The Effectiveness of Information-Motivation-Behavioural skills model-based Diabetes Self-Management Education among Patients with Type 2 Diabetes (IMBDSME); Randomized Clinical Trial

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Abstract:

Aim: to develop and examine the effectiveness of Information Motivational Behavioural Model-based Diabetes Self-Management Education intervention on three self-care activities: diet, physical activity and medications management self-care behaviours, and other outcomes such as quality of life and glycaemic control.

Setting: Outpatient clinics at two mains teaching hospitals in Jordan.

Participants: Sample of 151 participants who were diagnosed with Type 2 Diabetes Mellitus for more than six months, aged between 18 and 65 years old, HbA1c > 8% within the last two weeks prior to recruitment and are taking any form of hypoglycaemic agents.

Research design: This trial was a randomized clinical trial and was designed in line with MRC framework and IMB three main procedures: assessing, implementation and evaluation. IMB main determinants; knowledge, motivation and behavioural skills along with the performance of self-care behaviours, quality of life and HbA1c were assessed at baseline and evaluated at three-month visit and six-month visits.

Methods: A two parallel group trial with randomized allocation of 151 participants on 1:1 average for both groups. Intervention group received the IMBDSME intervention as well as the usual treatment while control group received the usual treatment only. IMBDSME was developed using an Arabic translated version of PRIDE educational toolkit. The educational toolkit was delivered using motivational interviewing and brief action planning approach according to IMB model assumption through two face-to-face

sessions and several interventional phone calls for each participant within two weeks from participation and for a duration of three-month period.

Results: For those who were in the IMBDMSE group, they reported statistically significant improvements in the level of knowledge, motivation, behavioural skills and quality of life at three-month and six-month visits. Similarly, significant improvements in the level of practicing diet and medications management self-care behaviours were found at three-month and six-month visits. HbA1a was improved significantly at three-month for those who attended JUH and received the intervention. While non-significant improvements were reported in physical activity behaviour and HbA1c at both time points among the same group.

Conclusion: This clinical trial conceptualised IMB behavioural change model in IMBDSME intervention and improved the level of performing diet and medications management self-care activities for those who received the intervention. IMBDSME provided a comprehensive understanding of how Jordanian patients' Knowledge, Motivation, Behavioural skills and metabolic outcomes changed overtime, in tandem with performing self-management behaviours.

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Abbreviations:

HbA1c	Glycosylated haemoglobin
MRC	Medical Research Council
T2DM	Type 2 Diabetes Mellitus
IMB	Information-Motivation-Behavioural
CI	Confidence Interval
CI	Chief Investigator
DSME	Diabetes Self-Management Education
CRF	Case Report Form
RCTs	Randomized Controlled Trials
DAP	Data Analysis Plan
IMBDSME	Information-Motivation-Behavioural skills Diabetes Self-Management Education
GCP	Good Clinical Practice
ICF	Informed Consent Form
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee

UoN	University of Nottingham
WHO	World Health Organization
SPSS	Software Package for Social Sciences
UKPDS	United Kingdom Prospective Diabetes Study
SDSCA	Summary of Diabetes Self-Care Activities
DSCB	Diabetes Self-Care Behaviours
SD	Standard Deviation
ADDQOL	Audit of Diabetes Dependent Quality of Life.
DKQ	Diabetes Knowledge Questionnaire.
DES	Diabetes Empowerment Scale.
MOS	Medical Outcomes Study.
PDSMS	Perceived Diabetes Self-Management Scale.
IPCs	Interventional Phone Calls
GEE	Generalized Estimating Equations

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1 Background and literature review:

1.1 Introduction:

According to World Health Organization (WHO) (2019), diabetes is defined as a group of metabolic disorders that are characterized by the presence of High glucose level in the absence of treatment. It may be caused by defects in insulin secretion, insulin action, or both, and disturbances of carbohydrate, fat and protein metabolism. The long-term complications of diabetes include retinopathy, nephropathy and neuropathy, among other complications. People with diabetes are also at increased risk of other diseases including heart, peripheral arterial and cerebrovascular disease, obesity, cataracts, erectile dysfunction, and non-alcoholic fatty liver disease. They are also at increased risk of some infectious diseases, such as tuberculosis.

On long term, it considers one of the primary reasons for cardiovascular and cerebrovascular diseases. According to the World Health Organization in 2000, 171 million people were estimated to be diagnosed with diabetes and this will increase to at least 366 million by 2030 (Wild et al., 2004). Another report published in 2015 stated that the number of those adults diagnosed with diabetes has been quadrupled to 422 million in 2014 since 1980 (WHO, 2015). Without interventions to halt the increase in diabetes, there will be at least 629 million people living with diabetes by 2045 (WHO) (2019). The number of deaths directly caused by diabetes was 1.5 million in 2015, and 3.7 million deaths were related to high blood glucose in 2012 which was about 9% of the total global deaths (WHO, 2015). Almost half of deaths before the age of 70 years were related to high blood glucose in 2012, and 80% of diabetes deaths occurred in low- and middle-income countries. WHO in (2019)

reported that half of people with diabetes (50%) die of cardiovascular disease (primarily heart disease and stroke), and 10-20% of people with diabetes die of kidney failure. This will eventually be the seventh leading cause of death by 2030. As this number is still growing, the proportion of healthcare budgets specified for Type 2 Diabetes Mellitus (T2DM) and its related complications is always increasing. Diabetes prevalence is rapidly increasing in the Eastern Mediterranean Region (EMR) in comparison to American and European Regions (AER). Prevalence of diabetes amplified by more than double from 5.9% in 1980 to 13.7% in 2014 in EMR, while the rise was only 1.5 folds in AER (WHO, 2016). EMR has the greatest rise in diabetes prevalence with the highest incidence of diabetes among WHO regions now (WHO, 2016). Diabetes in low and middle-income countries has risen faster than in high-income countries (WHO, 2015 , 2016); hence, cost effective treatment strategies are crucial to reverse this inclination in these countries.

International Diabetes Federation (IDF) published the diabetes Atlas 9th edition in 2019 where they estimated that almost half a billion people have diabetes, and this number is projected to reach 578 million by 2030, and 700 million by 2045 (Saeedi et al., 2019). They stated that over four million people aged 20–79 years are estimated to die from diabetes-related causes in 2019. The majority of the data sources used in IDF report were population-based studies that have been published in peer-reviewed periodicals, national health surveys, including some of the World Health Organization (WHO) STEPwise approach to Surveillance (STEPS) were used where they meet inclusion criteria. Findings of the latest edition confirmed that diabetes is one of the fastest growing global health emergencies of the 21st century.

1.2 Diabetes-related complications:

Uncontrolled glucose level in patients with T2DM is one of the leading causes of microvascular and macrovascular complications (Rosolova et al., 2008). Using anti-hyperglycaemic medications in managing diabetes showed an improvement in glucose level and reduced complications on the long term (Stratton et al., 2000). Results drawn from Randomized Controlled Trials (RCTs) have verified that intensive glycaemic control of HbA1c <7 is highly correlated with a considerable decline in the risk of microvascular complications in patients with T2DM (Stratton et al., 2000). However, a glycaemic target of HbA1c<7 is often not accomplished among patients with DM (ADA, 2015 , Saydah et al., 2004). Although using anti-hyperglycaemic medications to control blood-glucose level intensively improved metabolic outcomes in UKPDS study, side effects such as hypoglycaemia and weight gain were more likely to occur among study participants (UKPDS, 1998). However, this disease requires more efforts and attention to improve metabolic outcomes and minimising side effects through appropriate tailored glycaemic management (Sansgiry et al., 2013).

The United Kingdom Prospective Diabetes Study (UKPDS) clearly concluded that self-care behaviours to improve glycaemic control, lipid and blood pressure have shown to improve long-term outcomes for patients with T2DM (Turner et al., 1996). Epidemiological scrutiny of The United Kingdom Prospective Diabetes Study (UKPDS) showed that for each 1% decrease in HbA1c, there was a consistent reduction by 21% in any diabetes-related endpoint, with a decrease of 14% in myocardial infarction, 12% decrease in stroke incidence, and a 37% decrease for microvascular complications (Stratton et al., 2000).

