.4%) in the low-risk group developed ulcers after two-years; one in a thousand (0.1%) had an amputation Annual screening for people at low risk requires considerable NHS resource, at the expense of other preventative strategies or treatments. There is no clear evidence to support this recommendation; the optimal frequency of screening is unknown.

Cross-Sectional Design and Retrospective Study						
Author/ year	**Country/ study setting**	**Design study**	**N (subject) (intervention /control)**	**Criteria inclusion/exclusion**	**Intervention**	**Outcome**
Crawford, Chappell *et al.* (2020)	Scotland	A prognostic model using predictive modelling, calibration and discrimination techniques.	26,154	Data from an electronic health record for 26,154 people with diabetes mellitus in one Scottish health board were used to estimate the monitoring interval. The Prediction of Diabetic foot Ulcerations (PODUS) data set was used to develop and validate the clinical prediction rule.	The objectives were to produce an evidence-based clinical pathway for risk assessment and management of the foot in people with diabetes mellitus to estimate cost-effective monitoring intervals and to perform cost-effectiveness analyses and a value-of-information analysis.	The main outcome was the incidence of foot ulceration. This study compared the new clinical prediction rules in conjunction with the most effective preventative interventions at different monitoring intervals with a 'treat-all' strategy. Data There is evidence that interventions to prevent foot ulceration are effective, but it is not clear who would benefit most from receiving the interventions. The ulceration risk does not change over an 8-year period for most people with diabetes mellitus. A change in the monitoring interval from annually to every 2 years for those at low risk would be acceptable.

Foot Care Management Manuals from Websites and Organizations		
The Scottish Government, September 2013	Personal Footcare guidance	https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2013/09/personal-footcare-guidance/documents/personal-footcare-guidance/personal-footcare-guidance/govscot%3Adocument/00433259.pdf
The Scottish Government, August 2013	Personal footcare looking your feed *(Leaflet)*	http://www.knowledge.scot.nhs.uk/media/7090931/final%20looking%20after%20your%20feet%20booklet%20220813.pdf
	Personal footcare looking after someone else's feet *(Leaflet)*	http://www.knowledge.scot.nhs.uk/media/7090934/final%20looking%20after%20someone%20else%27s%20feet%20booklet%20220813.pdf
Public Health England Published: 26 August 2015, last updated: 11 October 2019	Diabetic foot problem: Prevention and management (NG19)	https://www.nice.org.uk/guidance/ng19
National Diabetes Working Group -HSE Health and Social Services (Ireland) (2011)	A national model of diabetic footcare	https://www.hse.ie/eng/services/list/2/primarycare/east-coast-diabetes-service/management-of-type-2-diabetes/foot-care/model-of-care-diabetic-foot.pdf
	Patient Information Leaflet for mid-risk of foot ulcers	https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/booklet-for-people-at-mid-risk-of-developing-foot-problems-hqp-28-11.pdf
	Patient Information Leaflet for high-risk of foot ulcers	https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/taking-steps-towards-good-foot-care-for-at-risk-feet-.pdf
East Midlands Diabetic Foot Groups	Low Risk Diabetes Foot Care information and advice leaflet	https://www.england.nhs.uk/midlands/wp-content/uploads/sites/46/2019/05/foot-health-low-risk.pdf
U.S. Department of Health and Human Services Health Resources and Services Administration Healthcare Systems Bureau National Hansen's Disease Programs	Footcare for a lifetime	https://www.hrsa.gov/sites/default/files/hansensdisease/leap/footcareforalifetime.pdf

IWGDF 2019 update Bus *et al.* (2020)	Guidelines on the prevention of foot ulcers in persons with diabetes	Examine a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of loss of protective sensation and peripheral artery disease, to determine if they are at increased risk for foot ulceration. Consider advising a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) to perform foot and mobility-related exercises with the aim of reducing risk factors of ulceration, that is, decreasing peak pressure and increasing foot and ankle range of motion and with the aim of improving neuropathy symptoms. Consider communicating to a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) that a moderate increase in the level of walking-related weight-bearing activity (i.e., an extra 1.000 steps/day) is likely to be safe. Advise this person to wear appropriate footwear when undertaking weight-bearing activities, and to frequently monitor the skin for pre-ulcerative signs or breakdown Screen a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) for: a history of foot ulceration or lower-extremity amputation; diagnosis of end-stage renal disease; presence or progression of foot deformity; limited joint mobility; abundant callus; and any pre-ulcerative sign on the foot. Repeat this screening once every 6-12 months for those classified as IWGDF risk 1, once every 3-6 months for IWGDF risk 2, and once every 1-3 months for IWGDF risk 3. (Strong; High) Instruct a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors. (Strong; Low) Instruct, and after that encourage and remind, a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to: inspect daily the entire surface of both feet and the inside of the shoes that will be worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toe nails straight across; and, avoid using chemical agents or plasters or any other technique to remove callus or corns. (Strong; Low) Provide structured education to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer. (Strong; Low) Consider instructing a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference is above-threshold between similar regions in the two feet on two consecutive days, instruct the patient to reduce ambulatory activity and consult an adequately trained health care professional for further diagnosis and treatment. (Weak; Moderate)

Foot Care Management Manuals from Websites and Organizations		
		Instruct a person with diabetes who is at moderate risk for foot ulceration (IWGDF risk 2) or who has healed from a non-plantar foot ulcer (IWGDF risk 3) to wear therapeutic footwear that accommodates the shape of the feet and that fits properly, to reduce plantar pressure and help prevent a foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing custom-made footwear, custom-made insoles, or toe orthoses. (Strong; Low)
Registered Nurses Association of Ontario (2004) RNAO (2007)	Reducing Foot Complications for People with Diabetes	The nurse has to communicate Risk Status Explain the level of risk and provide information on how to reduce the risk through self-care and regular foot examination, paying particular attention to the gaps in self-care knowledge. For low risk of foot ulcers: Explain risk for foot complications related to diabetes, teach or reinforce basic foot care practices and strategies for foot injury prevention, Reinforce benefits of annual foot examination. For high risk of foot ulcers: Explain risk for foot complications related to diabetes. Inform client of personal risk factors identified in this nursing assessment, Teach or reinforce basic foot care practices and strategies for foot injury prevention, Reinforce benefits of regular professional foot exam and risk assessment (every 3-6 months). Refer patient to primary care provider or diabetes care/ education program for further assessment and follow-up.
American Diabetes Association (ADA) Boulton *et al.* (2018)	Diagnosis and Management of Diabetic Foot Complications	ADA divide patient risk categories (i.e., very low, low, moderate, and high risk) and follow-up recommendations. Very low category (no LOPS or PAD): Patient seeks education on topics such as routine foot care, athletic training, appropriate footwear, or injury prevention Low category (LOPS ± longstanding, nonchanging deformity): Patient requires prescriptive or accommodative footwear
Mcinnes *et al.* (2011)	Consensus Statement: Foot care education in patients with diabetes at low risk of complication	The objective of this consensus statement is to propose a framework for educating patients with diabetes who are considered to be at a low risk of complications Four main health behaviours were identified for those at low risk of developing foot complications, namely: control of blood glucose levels; attendance at annual foot screening examination; reporting of any changes in foot health immediately; and the engagement in a simple daily foot care routine. There is currently little evidence-based literature to support specific foot care practices. Patients with diabetes at low risk of developing complications should be encouraged to undertake a basic foot care regimen to reduce their likelihood of developing complications.