1.3 Diabetes in Jordan:

Jordan is one of EMR countries according to WHO (2016) and classified as lower middle income country by the World Bank Group (WBG) in 2017 and diabetes prevalence was rising rapidly and alarming. In a cross-sectional study of 1121 Jordanians, Ajlouni et al. (2008) estimated that approximately one million people - 17.1% of the total population- were diagnosed with T2DM. This is a 31.5% increase in diabetes incidence to rates established 10 years earlier (Ajlouni et al., 1998) that was 13.4%. Moreover, WHO (2002 , 2015) stated in non-communicable diseases reports in Jordan profile that deaths related to T2DM increased from 1% in 2002 to 7% in 2010, and more than half million people have uncontrolled level of Glycosylated Haemoglobin A1c (HbA1c >7.5)[1] due to many factors such as a sedentary lifestyle and poor medication management (Khattab et al., 2010). Another study that was conducted in Jordan by Al-Khawaldeh et al. (2012) showed that more than half of Jordanian patients with T2DM had uncontrolled glycaemic level (HbA1c >7.0%) and had poor adherence to the universally recommended diabetes self-care behaviours. This is important since this study showed that glycaemic control was significantly predicted by practicing healthy diet behaviour and their self-efficacy score for diet self-care behaviour in the same sample (n=223). Studies with Jordanian populations are scarce but demonstrated that many Jordanian patients with T2DM were still in the pre-action stage of change for important self-care behaviours such as physical exercise and consuming five servings of fruits and vegetables per day

[1] HbA1c normal range is (4.6%-6.2%)

(Bawadi et al. (2012). Findings derived from the aforementioned studies in Jordan demonstrated that better diabetes management was needed.

1.4 Diabetes Self-Management Education (DSME):

Diabetes care is a complex process and requires multifactorial risk reduction strategies that necessitate complex interventions to address several essential components in diabetes management such as psychological, educational and behavioural change skills (ADA, 2015). DSME is considered as an essential element in diabetes treatment process since 1930 (Bartlett, 1986). DSME is an ongoing process that provides appropriate knowledge and skills related to patient's health condition, identifies needs and goals to enhance the capability of managing self-care behaviours, problem solving and decision-making (Marathe et al., 2017 , Beck et al., 2017). International Diabetes Federation (IDF) report in (2011) strongly recommended that patients with diabetes were encouraged to take responsibility toward better controlling glucose level and any symptoms associated. This can only be supported by appropriate diabetes educational programs on self-management. DSME was found to improve glucose level, maximized quality of life and prolonged or avoided chronic complications in a cost effectiveness manner (Haas et al., 2014 , ADA, 2015). Moreover, performing diabetes self-management activities was found to explain 90-98% of variance in glycaemic control (O'Connor et al., 2008 , Tuerk et al., 2008). Previous DSME programmes have been shown to improve metabolic outcomes for patients (Dube et al., 2015). However, these effects were generally short-lived and were not sustained for more than six months (Norris et al., 2001). They rationalised the shortcomings due to the lack of emphasis on factors such as a

patient's confidence in self-management or their problem-solving skills to address everyday barriers. However, most DSME programs in literature were not underpinned by a theoretical framework and specifically behavioural change models. Clement (1995) in a qualitative review stated that behavioural changes strategies were more effective than didactic programs, particularly, if it is integrated with a frequent reinforcement of educational messages in repeated sessions.

1.5 Why DSME is complex?

Although limited number of research studies described DSME as complex intervention (Cooper et al., 2003), management of chronic diseases such as T2DM always required extensive responsibility and high level of skills. The burden of meeting patients' needs shifted the responsibility away from health care professionals to patients by the virtue of the nature of chronic conditions. The management entails different activities such as taking medications, controlling symptoms, changing lifestyle and problem solving. Patients' involvement in the caring process was defined as self-management by Barlow et al. (2002) and necessary to reduce the disease impact on biological, psychological and social health status (Newman et al., 2004). They also stated that patients should be able to monitor his disease conditions to influence his cognition, behavioural and emotional responses to sustain an acceptable level of quality of life. Clark et al. (1991) stressed that self-management should be in accordance with the financial and social conditions of patients involved. They suggested that patients should possess appropriate knowledge of the disease and its treatment and necessary skills to successfully perform self-management activities. Optimum self-management process is

multifaceted and not only a simple adherence to treatment rules, because it includes patients' psychological and social aspects. Self-management practice was always found difficult to be achieved as reflected by poor rates of adherence to treatment regimens that were reported across several chronic diseases such as asthma, diabetes and heart failure (Cline et al., 1999 , Schmittdiel et al., 2008 , Bender, 2002). Diabetes care requires multifactorial risk reduction strategies and need a multifaceted intervention to address several essential components such as psychological, social and behavioural change in diabetes management (ADA, 2017). Therefore, these difficulties should be addressed in the development of any self-management intervention to tackle different aspects of patients' management of chronic disease. DSME reflects the characteristics of being complex intervention and should be developed as an intervention with an interacting component.

1.6 MRC framework:

The Medical Research Council (MRC), defined complex interventions as an intervention that consists of several interacting components and need to be formulated in a standardized way of design and evaluation (Craig et al., 2008). Therefore, developing and evaluating complex intervention entail systematic phased approach as have been described by Campbell et al. (2000). Developing the intervention starts by identifying an appropriate theoretical framework that correlates and link the active ingredients properly to cause a change, modelling the intervention (how does it work), and evaluation (Craig et al., 2008). Evaluation should be rigorous and comprehensive enough to understand how the intervention works and how its components are integrated within causal mechanism and manipulating

the desired effects (Greenhalgh, 2002). They stated that develop better future complex interventions requires to consider previous results from systematic reviews of DSME interventions and theoretical frameworks that were used in developing previous interventions to establish the best available evidence in literature.

MRC framework are described into five phases according to Campbell et al. (2000) and are presented in Table 1 .A pre-clinical phase to explore relevant behavioural change theories to ensure the best available evidences are followed in developing the intervention, hypothesis and familiarise with the confounders. The first phase is the modelling phase. Modelling the intervention means to recognise the active components of an intervention and understand the embedded causal mechanism that may influence the related outcomes. Understanding how components are correlated and interconnected provides a substantial information for designing both the intervention and evaluation process. The second phase is the exploratory phase that describes the constant and variable components of the intervention and outline a feasible protocol for comparing the intervention with control group. During this phase, a large amount of information is gathered throughout previous phases to be used in developing the intervention, study design and evaluation as well as defining the comparative arm. A previously established effect size is used to calculate the sample size for the definitive trial. Outcome measures should be comprehensive and relevant to the patients with the disease conditions and if possible, to be assessed in trials. The third phase is to compare the developed intervention with a control group using a controlled, replicable and theoretically based study design with appropriate statistical power that allocate participants randomly to study groups to prevent

selection bias. Outcomes should be classified to primary and secondary outcomes in this phase and long term follow up is necessary to determine the sustainability of the changes on short or long term. The fourth phase is to widely implement the intervention on long term and in other settings. Process and outcomes evaluation should be reported properly with a clear description of the intervention to allow replication and evidence synthesis using the study-related reporting guidelines to be used by others. A process evaluation adds more insight into trial intervention to understand the causal assumptions that underpinning the DSME intervention and how it works in real life. It provides more understanding into the way the intervention is implemented, how it works, elucidate causal mechanisms. Furthermore, it can identify the contextual factors that may be related to the changes in the outcomes to facilitate the assessment of the quality of the implementation. All the previous phases are recommended to be followed within any RCTs that examines the effectiveness of a complex intervention. As such, the process of developing and evaluating complex interventions require several studies, research team and fund to indicate all of them which is not feasible within PhD. However, researcher has addressed the MRC framework satisfactorily in this trial.

Pre-clinical phase	To explore relevant theories to ensure the best available evidence are followed in developing the intervention and hypothesis.
Phase 1	Modelling the intervention to recognise the active components of an intervention and understand the causal mechanism
Phase 2	The second phase is the exploratory phase that describes the components of the intervention and outline a feasible protocol.
Phase 3	The third phase is to conduct a randomised controlled trial to compare the developed intervention with a control group.
Phase 4	The fourth phase is to widely implement the intervention on long term and in other settings.

Table 1 MRC framework phases as was described by Campbell et al. (2000)

In conclusion, Campbell et al. (2007) from MRC, encourage researchers to implement behavioural change theories or models that conceptualizing measurable determinants while designing a behavioural intervention, permitting for recognizing whether the intervention was more or less effective in promoting behaviour, thus, improving the underlying mechanism of behavioural performance. The need for developing an effective DSME is crucial, and this process needs to be in a phased approach, starts by defining theoretical structure. In the next section, a review of the literature is presented to show how the intervention theoretical framework was identified using the best available evidence.

1.7 Literature review:

Searching and reviewing the literature occurred in an iterative approach to fulfil the systematic phased approach described in the above section by MRC framework. As per the recommendations of Craig et al. (2008) in their publication about developing complex interventions, published systematic reviews, stakeholders' statements and meta-analysis of studies about DSME programs were chosen to be reviewed to explore relevant evidence-based theoretical framework in the pre-clinical phase. Ideally, researcher is required to carry out systematic review unless there is one available in literature. Then, another search strategy was carried out to identify studies that used the chosen theoretical model to recognise the active components and their casual mechanism prior developing the DSME intervention.

1.7.1 DSME Systematic reviews (pre-clinical phase):

At this stage, reviewing literature review aimed to identify theoretical framework that was successful in improving the desired outcomes effectively after delivering DSME (Campbell et al., 2000). Therefore, researcher widely reviewed the literature through several databases such as MEDLINE, PubMed, CINAHL, PsycINFO, Web of Knowledge, Web of science and SCOPUS. Searching strategy used the following keywords and subject headings:

1- Diabetes: Diabetes Complications/ or Diabetes Mellitus, Type 2/ or Diabetes Mellitus/ or NIDDM/ or Non-Insulin Dependent Diabetes Mellitus.
2- Self-management: Self-Care
3- Education: Health Education/ or Patient Education as Topic/ or Education/ or Patient Education Handout/ or "Early Intervention (Education)"/ or "Physical

Education and Training"/ or Nursing Education Research/ or Competency-Based Education/ or Area Health Education Centres/ or Education, Nursing.

The outcome of the above searching strategy resulted in 642 studies where 189 studies were identified and included different delivery models such as technology or other chronic diseases alongside T2DM. Only 81 studies were about the effectiveness of DSME for patients with T2DM in RCTs. Those 81 studies were screened and found that 16 reviews had the highest quality to be included.

Zhao et al. (2017) published a systematic review and meta-analysis to synthesize the effects of theory-based self-management educational interventions on patients with T2DM in RCTs following Cochrane methods. They found that theory-based self-management education of patients with T2DM is limited in literature. The chosen studies showed improvements in the intervention groups in HbA1c, self-efficacy, diabetes knowledge, and self-care behaviours. It was noticeable that self-efficacy was improved in groups who received the intervention due to the psychological component in most of the interventions as they were theory-based. Conclusion on the quality-of-life level could not be drawn due to the heterogeneity factor.

Cheng et al. (2017) did a meta-analysis of RCTs to synthesis a scientific evidence on studies that examined the effectiveness of interactive self-management interventions in poorly controlled patients (HbA1c $\geq$ 7.5%) with T2DM. Their meta-analysis showed that interactive self-care behaviours improved significantly HbA1c, self-efficacy, diabetes knowledge and reduced diabetes-related stress. Behavioural change techniques such as providing tailored feedback on performance, problem-solving, and action planning, were associated with a significant reduction in HbA1c.

in their conclusion, they emphasized on the importance of developing complex interventions on theoretical frameworks due to the noticed weakness in the literature.

Almutairi et al. (2020) conducted a systematic review to assess the effectiveness of DSME that used patient activation intervention within patient with T2DM on their glycaemic level and self-management behaviours. They found that seven studies out of the reviewed ten studies showed significant reduction in HbA1c in patients who were in the intervention group, particularly, those who had high level of HbA1c at baseline. In addition, those that showed improvement in HbA1c had at least an improvement in one self-care behaviour such as diet, physical activity or glucose self-monitoring.

(Fredrix et al., 2018) reviewed the effectiveness of goal-setting interventions on diabetes outcomes and to identify the most frequent used behavioural change technique in those interventions. Their review found that Feedback and monitoring' techniques were less frequent and was found in only two of the 12 studies despite the fact that it is an active component of goal-setting theory and can have significant impact on diabetes-related outcomes especially HbA1c. They concluded that goal-setting technique appeared to reduce HbA1c, however, more research is needed to consolidate this evidence.

A systematic review conducted by Dube et al. (2015) on DSME studies that took place in high and low mortality developing countries. Their main aim was to provide a state of the art of current practices and assesses educational programs outcomes among published articles between 2009 and 2013. The inclusion criteria were restricted only

for studies that provided full description of the DSME intervention among patients with T2DM and were assessed using a validated checklist for measuring study quality. Accordingly, they identified three reviews and 23 primary studies that were conducted in developing countries. Despite the evidence of the effectiveness of DSME in this review, they also identified shortcomings in those DSME programs. They found that very few studies reported the qualification of those who delivered DSME or their training. They stated that without a qualified provider the quality of DSME program cannot be certain. Moreover, seven interventions were found to be steered by behavioural change theories or supported by theoretical frameworks and those found to produce significant improvement in patients' outcomes despite the methodological weaknesses in their study designs. However, they concluded that several influences were found to impact the effectiveness and sustainability of DSME programs outcomes; underpinning interventions by behavioural change theories, health care provider qualifications and the cultural sensitivity of programs. They added that by including these factors, it is predicted that the effectiveness of DSME programs in developing countries will be boosted. The ultimate goal of DSME is enabling patients adopting healthy lifestyle and it is all about the core component of changing daily behaviours, in other word, DSME programs should target patients' behavioural skills alongside with metabolic outcomes (Pbert, 2013).

Back in 2001, one of the milestones in DSME field was a systematic review that was done by Norris et al. (2001) to review the effectiveness of self-management training programs in 72 RCTs published between 1980-1999. They wanted to provide comprehensive guidelines to guide future diabetes self-management programs.

Their conclusion regarding interventions effectiveness and methodological quality assessment in the reviewed studies was noteworthy. They stated that didactic interventions that focused on providing knowledge showed a significant improvement on patients' information outcome within less than six months, mixed results on glycaemic level and blood pressure but not on weight. Despite the statistically significant relationship between the knowledge and glycaemic control in some studies, the effectiveness of knowledge on glucose level was mediated by other factors. These factors need to be addressed in future DSME interventions to improve the sustainability of glycaemic control. Although metabolic outcomes could be improved by intensive treatment, incorporating patient's attitudes and motivational strategies within educational programs proved to achieve better metabolic control than providing knowledge alone. The relationship between Self-Monitoring Blood Glucose (SMBG) and glycaemic control was not statistically significant in most studies.