NICE Guideline (2020) updated version Published: 26 August 2015 www.nice.org.uk/guidance/ng19	Diabetic foot problems: prevention and management	Managing the risk of developing a diabetic foot problem: For people who are at low risk of developing a diabetic foot problem, continue to carry out annual foot assessments, emphasise the importance of foot care, and advise them that they could progress to moderate or high risk. [2015] Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service. [2015] The foot protection service should assess newly referred people as follows: Within 2 to 4 weeks for people who are at high risk of developing a diabetic foot problem. Within 6 to 8 weeks for people who are at moderate risk of developing a diabetic foot problem. For people at moderate or high risk of developing a diabetic foot problem, the foot protection service should: • Assess the feet. • Give advice about, and provide, skin and nail care of the feet. • Assess the biomechanical status of the feet, including the need to provide specialist footwear and orthoses. • Assess the vascular status of the lower limbs. • Liaise with other healthcare professionals, for example, the person's GP, about the person's diabetes management and risk of cardiovascular disease. Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals: • Annually for people who are at low risk. • Frequently (for example, every 3 to 6 months) for people who are at moderate risk. More frequently (for example, every 1 to 2 months) for people who are at high risk, if there is no immediate concern. • Very frequently (for example, every 1 to 2 weeks) for people who are at high risk, if there is immediate concern. Consider more frequent reassessments for people who are at moderate or high risk, and for people who are unable to check their own feet. People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service. Patient information about the risk of developing a diabetic foot problem 1.3.13 Provide information and clear explanations to people with diabetes and/or their

Foot Care Management Manuals from Websites and Organizations		
		family members or carers (as appropriate) when diabetes is diagnosed, during assessments, and if problems arise. Information should be oral and written, and include the following: • Basic foot care advice and the importance of foot care. • Foot emergencies and who to contact. • Footwear advice. • The person's current individual risk of developing a foot problem. • Information about diabetes and the importance of blood glucose control (also
Diabetic Foot Australia (2016)	Australian and International Guidelines on Diabetic Foot Disease	The IWGDF calls their document "Guidance", rather than "Guideline", to underline that these documents are written for a general situation. As acknowledged in their summary guidance, principles in the IWGDF Guidance need to be adapted to local circumstances. Specific recommendations in the Australian guideline concerning the Indigenous population or rural and remote areas exemplify such "local translation". The IWGDF has 11 recommendations that deal with the topics of foot care, education, footwear, self-management and surgical interventions; whilst the Australian guideline has 3 recommendations concerning foot care and education. Foot care education should be provided to all people with diabetes to assist with prevention of foot complications.

Appendix B: Ethical Approval

University of Nottingham
UK | CHINA | MALAYSIA

Faculty of Medicine & Health Sciences
Research Ethics Committee
Faculty Hub
Room E41, E Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham, NG7 2UH
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24 May 2021

Ms Okatiranti
PhD Student, Nursing Studies
School of Health Sciences
B Floor, Medical School
Queen's Medical Centre Campus
University Hospitals Nottingham
Nottingham
NG7 2UH

Dear Ms Okatiranti

Ethics Reference No: FMHS 238-0421 – **please always quote**	
Study Title: Development of footcare education intervention delivered by Community Health Workers (CHWs) (FIne-CHWs) to Type 2 Diabetic Mellitus (T2DM) patients with Low-Risk Diabetes Foot Ulcers (DFUs).	
Location of Study: Community Health Centres, Kota Bandung, Jawa Barat, Indonesia	
Chief Investigator/Supervisor: Sarah Goldberg, Associate Professor of Older persons care/Director of Research, School of Health Sciences	
Lead Investigators/student: Okatiranti, PhD Student, Nursing Studies, School of Health Sciences	
Other Key Investigators: Richard Windle, Professor of Digital Learning, School of Health Sciences.	
Proposed Start Date: 17.05.2021	**Proposed End Date:** 30.03.2022

The Committee considered this application at its meeting on 23 April 2021 and the following documents were received:

- FMHS REC Application form and supporting documents version 1.0: 07.04.2021

These have been reviewed and are satisfactory and the research project has been given a favourable ethics opinion.

Please submit copies of letters of approval from the Indonesian IRB/REC Committee and letters of permission from the Community Health Centres when these are available so they can be noted to file. This must be completed before recruitment of participants commences.

Please note that this favourable ethics opinion has been given on the understanding that:

1. All appropriate ethical requirements and regulatory permissions are respected and followed in accordance with all local laws of the country in which the study is being conducted and those required by the host organisation/s involved.
2. The research project will adhere to ICH E6 (R2) Good Clinical Practice (GCP) which is the international ethical, scientific, and practical standard to which all clinical research is conducted.
3. The protocol agreed is followed and the Committee is informed of any changes using a notice of amendment form (please request a form).
4. The Chair is informed of any serious or unexpected adverse event.
5. An End of Project Progress Report is completed and submitted to FMHS REC within six months after the study has finished (Please request a form).

Yours sincerely

Dr John Williams, Associate Professor
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

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28 March 2022

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University Hospitals Nottingham
Nottingham
NG7 2UH

Dear Ms Okatiranti

Ethics Reference No: FMHS 238-0421 **– please always quote**	
Study Title: Development of footcare education intervention delivered by Community Health Workers (CHWs) (FIne-CHWs) to Type 2 Diabetic Mellitus (T2DM) patients with Low-Risk Diabetes Foot Ulcers (DFUs).	
Location of Study: Community Health Centres, Kota Bandung, Jawa Barat, Indonesia	
Chief Investigator/Supervisor: Sarah Goldberg, Associate Professor of Older persons care/Director of Research, School of Health Sciences	
Lead Investigators/student: Okatiranti, PhD Student, Nursing Studies, School of Health Sciences	
Other Key Investigators: Richard Windle, Professor of Digital Learning, School of Health Sciences.	
Proposed Start Date: 17.05.2021	**Proposed End Date:** 30.09.2022

Thank you for notifying the Committee of amendment no 2: 21/03/2022 in summary as follows:

- Time extension with a new end date of 30 September 2022

The following documents were received:

- FMHS REC Application form version 4.0: 18.03.2022

These have been reviewed and are satisfactory and amendment no 2: 21/03/2022 is Noted to File.

Yours sincerely

Dr John Williams, Associate Professor
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN,
RISET DAN TEKNOLOGI
UNIVERSITAS PADJADJARAN
KOMISI ETIK PENELITIAN
RESEARCH ETHICS COMMITTEE
Jl. Prof. Eyckman No. 38 Bandung 40161
Telp. & Fax. 022-2038997 e-mail: kep@unpad.ac.id, website: kep.unpad.ac.id

No. Reg.: 0621060645

PERSETUJUAN ETIK
ETHICAL APPROVAL

Nomor: 652/UN6.KEP/EC/2021

Komisi Etik Penelitian Universitas Padjadjaran Bandung, dalam upaya melindungi hak asasi dan kesejahteraan subjek penelitian serta menjamin bahwa penelitian yang menggunakan formulir survei/registrasi/surveilens/ Epidemiologi/Humaniora/Sosial Budaya/Bahan Biologi Tersimpan/Sel Punca dan non klinis lainnya berjalan dengan memperhatikan implikasi etik, hukum, sosial dan non klinis lainnya yang berlaku, telah mengkaji dengan teliti proposal penelitian berjudul:

The Research Ethics Committee Universitas Padjadjaran Bandung, in order to protect the rights and welfare of the research subject, and to guaranty that the research using survey questionnaire/registry/surveillance/ epidemiology/humaniora/social-cultural/archived biological materials/stem cell/other non clinical materials, will carried out according to ethical, legal, social implications and other applicable regulations, has been throughly reviewed the proposal entitled:

"*DEVELOPMENT OF A FOOTCARE EDUCATION INTERVENTION DELIVERED BY COMMUNITY HEALTH WORKERS (CHWS) (FINE-CHWS) TO TYPE 2 DIABETES (T2DM) PATIENTS WITH LOW-RISK DIABETIC FOOT ULCERS (DFUS)*"

Nama Peneliti Utama *Principal Researcher*	:	Dkatiranti
Pembimbing/Peneliti Lain *Supervisor/Other Researcher*	:	Dr. Sarah Goldberg Prof. Richard Windle
Nama Institusi *Institution*	:	School of Health Science School Of Medicine and Health Science University of Nottingham

proposal tersebut dapat disetujui pelaksanaannya.
hereby declare that the proposal is approved.