Norris et al. (2001) and the team clarified that results were consistent with previous DSME reviews. Clement (1995) in a qualitative review stated that behavioural changes strategies were more effective than didactic programs, particularly, if they were integrated with medications titration and frequent reinforcement of educational messages in more than single session. Other reviews noted that effective DSME should be individualized to patients' lifestyle and routine habits, goal setting and planning; a variety of self-management training and support, considering patients' readiness to change and self-efficacy (Anderson, 1990 , Von Korff et al., 1997 , Wagner et al., 1996 , Mullen et al., 1985). According to the methodological

quality assessment, Norris et al. (2001) stressed the noticeable lack of blinding outcomes assessors, deficits in the reliability and validity of the tools used to evaluate knowledge and self-care activities. Moreover, DSME interventions were inadequately described in literature, and few studies based their intervention on behavioural change theories and data were insufficient to choose the most effective behavioural theory. They concluded that behavioural change theories had vital role and should be employed in future DSME to improve the understanding of behaviour change in self-management. They added that the impact of DSME on patient's quality of life should be a major concern in future research. All these recommendations can guide future DSME intervention, but they did not emphasise or recommended specific behavioural change theory. Another meta-analysis conducted by Norris et al. (2002) on the effect of DSME on glycaemic control disclosed that contact time between health care provider/diabetes educator and patient was the only significant predictor to show improvement on glycaemic level. To explain, total duration of 23.6 hours of contact time found to predict an absolute decrease of 1% in HbA1c and this was found to be significant to avoid or prolong diabetes complications as have been shown by the epidemiological scrutiny of UKPDS results earlier in this chapter.

Gary et al. (2003) conducted a meta-analysis of randomized educational and behavioural interventions to assess their effect on body weight and glycaemic control among patients with T2DM. They identified 18 studies that were published between 1966 and 1999 and were used in the main quantitative analysis. Briefly, they found that educational and behavioural interventions were responsible for 0.45% decline in HbA1c and this improvement was statistically significant.

Furthermore, Knight et al. (2006) reviewed behavioural educational interventions that were examined in RCTs to summarize the empirical evidence-base of DSME. They identified 37 studies that were published between 1990 and 2003. The review showed that only 50% of studies incorporated a behavioural component, only one-third used psychosocial elements in those interventions and around 20% were theoretically based. They stated that interventions based on behavioural change theories were explicitly absent. They concluded that transferring knowledge can improve glucose level only by making people behave differently, and knowledge was an essential component of DSME process but not sufficient to enhance patient's abilities for behavioural change. In addition, they suggested that producing the most effective and positive outcomes needs to develop a multifactorial intervention that should include teaching, counselling and behavioural modification strategies. These factors can influence patient's knowledge and skills to make informed choices for autonomic self-care behaviours change, empowering them to engage self-management into daily lives, and ultimately, improve glycaemic level and reduce diabetes complications. Moreover, they emphasized on the Scottish Intercollegiate Guidelines Network statement that was published in 2001 and stated that patients with diabetes should receive lifestyle interventions based on valid theoretical framework such as empowerment or motivational interviewing, follow up behaviour modification and support by telephone (2001). Their conclusion recommended that DSME interventions should integrate behavioural change theories and psychosocial concepts that potentially strengthen the link between education process and the performance of self-management activities. This can occur by motivating patients to

maintain autonomy and independence, hence, improve the effectiveness of DSME program.

In order to clarify the effectiveness of DSME, Clark (2008) reviewed the published evidence in several systematic reviews in the literature. His review concluded that there is no one superior DSME program. However, programs incorporating psychological and behavioural change strategies, culturally and age appropriate additionally with ongoing support through phone calls and behavioural goal setting techniques would ultimately improve metabolic as well as quality of life outcomes. Similarly, Borgermans et al. (2008) published a review of 21 systematic reviews that aimed to explore views on high quality diabetes care and related quality indicators. They stressed that despite the wide variety and heterogeneity in DMSE programs, no single conceptual framework was comprehensive to provide an overview of attributes of high-quality diabetes care to self-care structure, process and outcome level, and eventually, metabolic outcomes. They addressed the need for a rigorous action to develop a standardized framework on high-quality diabetes care complemented by a practical tool to provide guidance to the design, implementation and evaluation of DSME programs.

While searching for either a conceptual model or theoretical framework, Greaves et al. (2011) conducted a systematic review of 30 reviews to summarise the evidence related to the content of interventions for promoting dietary and physical activity change to their effectiveness in behavioural change enactment. In their review, they found that interventions that used self-regulatory techniques such as goal-setting theory, self-monitoring practice, providing feedback on performance and goal review

had an association with an increased effectiveness in weight loss, change in dietary and physical activity behaviours.

The Cochrane Metabolic and Endocrine Disorders Group (CMEDG) published a systematic review that was done by Duke et al. (2009) to evaluate the effectiveness of individualized DSME interventions on metabolic control, diabetes knowledge and psychosocial outcomes. Their findings showed significant advantages of those individualized DSME on glycaemic control in a subgroup analysis among patients with a higher mean baseline HbA1c > 8%. This result proposed that one of the challenges in validating DSME benefits on diabetes patients' clinical parameters are related to the patients' characteristics who participated in previous DSME studies. This can inform future DSME programs to target the appropriate patients by detecting those who have uncontrolled glycaemic level HbA1c > 8.0% and refer them to diabetes educator. Furthermore, DSME that consisted of personally tailored and patient-centred messages proved to be more effective than the generic DSME "one-size-fits-all", which is commonly delivered in the form of targeted group-level curriculum (Kreuter and Skinner, 2000).

Another systematic review of RCTs that was conducted by Baker et al. (2011) aimed to understand and translate the evidence of effective behavioural change strategies for lifestyle T2DM prevention programs that was published between 1966 and 2009. This review showed that behavioural strategies used in these interventions, included a multiplicity of theoretical methodologies including Social Cognitive Theory, the Trans-theoretical Model, and the Theory of Planned Behaviour. Their implication for future research emphasized on the integration of vigorous behavioural change

strategies in DSME programs and the noticeable absence of thorough individualized educational delivery.

As a conclusion for the above reviews, there is a continuous need for further individualized diabetes education studies based on behavioural change theory and self-regulatory techniques that need to include knowledge provision, teaching self-care behavioural skills and focus on psychological aspects such as motivations and beliefs. This may help to secure optimal effectiveness on metabolic outcomes.

1.7.2 The Theoretical Model:

A systematic review of the psychometric properties and theoretical grounding of instruments evaluating self-management activities among patients with T2DM for the published studies between 1990 and 2012 was conducted by Caro-Bautista et al. (2014). This review aimed to provide valuable information for researchers on selecting the most appropriate instrument to evaluate patients' self-care requirements in diabetes care research. They indicated that diabetes care is multidimensional and barriers in diabetes self-care behaviours are consisted with the Information-Motivation-Behavioural skills model (IMB). This model focuses on the set of Informational (diabetes knowledge), Motivational (both personal and social) and Behavioural skills (targeted behaviour-related skills) factors that are conceptually and empirically associated with changing health-related behaviour See **Error! Reference source not found.**. Indeed, this model has been used previously to address behaviours in other contexts. For example, It has been shown to be effective in the construction of educational programmes and prevention interventions for clients living with HIV risk (Fisher and Fisher, 1992).

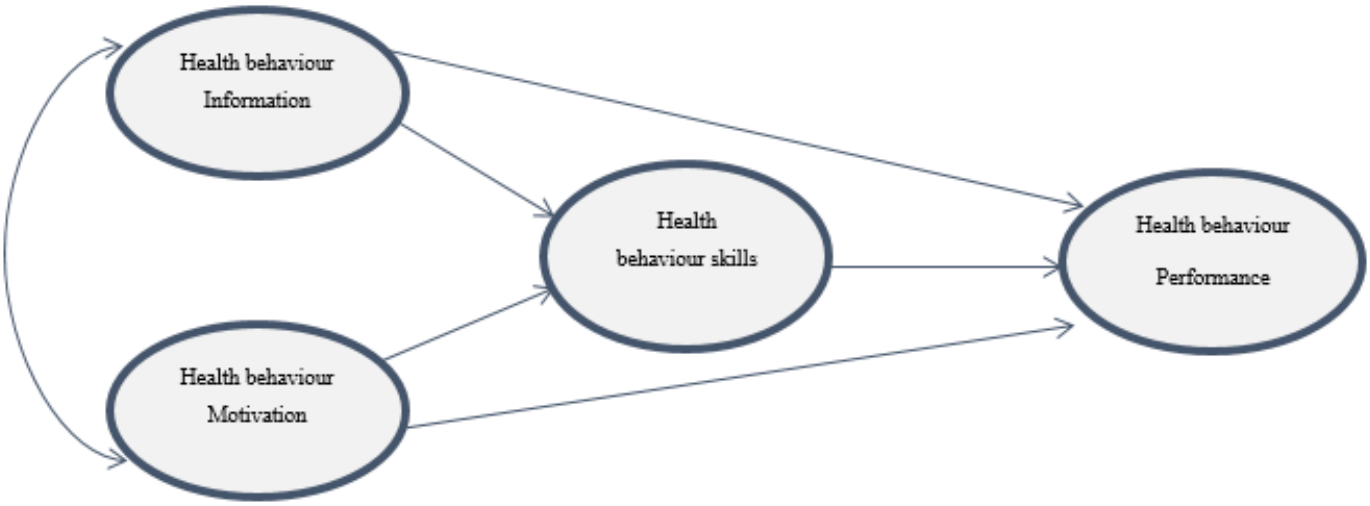


Figure 1 Information-Motivation-Behavioural model

IMB model included diabetes information and motivational constructs and both were considered the key determinants of changing patient behaviour, consequently, improving the glycaemic level. Therefore, instruments that were grounded by the IMB Model were extensive enough to assess the required personal and social motivations to promote behavioural change (Osborn and Egede, 2010).

After exploring the IMB behavioural change model, an extensive search for studies that used this model with diabetes patients took place in databases such as MEDLINE, PubMed, CINAHL, PsycINFO, Web of Knowledge, Web of science and SCOPUS for those published until 2017. Searching strategy used the following keywords and subject headings:

1- Diabetes: Diabetes Complications/ or Diabetes Mellitus, Type 2/ or Diabetes Mellitus/ or NIDDM/ or Non-Insulin Dependent Diabetes Mellitus.
2- Self-management: Self-Care
3- Education: Health Education/ or Patient Education as Topic/ or Education/ or Patient Education Handout/ or "Early Intervention (Education)"/ or "Physical

Education and Training"/ or Nursing Education Research/ or Competency-Based Education/ or Area Health Education Centres/ or Education, Nursing.

4- IMB model: Health Behaviour/ or Motivation/ or Models, Psychological/ or Adult/ or Health Education/
5- Motivation: Motivation/
6- Behavioural skills: Health Education/ or Health Knowledge, Attitudes, Practice/ or Adult/ or Behaviour Therapy/

Results of searching strategy found 393 studies where 383 studies were excluded for either being reviews, duplications or about other diseases. Ten publications were identified, and seven studies were relevant to IMB model with diabetes. In the next sections, an exploration of IMB model fundamental assumption is addressed additionally with an overview on the limited number of studies that used IMB model in the literature.

1.7.3 Diabetes self-care and IMB model:

Osborn and Egede (2010) hypothesized that the theoretical assumption of IMB model could be significantly associated with performing diabetes self-care behaviours, and this would be significantly associated with glycaemic status. Therefore, she conducted a cross sectional study to evaluate IMB model with consideration to diabetes self-management behaviour through structural equation model tests. The Information-Motivation-Behavioural skills model (IMB) was used to functionalize the main determinants of diabetes self-care behaviours and glycaemic control. They proposed that patients who had more diabetes knowledge, more personally motivated (positive attitudes toward healthy behaviour) and more socially supported for that behaviour are expected to impact the level of practicing self-care behaviours positively, thus, enhancing glycaemic control. Study findings showed that more diabetes knowledge, less fatalistic attitudes and more social motivations were not significantly correlated in the model by measuring the covariance. In contrast, they were significantly independent and direct interpreters of diabetes self-care behaviours that ended up explaining 17% of variance in SDSCA score (Osborn and Egede, 2010). Using IMB model, diabetes knowledge, diabetes fatalism and social support were not significantly associated with HbA1c, but diabetes self-care behaviours such as healthy diet, blood glucose testing and foot care were directly associated with lower HbA1c, which is consistent with IMB model assumption. These findings recommended that IMB model was appropriate to conceptualize the main determinants of diabetes self-care behaviours where information and motivation were essential elements. They concluded that more research is necessary to identify

the role of self-care behavioural skills, which were prerequisites for any behavioural change performance.

After IMB model Validation study, Osborn et al. (2010) conducted a randomized controlled trial to evaluate a brief intervention that was developed to address predefined barriers and facilitators of Diabetes Self-Care Behaviours (DSCBs). The intervention was delivered based on motivational interviewing strategies to provide Puerto Ricans patients with T2DM the knowledge and behavioural skills. The model drove the intervention's design, content, delivery, and evaluation. However, they hypothesized that patients in the intervention group are expected to have better outcomes than control group in glycaemic control and diet adherence and physical activities. They did not follow up study participants and delivered the educational message in one session.

The intervention was based on three elements of IMB model and interwoven into one session lasted approximately 1.5 hours. As far as the intervention was evaluated after three months endpoint, patients in the intervention group were reading food labels and adhering to the diet recommendation significantly more than patients in the control group from baseline. On the other hand, there was no significant effect on exercise behaviour between groups from baselines despite the higher score of physical activity among patients in the intervention group from baseline compared to control group. As for glycaemic control, patients in both groups showed an improvement in HbA1c and decreased from baseline, but improvement was only significant among patients in the intervention group. However, adjusted HbA1c values didn't change between the intervention and control groups at endpoint.

At the end, they concluded that intervention was effective enough to decrease HbA1c by 0.48% in the intervention group through an hour and a half contact time. Regarding contact time, Norris et al. (2002) proposed earlier that patient contact time was the only clinical significant predictor of improvement in HbA1c and concluded that 1% decrease in HbA1c required 23.6 hours of contact time. Osborn et al. (2011) stated that their IMB model-based intervention improved HbA1c by what it equals 11.8 hours to achieve according to the results published by Norris et al. (2002). Moreover, the they stated that the impact of their intervention was greatest among those with higher levels of HbA1c >7%, a secondary analysis showed a reduction of 0.80% in HbA1c in the intervention group from baseline in another publication for the same study (Osborn et al., 2011). This study was the first to design a culturally tailored diabetes self-management intervention based on IMB model. It showed the potential usefulness to be used for designing future individualized diabetes self-management interventions. They recommended that IMB model has shown its usefulness to be used for designing future individualized DSME interventions and suggested that providing several follow up sessions by phone calls or home visits over an extended period of time would enhance the intervention effectiveness by giving more time to practice the educational content to implement multiple behavioural changes. In addition, follow up period would be crucial in future studies to uncover the sustainability of the intervention impact on diabetes self-management behaviours and glycaemic control. Furthermore, Osborn et al. (2010) published an analysis of MB model on diet and exercise self-care behaviours for the same conducted RCT among Puerto Ricans to discuss the efficacy of using IMB model

in designing and evaluating DSME that are focused on promoting healthy eating and physical activity behaviours.

Data was analysed by structural equation modelling to identify the relationship among the constructs for each of the diet and exercise self-care behaviours. Osborn et al. (2010) showed that the model accounted for 46% of the variability in diet behaviour and was significantly related with lower HbA1c level. In contrast, exercise self-care behaviour has been explained by the IMB model and accounted for 23% of the variability but the behaviour was not significantly associated with lower HbA1c. However, she referred the non-significant association with HbA1c for the lack of sufficient sensitivity of the used measures to detect true relationships and the possibility of being a cross sectional study that measuring all constructs at a single point of time. She concluded that the results supported using IMB model to conceptualize diet and exercise behaviours determinants and to develop IMB model-based intervention targeting diet and exercise self-care behaviours.

In Iran, Gavgani et al. (2010) conducted a study to assess the effectiveness of IMB model on self-care behaviours and HbA1c among 30 patients with T2DM who had HbA1c>7% and attending an endocrine specialization clinic. Patients were assessed for their diabetes self-care activities by SDSCA, weight and HbA1c were measured at the day of clinic visit and after two months. They concluded that providing knowledge and motivation to improve behavioural skills in diet adherence and physical exercise were beneficial in improving behavioural change and HbA1c level among patients with T2DM. In Gavgani et al. (2010) study, there were limitations such as small sample size that would threat the generalizability of the results and limited statistical

power. In addition, there were not any details mentioned in study manuscript about study design, participants' allocation sequence or the description of intervention.