Ditetapkan di : Bandung
Issued in
Tanggal : 13-08-2021
Date

Ketua,
Chairman,

Nur Atik, dr, M.Kes., PhD
NIP. 19811010 200801 1 019

Keterangan/*notes*:
Persetujuan etik ini berlaku selama satu tahun sejak tanggal ditetapkan.
This ethical clearance is effective for one year from the due date.
Pada akhir penelitian, laporan pelaksanaan penelitian harus diserahkan ke Komisi Etik Penelitian.
In the end of the research, progress and final summary report should be submitted to the Research Ethics Committee.
Jika ada perubahan atau penyimpangan protokol dan/atau perpanjangan penelitian, harus mengajukan kembali permohonan kajian etik penelitian.
If there is any protocol modification or deviation and/or extension of the study, the Principal Investigator is required to resubmit the protocol for approval.
Jika ada kejadian serius yang tidak diinginkan (KTD) harus segera dilaporkan ke Komisi Etik Penelitian.
If there are Serious Adverse Events (SAE) should be immediately reported to the Research Ethics Committee

KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
UNIVERSITAS PADJADJARAN
KOMISI ETIK PENELITIAN
RESEARCH ETHICS COMMITTEE

Jl. Prof. Eyckman No. 38 Bandung 40161
Telp. & Fax. 022-2038697 email: etikunpad@gmail.com , website : kep.unpad.ac.id

Amandemen dari persetujuan etik nomor : 652/UN6.KEP/EC/2021
Amendment of ethical approved number

No.Reg.: 0621060645

PERSETUJUAN ETIK
ETHICAL APPROVAL

Nomor: 114/UN6.KEP/EC/2021

Komisi Etik Penelitian Universitas Padjadjaran Bandung, dalam upaya melindungi hak asasi dan kesejahteraan subjek penelitian serta menjamin bahwa penelitian yang menggunakan formulir survey/registrasi/surveilens/ Epidemiologi/Humaniora/Sosial Budaya/Bahan Biologi Tersimpan/Sel Punca dan non klinis lainnya berjalan dengan memperhatikan implikasi etik, hukum, sosial dan non klinis lainnya yang berlaku, telah mengkaji dengan teliti proposal penelitian berjudul:

The Research Ethics Committee Universitas Padjadjaran Bandung, in order to protect the rights and welfare of the research subject, and to guaranty that the research using survey questionnaire/registry/surveillance/ epidemiology/humaniora/social-cultural/archived biological materials/stem cell/other non clinical materials, will carried out according to ethical, legal, social implications and other applicable regulations, has been throughly reviewed the proposal entitled:

"*DEVELOPMENT OF A FOOTCARE EDUCATION INTERVENTION DELIVERED BY COMMUNITY HEALTH WORKERS (CHWS) (FINE-CHWS) TO TYPE 2 DIABETES (T2DM) PATIENTS WITH LOW-RISK DIABETIC FOOT ULCERS (DFUS)*"

Nama Peneliti Utama *Principal Researcher*	:	Okatiranti
Pembimbing/Peneliti Lain *Supervisor/Other Researcher*	:	Dr. Sarah Goldberg Prof. Richard Windle
Nama Institusi *Institution*	:	School of Health Science School Of Medicine and Health Science University of Nottingham

proposal tersebut dapat disetujui pelaksanaannya.
hereby declared that the proposal approved.

Ditetapkan di : Bandung
Specified in
Tanggal : 15-12-2021
Date

Ketua,
Chairman,

Nur Asik, dr, M.Kes., PhD
NIP. 19811010 200801 1 019

Keterangan/notes:
Persetujuan etik ini berlaku sampai 13 Agustus 2022
This ethical clearance is effective until 13th August 2022
Pada akhir penelitian, laporan pelaksanaan penelitian harus diserahkan ke Komisi Etik Penelitian.
In the end of the research, progress and final summary report should be submitted to the Research Ethics Committee.
Jika ada perubahan atau penyimpangan protokol dan/atau perpanjangan penelitian, harus mengajukan kembali permohonan kajian etik penelitian.
If there be any protocol modification or deviation and/or extension of the study, the Principal Investigator is required to resubmit the protocol for approval.
Jika ada kejadian serius yang tidak diinginkan (KTD) harus segera dilaporkan ke Komisi Etik Penelitian.
If there are Serious Adverse Events (SAE) should be immediately reported to the Research Ethics Committee

[AUTHORIZED TRANSLATION]

GOVERNMENT OF BANDUNG CITY
NATIONAL AND POLITICAL UNITY AGENCY
Jalan Wastukencana No. 2 Tel. 022 4230097 Bandung

PERMISSION TO CONDUCT RESEARCH
NUMBER: PP.09.01/966-Kesbangpol/VI/2021

Based on : 1. Law of the Republic of Indonesia Number 14 of 2008 regarding Disclosure of Public Information
2. Law of the Republic of Indonesia Number 25 of 2009 regarding Public Services
3. Government Regulation of the Republic of Indonesia Number 18 of 2016 regarding Regional Apparatus
4. Regulation of the Ministry of Home Affairs Number 3 of 2018 regarding Issuance of Research Certificate
5. Regional Regulation of Bandung City Number 08 of 2016 regarding Formation and Structure of Bandung City Regional Apparatus

Considering : Letter from University of Nottingham Number: -, Dated June 8, 2021, Regarding Research

HEREBY WE NOTIFY THAT WE GRANT PERMISSION TO:

a. Name : **OKATIRANTI**
b. Full Address : Jl. Pasir Impun Atas Kp. Cikaso No. 63, RT 004/RW 009, Des. Cikadut, Kec. Cimenyan, Bandung Regency
ID Number, Hp : ID Number 3204065610750002, Hp. 085718270279
c. To : 1) Conduct the Research entitled "*Development of a footcare education intervention delivered by Community Health Workers (CHWs) (FIne-CHWs) to Type 2 Diabetes (T2DM) patients with Low-Risk Diabetic Foot Ulcers (DFUs)*".
2) Location : Department of Health, UPT Puskesmas Babakan Sari, UPT Puskesmas Arcamanik, Bandung City
3) Team Member : -
4) Research Field : -
5) Research Status : New
6) Implementation Time : June 17, 2021 to December 17, 2021

d. And to report the results of the research to the Mayor of Bandung c.q. Head of National and Political Unity Agency of Bandung City, no later than 1 week after completion.

In witness whereof, it is made to be used as appropriate.

Bandung, June 17, 2021
on behalf of HEAD OF NATIONAL AND POLITICAL UNITY AGENCY
Secretary
(signed and sealed)
Drs. INCI DERMAGA MA, MAP
First Class Administrator
CSID No. 19690320 199008 1 001

AFFIDAVIT
This is to certify that I have translated the foregoing from Indonesian to English that it is true and complete and that I am competent in both languages.
Translated in Jakarta on November 29, 2021

SOESILO
AUTHORIZED & SWORN TRANSLATOR
Decree of Governor of DKI Jakarta No. 527/1995
Address: Jalan Otista III/117, Jakarta Timur 13340, Tel: 8503944

[AUTHORIZED TRANSLATION]

GOVERNMENT OF BANDUNG CITY
DEPARTMENT OF HEALTH
Jalan Supratman Nomor 73 Tel. 022 87244572 Bandung

CERTIFICATE
Number: PP.06.02/9266/Dinkes/VI/2021

1. The undersigned:
   a. Name : **ANHAR HADIAN, SKM**
   b. Position : Secretary of the Department of Health of Bandung City
   Hereby certifies that:
   a. Name : **OKATIRANTI**
   b. Address : Jl. Pasir Impun Atas Kp. Cikaso No. 63, Rt 004/Rw 009, Desa Cikadut, Kec. Cimenyan, Bandung Regency
   c. Purpose : Application for Research entitled "Development of a footcare education intervention delivered by Community Health Workers (CHWs) (FIne-CHWs) to Type 2 Diabetes (T2DM) patients with Low-Risk Diabetic Foot Ulcers (DFUs)"
   d. Implementation Time : Starting from June 22, 2021 to December 17, 2021
2. This Certificate is made on the basis of:
   a. Recommendation letter from the Head of National and Political Unity Agency (BKBP) Number: PP.09.01/966-kesbangpol/VI/2021 dated June 17, 2021
   b. Application letter from: University of Nottingham Number:-, dated June 14, 2021
3. In connection with the subject, it is requested that the relevant work units provide necessary assistance and facilities as long as it does not interfere with the smoothness of work activities and does not involve the confidentiality of the position.