1.7.4 Diabetes self-care in Jordan:

The only study in Jordan was a RCT conducted by Jarab et al. (2012) to evaluate the effectiveness of a pharmacist-led intervention program on metabolic outcomes and self-management behaviours among uncontrolled T2DM patients (HbA1c>7.5%). Patients were recruited and allocated to either intervention group or control group within a period of four months. However, patients in the intervention group were given a home copy of an educational booklet on meal planning, physical activity and medications management and were prepared to assist them in educational sessions. Each patient received 8 weekly phone calls to provide feedback for their concerns. Each call lasted approximately 20 minutes to emphasize the importance of adherence to the prepared plan. On the other hand, patients in the control group received only the usual care that included a treating physician visit each three or six months. In their study, a sample size of 250 patients attended the primary clinic and were assessed for eligibility where only 180 patients were eligible. Clearly, due to many causes such as refused to complete follow up period or absence of outcome measurements, 77 patients completed the study in the intervention group and 79 patients in control group. Patients in both groups were assessed at baseline and at the end of 6 months for medications adherence and diabetes self-care behaviours. After data analysis, patients in the intervention group showed a significant reduction in both systolic and diastolic blood pressure, lipid Profile except HDL and a significant reduction of 0.8% in HbA1c over six months compared to patients in the control

group. Whereas for BMI, patients in the intervention group experienced reduction in weight compared to control group, but this reduction was not statistically significant.

They concluded with the recommendations of providing individualized self-management education by determining types and proportions of healthy eating, physical exercise, regular telephone follow up support as well as optimizing pharmacotherapy. All these factors helped in significant improvements in study outcomes. But there were some methodological limitations in their study; for example, the educational intervention was not established on theoretical framework and was not explicitly described and lacked in assessing the outcomes blindly by an independent assessor.

1.7.5 Why using IMB model?

In particular, IMB model provides a simple theoretical framework for complex behaviours that makes it easier to be translated empirically as well as specify relationships between constructs. In Osborn et al. (2010) study, the effectiveness of DSME using IMB model in 1.5 hours session was significant enough to decrease HbA1c compared to 11.8 hours needed to accomplish the same decrement. Although, this considerable improvement was as a result of one session, using ongoing educational support that addresses multiple self-care behaviours can enhance the sustainability of patients' self-management behaviours, which was recommended by Norris et al. (2001); thus, extend the improvement of glycaemic control. In addition, Chang et al. (2014) systematically reviewed the IMB model-based behavioural interventions to investigate specific intervention strategies and to evaluate their effectiveness for people with different chronic diseases. They detected

12 studies, of which nine studies investigated patients with HIV. They concluded that IMB model is a robust theoretical framework for developing behavioural interventions among patients suffering from chronic diseases. In their review, they found that the effects of IMB model-based interventions on behavioural changes can persisted up to 12 months and this was clear in those studies that followed up patients for 12 months. Moreover, a report by Fisher et al. (2014) stated that IMB model was widely used in cross sectional studies and need to be further tested in experimental research. They stated that those studies that used IMB model and tracked the induced changes in IMB main determinants are very few in literature and remain a challenge.

1.7.6 Current Research Gap:

The literature is still limited in studies examined individualized DSME programs underpinned by theoretical framework, particularly, behavioural change theories. Several limitations in literature should be addressed in future studies such as: frequent reinforcement of educational messages more than single session, integrates psychological factors and being individually tailored, patient centred as well as suites busy clinic.

Rigour methodological techniques in developing intervention and study designs such as employing blinding outcomes assessor additionally with using reliable and valid tools to evaluate the intervention are prerequisites in forthcoming studies. In addition, implementing IMB model would consider a unique step in diabetes care providing a high-quality standardized framework to guide the design, implementation and evaluation of DSME program.

DSME interventions were widely examined through RCTs in literature and very few studies used qualitative method or used combined methods to evaluate the effectiveness. therefore, the original plan was to study the effectiveness of IMB model-based intervention using a a mixed-methods approach but due to the timeline of the PhD program, it was agreed to examined the effectiveness through randomised controlled design due to the high level of control in this design in comparison to other study designs.

1.7.7 Research hypothesis:

The primary hypothesis in this trial entailed that participants who received the IMB model based DSME in the intervention group were predicted to experience greater improvement in three self-care behaviours; diet, physical activity and medications management, than participants who received the Treatment As Usual (TAU) in control group at three-month and six-month points. A secondary hypothesis proposed that those who received the IMB model based DSME were also predicted to report greater level in diabetes knowledge, motivation, behavioural skills, quality of life and glycaemic control compared to those in control group at three-month and six-month points.

1.7.8 Research question:

The research question in this trial was formulated as follow: what is the effectiveness of the IMB model based DSME intervention on the three self-care behaviours, diet, physical activity, medications management self-care behaviours and on other secondary measures such as HbA1c and quality of life at three-month and six-month visits among patients with T2DM compared to the usual care in Jordan?

2 Developing and designing the IMBDSME intervention:

As mentioned above in section (1.4), DSME interventions are important in diabetes management to change unhealthy lifestyle behaviours to improve glucose level and avoid microvascular or macrovascular complications. DSME needs to be multifaceted and includes several interactive components to be effective as was described by the MRC as complex interventions. Therefore, DSME interventions should be underpinned by behavioural change theories and effective strategies to alter patients' behaviours and achieve constructive behavioural outcomes.

According to MRC framework in section (1.6), the process of developing complex intervention such as DSME is a phasic process and starts with collecting the best evidence and choosing a theoretical framework from the literature before progressing to modelling. In the previous chapter, it was explained why the IMB model was chosen as the theoretical framework where it was used to link the essential determinants of the IMB model with the required behavioural change techniques in this DSME intervention.

2.1 Theoretical framework (IMB model):

The Information-Motivation-Behavioural skills (IMB) model focuses on set of factors of informational, motivational and behavioural skills that are conceptually and empirically associated with changing health-related behaviours. It determines a set of causal relationships among the constructs as well as a set of techniques to be employed in translating the model into behavioural change interventions (Fisher and Fisher, 2000). This section introduces the origins of the IMB model and its fundamental assumptions.

2.1.1 IMB model development:

William Fisher and Jeffery Fisher, both used the concepts of previous models and theories such as the theory of reasoned action (Fishbein and Ajzen, 1975), theory of planned behaviour (Ajzen, 1991) and social-cognitive theory (Bandura, 1977) to construct the Information-Motivation-Behavioural skills (IMB) Model. The IMB model was critically constructed based on analysing previous prevention programs and health promotion interventions as well as addressing limitations of the aforementioned theories that have been used in other areas of health behaviour in the literature such as HIV risk and prevention interventions (Fisher and Fisher, 1992). Limitations such as the absence of a clear definition of the specifications of the relationships between active ingredients, weakness of predictive validity between the constructs, lack of constructs that might be essential to the changing of health-related behaviours and finally the difficulties in empirically translating the theoretical constructs were inherited in those theories. As a result, those theories became intuitively translated and the benefits were diminished to generate substantial literature (Fisher et al., 2003). They developed the IMB model to involve and implement social psychological factors of HIV risk in future preventive behaviours (Fisher and Fisher, 1992 , Fisher and Fisher, 1993).

2.1.2 IMB fundamental assumption:

The IMB model fundamental assumption proposed that health-related behaviour information, motivation and behavioural skills were primary determinants of promoting health behaviour. As a fact, the model assumes that a well-informed client, well-motivated and possess the required behavioural skills of a specific

behaviour is more likely to initiate and adjust a health promotion behaviour positively. Figure 2 presents the IMB model constructs.

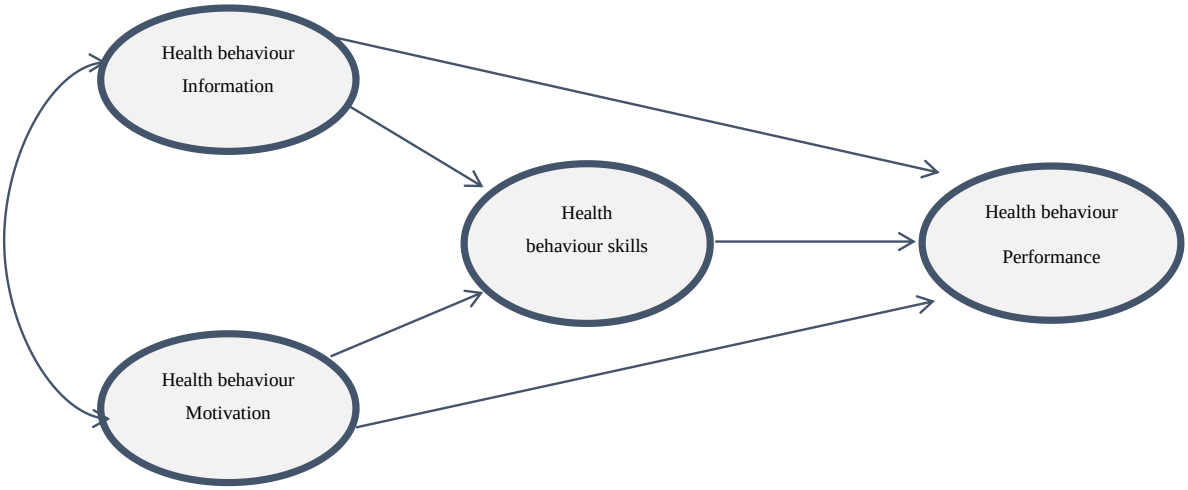


Figure 2 IMB model constructs adapted from Fisher and Fisher (1992)

According to the IMB model, health behaviour information is directly associated with the health behaviour skills and can be indorsed easily in client's social environment, which is essential in behavioural performance, and can indicate simple facts or relevant heuristics that tolerate rational decisions automatically to interfere and guide effective health promotion behaviour (DiClemente et al., 2002).

Motivations to involve in health promotion behaviour is another primary determinant of health behavioural change that well-informed individual is persuaded to perform what they know about health behavioural skills. According to IMB model, motivation has a critical influence on performance of health promotion behaviour in two ways, personal motivation and social motivation. Clearly, personal motivation is demonstrated in the personal attitudes toward performing specific health–related behaviour, and social motivation is implied as the perception of social support for engagement in a health-related behaviour (Fisher et al., 2003).

Behavioural skills determinant is the third and last critical part of the IMB model of whether well-informed and well-motivated individual is more likely to practice the health promotion behaviour effectively. The behavioural skills determinant is composed of client's actual objective abilities and his perceived self-efficacy regarding the practice of specific health behaviour (Fisher et al., 2003).

The IMB model determines that both information and motivation of a health-related behaviour are expressed through the deployment of behavioural skills, which directly influence and initiate the performance of that behaviour (Fisher and Fisher, 2000). Furthermore, the model also asserts that information and motivation have direct effect on initiate and practice the behaviour, in a fashion that behaviour does not requisite to possess such behavioural skills as critical element (Fisher and Fisher, 2000). From IMB model perspectives, well informed client should not be necessarily well motivated to perform health promotion behaviour, and highly motivated client should not be necessarily well informed to practice health promotion behaviour, which potentially implies that those two constructs are independently associated (Fisher and Fisher, 2000).

2.1.3 IMB model procedures:

The IMB approach to promote and understand specific health-related behaviour specifies number of procedures in order to design, implement and evaluate particular population's health promotion behaviour of interest. **The first procedure** is to assess weaknesses and properties related to the information, motivation and behavioural skills of specific health behaviour for particular population of interest (Fisher et al., 2003).

The second procedure involved designing and implementing conceptually based and empirically targeted intervention. The identified weaknesses and properties in the assessment procedure and are related to the information, motivation and behavioural skills determinants should be addressed and treated in the empirically targeted intervention (Fisher et al., 2003).

The third and final procedure involved the conduct of methodologically rigorous intervention evaluation to conclude whether the intervention can produce significant effects on the level of information, motivation and behavioural skills determinants that are directly related with performing and maintaining particular health promotion behaviour (Fisher et al., 2003). The IMB model set of procedures are well explained in Figure 3.

Figure 3 the IMB model set of procedures

2.2 Developing the trial Intervention:

The process of developing and designing complex interventions has always been considered as challenging. In literature review in (1.7), it can be seen that theories of behavioural change offer little information about how to select and identify the appropriate methods or techniques and translating them into practice. Equally, there is a lack of a detailed guidance on how to progress through the initial phases of the MRC framework for developing complex intervention, in particular, the referral to develop a theory-based intervention. Subsequently, these theories were used more commonly to inspire the development of interventions or to develop measures rather than developing theory-based interventions. As a result, a framework was required to provide researcher with a manual to decide at each step during intervention development, and in this trial, researcher followed the Intervention Mapping (IM) approach.

2.2.1 Intervention Mapping (IM) concept:

The process of mapping behavioural change techniques on the behavioural determinants of a chosen theory is called Intervention Mapping (IM). It is a problem-driven process and explains how to integrate theories and behavioural outcomes stage by stage during the intervention development. IM is essential to advance the benefits of developing theory-based intervention and achieve behavioural outcomes (Eldredge et al., 2016 , Bartholomew and Mullen, 2011). It was used to develop self-management programs for several chronic diseases such as stroke, asthma, diet and physical activity (Schmid et al., 2010 , Dima et al., 2016 , Brug et al., 2005). The IM approach can be applied to target multiple levels such as individual, community or

organisation. However, in this trial, the aim was to develop and examine an individualised DSME intervention to change the behaviours of patients with T2DM as mentioned in section (1.7.7), thus, IM was utilised to design an individualised DSME intervention based on the IMB model. Although IM approach can be applied through several steps and each one forms the base for the other, IMB model also proposed its own set of procedures and behavioural determinants which were presented earlier in this chapter in (2.1.3). Therefore, researcher integrated both to develop the intervention and to inform the design of this trial and the intervention delivery. The DSME intervention in this trial is called IMBDSME throughout this document.

2.2.2 Intervention Mapping (IM) steps:

First, according to the first procedure of IMB model, an assessment for behavioural determinants of a health behaviour was required before implementing the intervention. It was required first to choose health behaviours that need to be changed or improved. However, by following the first step of IM approach, the needs of patients with T2DM in Jordan were identified within the literature. Those self-care behaviours were diet, physical activity and medications management as was explained clearly in (1.7.4). Therefore, their behavioural determinants according to the IMB model (Information, Motivation, Behavioural skills) were assessed along with clinical measurements during the trial as is presented in trial design in section (3.11).

Second step by IM approach was defining goals and behavioural outcomes. Fundamentally, trial outcomes were required to be linked with the targeted health behaviours. After detecting the behaviours of interest during the need's assessment,

trial outcomes were defined, and they are presented in (3.7) and (3.8) and were linked to the IMBDSME intervention.

The following step by IM was to identify a theory that provides a theoretical base of determinants of behaviour change. Correspondingly, this step was the core of the second procedure of IMB where it discussed the need to develop and design a theory-based intervention. This step was crucial because it required the linkage of IMB determinants (knowledge, motivation, behavioural skills) with behavioural techniques by creating a matrix guided by the IMB theory determinants. By creating the matrix, it was simpler to stem proximal change objectives. Those change objectives were considered as the mediating factors for changing specific behaviours and were demanding IMBDSME intervention to influence the targeted behaviours, and thus, achieve the desired performance and improve quality of life and glycaemic control. In this case, the change in IMB determinants (knowledge, motivation, behavioural skills) were demanding the IMBDSME intervention to influence diet, physical activity and medications management self-care behaviours.

At that point, it was required to select the methods and strategies to develop the IMB determinants to achieve each change outcome. Not all determinants required the same strategies or methods. So, due to practicality reasons as well as the timeline of the development of DSME intervention, researcher selected different strategies or methods to fulfil the requirement of every determinant as shown in sections (0), (0) and (2.2.2.3) below.