Bandung, June 22, 2022
On behalf of HEAD OF DEPARTMENT OF HEALTH
BANDUNG CITY
Secretary

(signed and sealed)
ANHAR HADIAN, SKM
CSID No. 19720611 199503 1 003

NOTE
- **Researcher above mentioned is requested to make a report on the results of activities through the Head of General Sub-Section and Personnel, Department of Health of Bandung City.**

Carbon copy, delivered to the Respected:
1. Head of Department of Health of Bandung City (As Report)
2. Head of Health Services
3. Head of Disease Control and Eradication (P2P)
4. Head of Public Health
5. Head of Health Resources (SDK)
6. Head of UPT Puskesmas Babakan Sari
7. Head of UPT Puskesmas Arcamanik

AFFIDAVIT
This is to certify that I have translated the foregoing from Indonesian to English that it is true and complete and that I am competent in both languages.
Translated in Jakarta on November 29, 2021

SOESILO
AUTHORIZED & SWORN TRANSLATOR
Decree of Governor of DKI Jakarta No. 527/1995
Address: Jalan Otista III/117, Jakarta Timur 13340, Tel: 8503944

Appendix C: Sample Draft Interview Schedule for FIne-CHWs

Opening	
Establish rapport	The researcher will introduce herself and explain the purpose of the study
	Interviewee will be asked to introduce themselves
Timeline	The researcher to explain that interviews expected to last between 45-60 minutes. *Are you available to respond to some questions at this time?*
Media preference	Interviewees will be asked if they wish to use video or phone call only. If the interviewee does not wish to use video, or technical problems prevent video conferencing, the interview will be equivalent to a traditional telephone interview. Text options will be used to ask and answer questions; this text will be copied and pasted into the interview transcription in addition to the spoken text.
Confidentiality	The assurance of confidentiality and anonymity will be given to the participants before beginning the interviews. All participant data reported in the study will be rendered anonymous, preventing the identification of participants.
*(*Transition*: Let me begin by asking you some questions about your experience about footcare (patients and family members) or managing footcare in the community (CHWs and clinicians)*)	
Theme for interview	
1. Understanding about self-footcare	What do you understand about footcare? Prompt - How would you rate your current footcare knowledge? How would you rate your current support in relation to footcare? Who provides you with the current footcare education you have or have had?
2. Footcare delivered by CHW	What do you think if CHW provided foot care education? If they answer CHW it is possible to provide foot care education_ Prompt - How does it work? What kind of intervention do you want? What types of foot care education provided by CHW are currently available in the community? If they answered, they tended to reject the idea that the CHWs provided an intervention Prompt – Why do you think it does not work?
3. Content of foot care for LR-DFUs/ personal foot care	What foot care educational content should CHW provide you with? Prompt:

	1. Regular foot checking (checking for abnormalities). 2. Daily self-care (washing and drying between your toes, moisturizing). 3. Injury prevention (not walking bare foot, wearing appropriate shoe gear). 4. Recognize when to make referral (reporting of any changes in foot health immediately).
4. Barrier to and support CHW to deliver footcare education	What are the barriers to and support for CHWs delivering footcare education? 1. As patients 2. As family member 3. As CHW 4. As Clinicians
	Prompt **(For Clinicians)** 1. Health system (Annual footcare examination, role of health workers, treatment > prevention) 2. Program Implementation (CHWs training programme, control blood glucose) 3. Knowledge support (HE in managing footcare) 4. Feasibility
5. Scenario (explore the current practice and knowledge, self-confidence, capability of CHWs deliver intervention)	Scenario (explore the current practice and knowledge, self-confidence, capability of CHWs deliver intervention) **(For CHWs)** A woman of 54 years has had type 2 diabetes, visiting the Posbindu PTM and asking how to manage callus on her feed? 1. How would you manage this case? 2. What advice would you give to her?
(Transition*: Well, it has been a pleasure finding out more about you. Let me briefly summarize the information that I have recorded during our interview)*	
Closing	
	The researcher will summarize the interview *I appreciate the time you took for this interview. Thank you for agreeing to take part in this interview.*

Appendix D: Verbal Consent Form

University of Nottingham
UK | CHINA | MALAYSIA

Faculty of Medicine & Health Sciences
School of Health Sciences
B33 Room Postgraduate Research Office
School of Health Sciences, University of Nottingham
Queen's Medical Centre, Nottingham, NG7 2HA

Footcare Intervention delivered by CHWs (Fine-CHWs)

Verbal Consent Script

Participant ID:	Initials:
Date of Birth:	Hospital Number:
PhD student/ co-investigator : Mrs Okatiranti, PhD Nursing Studies at School of Health Sciences **Chief Academic/Supervisor: Dr Sarah Goldberg,** Associate Professor in older persons care and Directo Research School of Health Sciences, University of Nottingham; **Other key researchers/collaborators: Prof Richard Windle,** Professor of Digital Learning, Faculty of Medicine & Health Sciences, University of Nottingham and	
Date of verbal consent call: __/__/____(dd/mmm/yyyy) Time of verbal consent call: __/__ __(00.00 hr)	
Format of verbal consent e.g. Skype, phone call:	

Telephone/contact the participant and confirm that you are speaking to the relevant person, and that it is a convenient time to call (if not, establish if the participant wishes to be contacted at an alternative time; or whether the participant no longer wishes to be contacted regarding the study). Then continue with the script below:

Hello *[name of participant]*, my name is Okatiranti and I am a *PhD student at University of Nottingham* working on research in *Footcare education intervention delivered by CHWs*, which you *[have shown interest in / have been given information about / are currently taking part in].*

You may have received some documents from us recently regarding the *[Footcare intervention delivered by CHWs]* research study and we wondered if you have had a chance to read them? ***(Allow participants to respond – if they have read it and no longer wish to be contacted with regards to this study, then thank them for their time and say goodbye – if they are unsure or more positive then continue below).***

University of Nottingham
UK | CHINA | MALAYSIA

Faculty of Medicine & Health Sciences
School of Health Sciences
B33 Room Postgraduate Research Office
School of Health Sciences, University of Nottingham
Queen's Medical Centre, Nottingham, NG7 2HA

I am calling today to invite you to take part in a remote interview. We would like to develop a footcare education intervention delivered by CHWs for T2DM patients with low-risk diabetic foot ulcers (DFUs). You will be interviewed remotely using WhatsApp video calls on smartphones, in interviews expected to last between 45-60 minutes. However, consideration can be given to other applications, especially if you are more familiar with Skype and MS Teams. You will be asked prior to the interview if you wish to use video or voice only. If you do not wish to use video, or technical problems prevent video conferencing, the interview will be equivalent to a traditional telephone interview. If there is a failure in the connection/technology attempts will be made to re-connect or rescheduling the interview.

The Ethics Committee, whose role it is to scrutinise research and protect participants has agreed that we can obtain verbal consent from you over the phone, but please let me reassure you that whatever you decide, it will not change your treatment or employee right. Do you have any questions you would like to ask me at this stage?

Record participant's response: Yes / No

If yes, record any questions and responses given, below:

_____

_____

_____

_____

Just so that I can check that I have explained myself clearly to you, can you please confirm if you understand what I have told you?
In this verbal consent, your involvement is known by the witness on your side, and we will ask for the name and telephone number of the witness if you do not have any objection.

Record participant's response: Yes / No

If you are happy with my responses, can you please let me know whether you agree or not, to take part in the *[Footcare education intervention delivered by CHWs]* study?

Record participant's response: Yes / No

(If participant answered yes, continue overleaf; if no, then thank the participant for their time and say goodbye)

Finally, could I please ask you to confirm a few details to record your consent?

Version and date of information sheet received by participant: Version: ____ Dated: ___ / ____ / _____

Date the study information was received (dd/mmm/yyyy)? ___ / ____ / _____

University of Nottingham
UK | CHINA | MALAYSIA

Faculty of Medicine & Health Sciences
School of Health Sciences
B33 Room Postgraduate Research Office
School of Health Sciences, University of Nottingham
Queen's Medical Centre, Nottingham, NG7 2HA

We would like to send you a copy of the consent form to keep for your information. Could you please confirm for me how you would like to receive this, via post or email? Please confirm your contact details for me:

Address: .....

.....

.....

Email: .....

PARTICIPANT VERBAL CONSENT CONFIRMATION FORM

	Please initial (researcher)	
	Yes	No
1. After explaining the study information to the participant, I can confirm that the participant understands and agrees to participate in the above research study.	☐	☐
2. The participant understands that the study is voluntary, and that they can withdraw at any time without their medical care or legal rights being affected; although data and samples already collected will be retained for use in the study.	☐	☐
3. The participant understands that their personal data may be collected and stored electronically for the purposes of this study.	☐	☐
4. The participant understands that we may contact their GP or any other relevant medical professional treating them about their participation in the study.	☐	☐
5. Statement of consent to participate in this study is known by a witness who knows your involvement in this research.	☐	☐

Participant

Full name (*block capitals*): ☐

Date of Birth: DD/MM/YYYY ..... / ..... / .....

Date/time verbal consent provided by participant: DD/MM/YYYY ..... / ..... / ..... Time (24 hr) .....:.....

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Faculty of Medicine & Health Sciences
School of Health Sciences
B33 Room Postgraduate Research Office
School of Health Sciences, University of Nottingham
Queen's Medical Centre, Nottingham, NG7 2HA

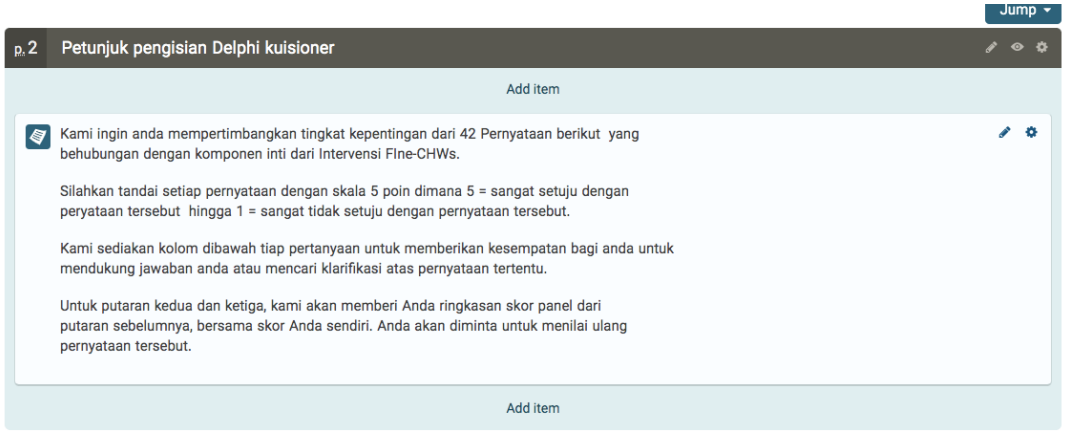
Person taking consent

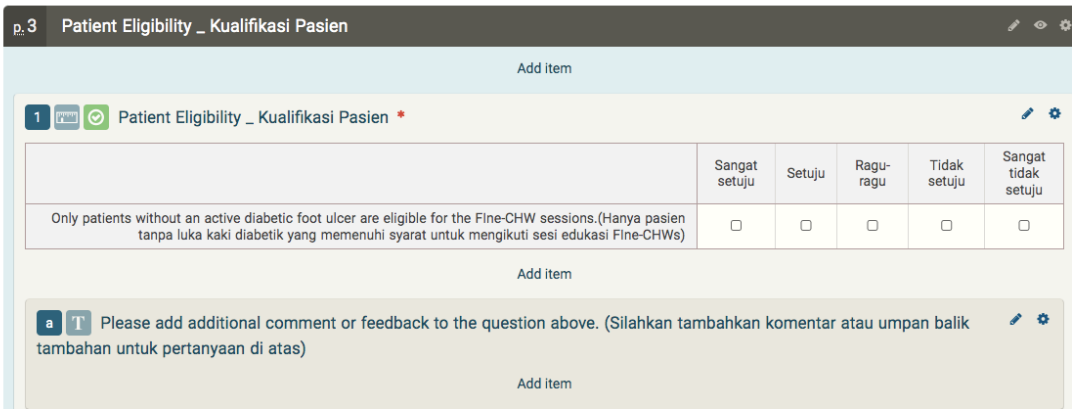
I have explained the study to the above-named participant and they have indicated their willingness to participate.

Full name (*block capitals*):	
Signature:	
Date:	DD/MMM/YYYY …… / …… / ……

Original to be retained and filed in the site file, one copy for the participant, and one copy to be filed in the participant's medical notes.

Appendix E: Delphi Survey on Jisc Online Surveys





Appendix F: COREQ Checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	97
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	97
Occupation	3	What was their occupation at the time of the study?	105
Gender	4	Was the researcher male or female?	105
Experience and training	5	What experience or training did the researcher have?	97
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	169
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	169
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	103-105
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	95
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	159, 264
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	162-163, 264
Sample size	12	How many participants were in the study?	158, 264
Non-participation	13	How many people refused to participate or dropped out? Reasons?	265
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	162
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	163
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	162, 264
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	167
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	-
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	166
Field notes	20	Were field notes made during and/or after the inter view or focus group?	172
Duration	21	What was the duration of the inter views or focus group?	169
Data saturation	22	Was data saturation discussed?	159
Transcripts returned	23	Were transcripts returned to participants for comment and/or	-

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	178
Description of the coding tree	25	Did authors provide a description of the coding tree?	182
Derivation of themes	26	Were themes identified in advance or derived from the data?	179
Software	27	What software, if applicable, was used to manage the data?	178
Participant checking	28	Did participants provide feedback on the findings?	-
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	183-222
Data and findings consistent	30	Was there consistency between the data presented and the findings?	182
Clarity of major themes	31	Were major themes clearly presented in the findings?	284
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	284-296

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix G: Data Triangulation Table

Triangulation data	Procedure of Intervention	Noted
Literature review	The CHWs performed a full foot examination, including visual inspection, assessment of pedal pulses, and monofilament testing. Results were documented in the CoDE chart and the clinic medical record. Foot abnormalities were reported immediately to the physician. Appropriate footwear and daily home foot care were discussed (Culica and Prezio et al., 2014). Taking baseline data before delivering foot care intervention was followed by multifaceted education sessions and hands-on practice. The several studies supported that blood glucose test of participant as baseline data. Foot care intervention are delivered after HCPs screened the feet dan decided the risk foot ulcers (Borges and Ostwald, 2008; Fan *et al.*, 2013; Nguyen *et al.*, 2019). Consensus statement for educating patients diabetes with low risk of complications, namely: control of blood glucose levels; attendance at annual foot screening examination (Mcinnes et al., 2011). Physical examination of the feet to assess risk factors for foot ulceration/ amputation should be performed by a HCPs (RNAO,2016). Offer clear explanations and information to those diagnosed with diabetes and their caretakers (NICE, 2020).	
Interview data	The nurses and GPs held the view that the brief foot examination of diabetic patients by HCPs can be conducted before CHWs provide intervention *It is possibly nurses and midwives; we measure blood pressure (at Posbindu) and blood glucose test while asking diabetics whether there are wounds or not (N3).* *The procedure for handling people with diabetes is still the same, namely measuring blood sugar, administering drugs or blood tests, administering drugs based on the results of blood glucose examinations, then checking blood glucose every two months for people who visit Prolanis" (N3)* *Maybe if the screening is being done by the nutritionist or other professions, they do not really understand. But if it's done by the nurse it's okay (GP1)* *Keep blood glucose levels under control (..) so that this action will prevent of DFU (N2)*	
Convergence	Blood glucose test of participant as baseline data. A HCPs should assess risk factors for risk DFUs	Blood glucose test is standard procedure on diabetes management Feed screening before prior to intervention by HCPs
Complementary	Some studies measured degree of risk of DFUs or classified based on with or without DFU prior the intervention.	
Dissonance	CHWs performed complete foot screening in the US. Interview data support the nurse do feet screening.	
Silence	The patient's participants did not experience feed screening There is no information about grade risk DFUs from the CHW intervention.	

Conclusions **Number of Delphi statement**	1 Only patient without an active diabetic foot ulcer are eligible for the FIne-CHW sessions. 2. A registered healthcare professional (such as a nurse, doctor or podiatrist) must screen all patients' feet for active diabetic foot ulcers before referring them to the FIne-CHWs educational sessions 3. All patients should have their blood glucose levels measured within one month before attending the first FIne-CHWs session	

Triangulation data	**Intervention Provider (CHWs)**	**Noted**
Literature review	Seven studies in CHWs delivered DSME, including foot care intervention clearly showed that CHWs were solely educators in DSME, including foot care intervention. (Islam et al., 2013; Spencer et al., 2011, Castillo et al.,2014; Pacheco et al., 2017; Schoenberg et al., 2017; Prezio et al., 2014; Hughes et al., 2016). CHWs were referred to as trained CHWs or bilingual CHWs. CHWs were trained prior to the intervention, In rural Philippines, no specific academic background was needed for CHWs to provide DSME. In the US, CHWs working with underserved Hispanic populations required a high school equivalency certificate. Some studies described the training of CHWs to manage DSME. The CHWs gained training from endocrinologists in a two-day workshop. They received a course manual describing the course content and teaching process and returned demonstration skills (Pacheco et al., 2017;). The CHWs passed a written final examination (available on request) with questions derived from the American Association of Diabetes Educators' core curriculum and received continuing education during monthly case conferences and weekly chart reviews provided by the physicians in the clinic (Culica and Prezio et al., 2014). One study reported that CHWs gain public confidence by acknowledging the connections of CHWs and training in the School of Medicine cited as credentials that facilitate trust with participants (Islam et al, 2013)	
Interview data	The CHW is known as the educators, data collection and recording data. *Usually they do some health education that can be done by CHW such as diabetic foot exercises, they can also do it (...) through the health education that has been carried out by the cadres, patients will understand more about treatment at home (GP1)* Some requirement for CHWs selection to deliver FIne-CHWs are: *"I could not do anything; I'm afraid that other people will be educated and graduate from school, while I'm not. I'm afraid I can't do it. I'm worried I won't be able to. on how that my way of speaking and knowledge is not like other people who have a high level of education" (CHW6)* *The chosen ones are not seen from their educational background or socio-economic background, but only their performance... the performance is then supported by a way of interacting... able to make sense because after all, they are CHWs, their job is to talk to people (FM2)* *In my time, I was the village head... If you changed the village head then the passengers changed, the passengers here are the people [involved], changed to a different one. then the previous (CHWs) is no longer active (...) the Puskesmas (PHC) should not recruit CHW from a politician. whoever it is, whatever colour it is [colour is a symbol of a political party] ... well this is one of the reasons that people's respect is decreasing... so don't have*	

	activists there, it's just a pure community... housewives (...) so that community will become the victims (FM2) CHWs are used to managing two ISP posts (maternal and children Post and NCD Post); both community posts were held simultaneously. *When Posyandu hmmm, let's say we start at 08:00 in the morning, we will focus on toddlers while waiting for health workers from the health centre (PHC) to come. We concentrate on the Posyandu while weighing the toddlers first. Maybe around 10:00 am or around 09:00 until 10:00 am, the health workers arrived; after that, we just updated this information through a WhatsApp group for Posyandu and Posbindu.* The training does not guarantee that CHW will independently teach foot care directly to the community. There is always supervision from HCPs to follow foot care counselling. *Maybe CHW should be trained, and we (HCPs) should be present (when CHW provides Intervention) to gain people's trust and make them (CHW) more confident if they receive questions (from community members) (N3)* CHWs are officially managed by the local government, but their responsibilities within the community are ultimately determined by delegating tasks from healthcare professionals. *because in the past the CHW belonged to the Puskesmas (PHC), now it belongs to the mayor, but the operations are at the Puskesmas... now the organic is the municipal government (FM2).* One nurse stated the possibility of nurse refer to FIne-CHWs *If they have a DFU we refer to a health worker and for those who are not having send it to CHW (N3).* CHWs believed that they could educate the community effectively with proper training and specific foot care. Additionally, by imparting knowledge and skills, the CHWs felt more confident in their educator role and gained people's trust in their capability. *If they get training (CHW), sure, I trust them (P1)* Furthermore, the nurse thought that teaching skill practice more effective since many of CHWs are in advanced age. *they better get a demonstration skill (foot care). So, they see [every step]. It is more effective to teach foot care practice. Mainly because they are at an advanced age, (they) do not like reading books, so it is easier to see, hear, and be more effective than asking them to read.* CHWs need fairer transportation allowances as they have multiple responsibilities. *(...) improve the welfare of the CHW too (N2)* *(...) the posyandu cadres never complain, although sometimes it's not enough with fifty thousand rupiahs (FM2)* Interacting with elderly visitors in a friendly and kind manner to build rapport has proven effective.	

	They should be asked. So, every time we meet, "How are you? Are you healthy? Thank God." That's it. So the elderly should not be ignored. So, we have to love them and courted them. But the elderly is very lovely when we are friendly. Yes, we have to be able to communicate nicely (CHW7). Make educational content engaging with visuals like pamphlets. This helps retention of information for patients and CHWs. *"If would be better if a book [module/brochure] is provided, it's possible. We can explain it later. If someone asked further questions. The elderly usually forgets or doesn't understand. They will ask, how about this and that… So, we can explain further" (CHW5)*	
Convergence	CHWs play a vital role in many fields, including making referrals, providing health education and motivation for behaviour change to community members, collecting and recording data, and providing psychosocial support. The requirement process should consider good communication skills and education level to deliver FIne-CHWs. CHWs required a high school equivalency certificate CHWs received training as it will positively influence their performance, community trust. Method of CHWs training is combining classroom-based theory sessions with practical and participatory to enhance CHW' capability and completed with manual detailing of how deliver intervention. Referring patients to the CHWs program. CHWs should be reimbursed their transportation cost.	CHWs should CHWs should have right personal specification, such communication skill, fair level of education. Specific method of training
Complementary	CHWs in Indonesia manage community posts (ISPs) and should have a clear role as educators. CHWs pass written examinations and certificates to boost CHWs and patient's confidence. CHWs treat elderly visitors with respect and compassion. CHWs should be reimbursed for their transportation cost.	
Dissonance	CHWs expected do not have political affiliation when deliver FIne-CHWs	
Silence	There is no known evidence about the ideal and or maximum number or mix of CHW job tasks that will ensure the highest level of CHW productivity. No information about CHWs allowance from scoping review data.	
Conclusions **Number of Delphi statement**	4. CHWs delivering the FIne-CHWs sessions must have passed senior high school. 5. CHWs with the right personal specifications can be trained to competently deliver the FIne-CHWs education sessions. 6. The CHW delivering the sessions must not have any political affiliations. 7. CHWs delivering the FIne-CHWs sessions must have good communication skills and be motivated to deliver diabetic foot care intervention. 8. Training on diabetic foot ulcer care must be provided to CHWs before they can deliver the FIne-CHWs sessions. 9. The curriculum for training CHWs should also cover how to treat patients with dignity, compassion and respect. 10. The CHW should be provided a course manual detailing how they should deliver the sessions. 11. The training of CHWs should use the teach-back method to emphasise practical skills. 12. The CHWs knowledge, skills and attitudes must be tested through an examination prior to them providing training to patients.	

	13. The CHWs providing the FIne-CHW sessions must be under the management of the community health centre or Posbindu PTM 14. There must be a policy for referring patients to the FIne-CHWs intervention. 15. The CHW must be reimbursed for their travel costs to the community centre or Posbindu PTM or the patients homes.	

Triangulation data	Intervention Provider (Healthcare professional)	Noted
Literature reviews	Foot care education delivered by HCPs reported that the educator of footcare intervention are nurse, multiteam doctor, nurse, mental health professional and podiatrist	
Interview data	All three stakeholder groups expressed that HCPs must present when CHW deliver the intervention to gather community trust and enhance CHWs' confidence. *"~~HCPs~~ should be present (when CHW provides Intervention) to gain people's trust and make them (CHW) more confident if they receive questions (from community members)" (N3)* One GP believed that HCPs have to be involved because only HCPs could screen foot condition. She doubts the capability of CHWs for screening, ultimately identifying specific signs of diabetes foot problems. *"health workers must be involved and indeed have to go down for screening .... they must be willing to one-minute screening. But whether CHW is ready for it, for example, CHW doubts whether it is true that the patient's foot has problems" (GP2)* The intervention providers in ISP-NCD (Posbindu) include doctors, nurses, midwives, and public health workers. A GP suggested that nurses would be the best teachers for CHWs in foot care. *.....because there are not limited number of nurses, there are only 6 nurses. So, the other professions are often scheduled for supervision Posbindu, such as midwives. Maybe if the screening is being done by the nutritionist or other professions, they do not really understand. But if it's done by the nurse it's okay (GP2)* All group participants requested ~~HCPs'~~ presence as supervisor when CHWs deliver health education *"Not all nurses understand about foot care, except for those who is responsible as the leader of diabetes program(N2) (...)* One of the wound care specialist nurses showed good knowledge of screening DFUs. *If I checked patient condition, at least I asked (them) for screening, (such us) if they felt numbness or pain on their feet, whether thy had (adequate) rest or not, felt less sensitive in their feet or not. I taught the patient to measure the arterial pulse on the leg, (I asked) did it look pale? then touch it, measure it in minutes, then feel the cold on the foot, stiffness, dry skin, something like that ... checked the shape of the foot (N2)* *for diabetics without wounds, we usually asked for the information above, and for new wounds, we choose to wound care. I did not know yet foot screening DFUs (N3)*	
Convergence	No specific information about training HCPs.	
Complementary	Midwives was also suggested to involve in supervising of CHWs CHWs are not allowed for screening DFUs risk. Nurses were not familiar on screening of DFUs in Indonesia context.	

Dissonance	CHWs as educators not always involved healthcare professional to supervise them when they deliver intervention.	CHWs providing FIne-CHWs require the attendance of HCPs. No evidence midwives did foot screenings
Silence	There is no data support role of midwife on diabetes education specially foot prevention from literature reviews.	
Conclusions **Number of Delphi statement**	16. CHWs providing the FIne-CHW sessions should be supervised by a GP or registered nurses. 17. A registered nurse should be present at the community centre or Posbindu PTM to supervise CHWs whilst they are delivering the sessions. 18.The nurse supervising the CHWs delivering the session should have previously received training in care of patients with diabetic foot ulcers. 19. Foot care training for nurses should also emphasize foot screening to categorize the risk of DFUs.	

Triangulation data	Place of Intervention	Noted
Literature review	**Evidences from Scoping review of DSME delivered by CHWs** CHWs' Interventions were primarily conducted in community settings such as the village health centre, a faith urban clinic and a community self-care centre (Islam et al., 2013; Spencer et al., 2011, Castillo et al.,2014; Pacheco et al., 2017; Schoenberg et al., 2017; Prezio et al., 2014). The patient's home (Hughes et al., 2016; Schoenberg et al., 2017; Islam et al., 2013), community places such as a church, school, senior centre and community centre (Castillo et al.,2014). Combine community setting and conducted home visits are suggested by three studies (Islam et al., 2013; Spencer et al., 2011; Schoenberg et al., 2017) **Foot care intervention delivered by HCPs** reported that intervention was shown in many settings; in a hospital, the community health centre, health clinic, diabetic clinics, endocrinology OPD.	
Interview data	All participants indicated to use community spaces, or patients' / CHWs' houses, *"The best place in the community head office, the usual place for Posbindu (ISP-NCDs) "(CHW3)* One nurse suggested using religious community events or "arisan" (women's neighbourhood events) to teach patients. This allows for a variety of activities beyond ISP-NCDs.	
Convergence	Intervention can be hold in the community setting, while also offering a home visit.	Agreement on intervention sites: community setting and visit to the patient' house.
Complementary	The intervention was also conducted in PHC or community clinic Intervention can be held in a religious place (church) or embedded with a religious community event.	
Dissonance	The site of intervention in CHWs' house.	
Silence	The CHWs did not hold intervention in the hospital setting such us diabetic clinics, endocrinology OPD	
Conclusions	20. The FIne_CHWs intervention should be delivered in the community centre such as the Posbindu or delivered at the community health centre unless the patients are assessed as needing a home visit.	

Number of Delphi statement	21. Where patients are assessed as unable to visit the Posbindu (for example, due to physical mobility issues), the CHWs will provide the intervention in the patient's own home with booster sessions provided by telephone.	

Triangulation data	Time and duration of intervention	Noted
Literature reviews	**The studies DSME delivered by CHWs** involved teaching about foot care. The intervention sessions lasted for 60-150 minutes per session (Islam et al., 2013; Spencer et al., 2011, Castillo et al., 2010; Prezio et al., 2014; Pacheco et al., 2017)., one-on-one visits at months 3, 6, and 9, lasting for 60-90 minutes each took place at convenient locations for the participants (Islam et al., 2013). Two studies offered home visits to teach patients personally or accompany them to clinic visits but did not provide data on the length of home visits (Spencer et al., 2011; Hughes et al., 2016). **HCPs delivered the foot care intervention** face-to-face, with delivery times ranging from 20 to 120 minutes, with four studies lasting 30-60 minutes per session (Fan et al.2013; Nguyen et al 2019.; Fardazar et al.; Fujiwara,2012). Two studies used multimedia platforms (mobile education app, audio-visual, and pamphlet) with intervention time of 9 minutes ± 0 (Rahaman et al., 2018; Dincer and Bahcecik, 2021). Two studies employed a telephone contact booster two to three times after main sessions, about 10 to 15 minutes (Fan et al., 2013; Nguyen et al., 2019), to reinforce learning and self-care practices Two other studies followed up with home visits for one month (Borges and Oswald,2008) or three months (Fardazar et al., 2018) after the intervention. No specifying the exact time for teaching the skills (Nguyen et al.2019 ; Fardazar et al, 2018.; Borges and Oswald, 2008) Four studies taught foot care skills (Fan et al.; Nguyen et al.; Fardazar et al.; Borges and Oswald, 2008), but without specifying the exact time for teaching the skills while one study dedicated a separate session to hand skills for 60 minutes (Fan et al., 2013).	
Interview data	Most participants thought it took less than an hour to teach a diabetic patient about foot care; many participants felt that 30 to 60 minutes was sufficient for the intervention. One CHW worried that elderly patients would be tired if the educational intervention lasted longer than 15 minutes. *Maybe 15 minutes, it's okay. If it takes too longer, patients who are … elderly might be restless when the health education takes too long (CHW5)* Most of the participants raised the issue that patients and CHWs would be bored, and another consideration was that the elderly did not want to sit longer because they were busy with household chores and CHWs as well. *"Sometimes the cadres (CHWs) are bored <laugh> and also people who were invited maybe <laugh>a bit bored... better to put it together. just at one time ~~as~~ later sometimes people want to come, the next day they don't come (N5)* *Don't take too long. We're also tired of being trained by cadres (CHWs). ……. Cadres (CHWs) they are volunteers, they also have their own activities at home, so they have to manage their time (P7)*	

	One nurse specialising in wound care believed that separate time to teach hands-on skills for foot care is recommended for patients to remember the intervention procedure easily. *If this training is included in the skills practice, two days are sufficient, one-day demonstration foot care intervention…Usually, a maximum of one hour before starting ISP-NCD (Posbindu) activities (N3)*	
Convergence	The studies of CHWs delivered Diabetes Self-Management Education (DSME), which included teaching about foot care, spent approximately 60 -150 minutes per intervention session. The HCPs delivered foot care interventions ranging from 20-120 minutes, mostly around 30-60 minutes per session. On the other hand, most interview participants mentioned that the sufficient intervention time is less than one hour, considering one hour was the longest time both CHWs and patients attended the intervention. Teaching foot care for an hour is similar to a nurse's perspective on teaching foot care separate from lecture. Provide home visits after giving intervention. Developing multimedia education can be considered an alternative to foot care education.	The intervention session should not exceed 120-150 minutes. Participants recommended a one-hour lecture and one-hour hands-on skill teaching. The total time for foot care intervention should not exceed 120 minutes, and average hour around 60 minute per sessions.
Complementary	A telephone contact booster was used as a reminder to adhere to the foot care intervention. Developing multimedia education can be considered an alternative to foot care education.	
Dissonance	One-to-one teaching patients may require around 15 minutes for educational intervention. It is important to note that the 15-minute intervention time is only feasible in the emergency room and not in a community setting with elderly people.	An intervention of around 15 minutes in a community setting might not work.
Silence	There is no detailed information on how long it takes to teach foot care in CHWs' intervention. None of the participants interviewed mentioned the timing of multimedia delivery, such as animation or short audio-visuals.	
Conclusions	29.Fine-CHWs sessions should be provided in four sessions; two one-hour educational sessions and two 15-30-minute booster sessions	
Number of Delphi statement	30.The booster sessions will reinforce the teaching and learning from the first two sessions and the need for patient to perform daily foot care.	
	31.The FIne-CHW sessions should be given over a six months period.	

Triangulation data	Content of education	Noted
Literature review	The content of education when foot care as part of diabetes management delivered by CHWs not specifically mention in six of the studies All the studies discussed the overview of diabetes, including myths and facts, risk factors and information surrounding the disease (Islam et al., 2013; Spencer et al., 2011, Castillo et al.,2014; Pacheco et al., 2017; Schoenberg et al., 2017; Prezio et al., 2014; Hughes et al., 2016). Physical activities and exercise (Islam et al., 2013; Pacheco et al., 2017).	

	The studies about foot care intervention delivered by HCPs reported that basic foot care information conveyed to patients diagnosed with diabetes, including: 1. Awareness about Diabetes and foot complications, the definition of the diabetic foot, its types, ethology, the identification of at-risk foot, risk factors and warning signs; (Fan et al., 2014a; Fardazar, Tahari and Solhi, 2018; Nguyen et al., 2019) 2. Daily self-footcare included daily washing, inspecting feet for problems, moisturizing, massaging foot; wearing proper shoes and socks; toenail care (Ooi et al., 2007; Fan et al., 2014; Nguyen et al., 2019; Dincer and Bahcecik, 2021) 3. Seek help (when, where, how) (Fan et al., 2013, 2014; Nguyen et al., 2019) 4. Stress management related to footcare (Fardazar, Tahari and Solhi, 2018) A study conducted in Iran added special feet exercise to be included in education content and stress management (Fardazar, Tahari and Solhi, 2018). Provide information and clear explanations to people with diabetes and their family members or carers (as appropriate) when diabetes is diagnosed. Information should be oral and written and include the following: basic foot care advice and the importance of foot care; foot emergencies and who to contact; footwear advice; the person's current individual risk of developing a foot problem. Information about diabetes and the importance of blood glucose control (NICE,2020). ADA, 2018 recommend patient with very low (ADA risk category 0) with no issue with LOPS or PAD engage in education on topics such as routine footcare, athletic training, appropriate footwear, or injury prevention, while patient with low risk of foot ulcers (ADA risk category 1; LOPS ± longstanding, nonchanging deformity emphasize requires prescriptive or accommodative footwear (Boulton et al., 2018). More specific explanation on foot care education was given by a national model of diabetic footcare (Ireland) (2011) are: nail care; emollient use; Footwear; Daily self-examination of the feet; not walking in bare feet; checking footwear and hosiery before putting them on; "Breaking shoes in" never to be attempted; any hot water bottles; checking bath and shower temperature; avoidance of home remedies e.g. corn plasters; what to do and the appropriate person to contact if foot problems develop.	
Interview data	All the participants interviewed believed foot exercise using newspapers is one strategy to combat DFUs. One of the GPs narrated the educational content *Perhaps the most important thing is to look at the condition of their feet every day; if, for example, they can't see the soles of their feet, maybe they can help ask other family members for help. Perhaps that was when they self-started to feel like a mole or callus or something, so they should have started to realize that someone had to visit a health facility. Maybe wash their feet more diligently with soap and don't leave them moist like that; maybe don't take too long when bathing your feet. Another part that needs to be paid attention to is also between the fingers, don't forget the outer part between the fingers must be the same as clean; wear moisturizer, and use footwear because sometimes there is numbness at home; it is better to use footwear, what needs to be paid attention to is the selection of footwear not to make the footwear narrow, the most important thing is to prevent injuries, rubbing and all kinds, from the way you cut your nails to the point where your fingernails pierce the skin. Finally, you have to check the sugar levels (GP2)* Most patients and CHWs indicated a lack of knowledge about diabetes and its complications, the sign of diabetes and how patients and CHWs do not clearly define its influence on patients' health.	

	Diabetes... how could I tell you...(P5) Patients and family members raised the topic of managing mental health to encourage patients to adapt to their illness. *"but then someone said don't panic, don't overthink, your illness would be worse" (P2)* A GP suggested self-foot care but cautioned against buying new shoes due to financial concerns. *Patients can do it themselves, don't need help from other people, and don't have to buy everything, which is easy. Then yes, it was back again to getting support from the family. We teach simple things; people don't have to be highly educated to understand. Anyone can understand the language used by using pictures, talking about footwear related to cost, how they can buy shoes or things like that (GP2).*	
Convergence	The interview data indicated that footcare education content closely aligns with evidence-based literature reviews. Topics covered include awareness about diabetes and foot complications, daily self-footcare, such as washing, and stress management related to footcare.	There is agreement on footcare education content except foot care exercises using newspaper
Complementary	Patients should be aware of when, where, and how to seek help.	
Dissonance	The technique of using newspapers for foot exercises may differ from a study conducted in Iran.	
Silence	No detailed information of educational content for food care in CHW's intervention. No detailed information was provided regarding foot exercises using newspapers or papers.	
Conclusions **Number of Delphi statement**	32 The content of education should cover knowledge on awareness about diabetes and foot complications: definition of the diabetic foot, its types, warning signs, foot care, etc. 33. Washing feet 34. Inspecting foot for problems 35. Moisturizing and massaging foot 36. Foot exercise (for example foot exercise using newspaper/ papers) 37. Toenail care 38. Wearing appropriate shoes and socks 39. Help seeking (when, where, how) 40. Stress management related to foot problem.	

Triangulation data	Tailoring Intervention	Noted
Literature review	The diabetes intervention delivered by CHWs using curriculum were culturally dan linguistically tailored ((Islam et al., 2013; Spencer et al., 2011, Castillo et al.,2014; Pacheco *et al.*, 2017; Schoenberg et al., 2017 ; Prezio *et al.*, 2014; Hughes *et al.*, 2016), as the intervention referred to disadvantages group, underserved medical service or minority. Two studies also considered patient level literacy (Prezio *et al.*, 2014; Schoenberg et al., 2017). Using bilingual CHWs (Islam et al, 2013; Prezio et al., 2014)	
Interview data	The patients, CHWs, and nurses believed that offering snacks could boost patients' motivation to attend Posbindu monthly. *"at least ate colenak [traditional food] together...It also seemed they were happy" (FM2)* *to make them happy and enthusiastic, given something such us snack or anything, they like to listen to the health education while eating (CHW8)* One diabetic patient and family member suggested using their local language to attract visitors and using simple terms easily understood by the local community. *It must be understandable by patients and has to be easy. Don't use complicated terms... like in English. Older people don't like it, so just use our language that can be understandable <laugh> (P7)*	
Convergence	Tailoring intervention culturally dan linguistically with the local context with consider level of literacy	CHW is supposed to have the same language as the patients.
Complementary	Providing food to increase the participation of patients in the CHWs program.	
Dissonance		
Silence	No evidence support providing food from literature review	
Conclusions **Number of Delphi statement**	41 Patients and family members who participate in the FIne-CHWs education sessions should be given healthy snacks if there is sufficient budget. 42 FIne-CHWs Sessions should be delivered in the local language.	