After selecting methods and strategies, researcher proceeded to construct IMB determinants together along with their methods and planned for the

implementation and delivery as explained in detail in sections2.2.2.4) and (2.2.2.5). Then, following IM approach and IMB procedures, last step was to perform an evaluation of the effectiveness of delivering IMBDSME intervention on the main determinants, clinical outcomes and on the performance of self-care behaviours. Therefore, evaluation was conducted by an independent assessor after the delivering the intervention and after following up period as explained later in chapter (3).

2.2.2.1 Knowledge determinant:

To start with the knowledge determinant, literature was searched for an educational material to be utilised as a source of diabetes-related information. Evidences in literature stressed that patients with low literacy and numeracy levels were independently associated with poor health-related outcomes such as glycaemic control (HbA1c) and self-care behaviours (Schillinger et al., 2002 , Cavanaugh et al., 2008 , Tang et al., 2008). Moreover, Cavanaugh (2011) stated that low level of health literacy is prevalent among patients with T2DM and might range from 15%-40% depending on the targeted population. For Jordanian population, Ajlouni et al. (2008) found that patients with T2DM in Jordan were older and less educated compared to those who had a normal glucose level in their prevalence study. Out of those who were diagnosed with T2DM, they had a mean age of 55.5±10.6 years, and mean level of education of 6.3±5.6 years of education. Based on their results, patients with T2DM in Jordan were more likely to be older age and having an elementary level of education. It was clear that any efforts to develop IMBDSME programs should consider the low level of literacy for Jordanian patients with T2DM to produce an effective and comprehensible DSME intervention. An educational toolkit called PRIDE that fir the above requirement was selected and adopted to provide the knowledge regarding the targeted diabetes self-care behaviours.

PRIDE toolkit builds on the previously validated Diabetes Literacy and Numeracy Education Toolkit (DLNET), which was developed by Wolff et al. (2009), the American College of Physicians Foundation's Living with Diabetes Guide (CPFLDG) and the American Association of Diabetes Educators (AADE). DLNET was modified to produce

PRIDE based on the recommendations of American Diabetes Association (ADA) and AADE national standards for DSME as they stated that DSME materials should allow for cultural adaptation, interactive, include action oriented behavioural goals, be sensitive to patients with low literacy and numeracy skills and capabilities to afford treatment. The PRIDE toolkit text, layout and format were developed by literacy and numeracy experts, behavioural psychologist and diabetes specialists allowing for patients with low-literacy and numeracy skills to be educated through behavioural-oriented images and pictograms, colour coding and plain simple language to avoid information complexity. PRIDE toolkit included a comprehensive set of 30 education modules in English to support different self-care health behaviours of T1DM and T2DM. All modules were designed to be used interactively between health care providers and patients. They were grouped into 12 categories: general information about diabetes, blood glucose monitoring, nutrition information, oral diabetes medication, insulin and exenatide, lifestyle management and behaviour change, foot care, cardiovascular risk factors, coping with stress and depression, oral health, women's health, and men's health. PRIDE modules are shown in Appendix 1.

Wolff et al. (2016) used the Suitability Assessment of Materials (SAM) instrument to evaluate the PRIDE modules. SAM instrument was used to determine the weaknesses of each module that may decrease their suitability for low-literacy patients. The mean score of SAM instrument received for the modules was 91.2% (SD ± 5.4), which is a superior score according to SAM scoring criteria that was evaluated by two independents assessors. The mean reading grade level of the 30 modules was 5.3 ±1.0 ranging from the lowest of 3.7 when it was calculated by the Automated

Readability Index (ARI), and to a maximum of 7.7 when it was calculated by Simple Measure of Gobbledygook (SMOG). ARI and SMOG are online instruments; ARI is a readability test to assess the understandability of a text, while SMOG formula is method to evaluate the reading level of a written material. As for the content of the PRIDE, they concluded that all 30 modules scored at or below 8th grade level using SAM. Wolff et al. (2016) concluded that PRIDE modules were found to be literacy sensitive to patients with T2DM who have literacy and numeracy skills deficiencies.

In this trial, the selected PRIDE modules were related to the targeted self-care behaviours diet, physical activity and medications management and included in IMBDSME intervention. As an introduction to diabetes, general information about diabetes low blood glucose and were included in the first chapter for those who received the intervention. However, insulin and glucose monitoring modules were not included and handed unless they were being treated by insulin. Hence, insulin and glucose monitoring modules were prepared separately to be delivered for those who required them. For diet self-care behaviour, modules such as “Introduction to Eating with Diabetes”, “using your plate to control your carbs”, “Eating Out”, “How Losing Weight Can Help Me”, “What Can I Eat for a Snack” and “Cholesterol” were used to inform about healthy diet lifestyle as was recommended by guidelines of ADA (2019) and AADE. For example, the three main food groups (carbs, protein and fat), how food affects the blood glucose level, tips on healthy cooking and how to reduce fat or control the cholesterol level, what consider as a snack, difference between high and low carbs food as well as lists of culturally appropriate (Jordanian) food for each food group that can be consumed on breakfast, lunch and dinner. For physical

activity, “Be Active” module was used to inform patients how to be more active during the day. For example, exercising healthy walking, using stairs instead of lifts and creating fun ways such as dancing. For medications management, “Diabetes Pills” and “Taking your Medicines” modules were used to inform patients about the importance of adhering and managing their medicines. While for patients on insulin treatment, modules such as “Drawing and Self-Injecting Insulin”, “Where to Give Insulin Shots” and “How to Use Insulin Pen” were explained through linear steps pictograms to show patients the correct way of using and injecting different types of Insulin such as pre-mixed, long or short acting insulin whether they use pen or syringe. To achieve the maximum benefit from insulin and reduce hypoglycaemic episodes, copies of blood glucose log sheets enough for the trial period were given to follow their blood glucose readings and the amount of administered insulin prior each meal. The log sheet aimed to correct their insulin doses according to their glucose readings during the interventional phone calls to stabilise HbA1c level.

2.2.2.1.1 Translating and adapting PRIDE:

To start with the adaptation and translation process, corresponding authors of PRIDE toolkit were contacted in Vanderbilt university by email, and they sent all the PRIDE modules with the permission to translate it to Arabic language and to use it as an educational toolkit in this trial. However, the required PRIDE modules were translated literally to Arabic language except the original food lists for breakfast, lunch and dinner as they need to be set by a dietician. In that meantime, two independent bilingual Jordanian dieticians offered to contribute to the food lists chapter of the PRIDE Arabic-version. They replaced all western food lists with an

Arabic-translated local food lists that match the Jordanian culture regarding all daily meals. It was stressed out that any food lists replacement must be coherent with the contents of the English-version PRIDE. All translated materials were sent to an independent professional translator to back translate them into English language except for Jordanian food lists. Then, the translated and back translated PRIDE versions were thoroughly scrutinised by researcher, two dieticians and a Jordanian bilingual endocrinologist to produce the final version of PRIDE Arabic-version. The final Arabic-version was handed to three senior patients with T2DM who were randomly chosen to comment on and express their opinions upon the modules and food lists. As a result, although they were pleased with the graphical content and the simplicity of the design and guidance style, they suggested to add some local food that are being eaten in rural areas of Jordan. However, their suggestions were introduced to the dieticians who were aligned with the new input and the final Arabic-version of PRIDE modules was produced and printed without any changes to the original design and format. The PRIDE Arabic-version was used to support the knowledge determinant in the IMBDSME intervention and piloting the final version prior starting the trial was not feasible due to the timeline of the PhD program.

2.2.2.2 Motivation determinant:

It is very clear that motivating disinclined patients is considerable a significant challenge among Health Care Professionals (HCPs) (Hardcastle et al., 2015). As for the motivation determinant, Motivational Interviewing (MI) approach was utilised and was first described by Miller and Rollnick (1991). To be trained for using MI style, researcher received an advanced training in MI by Stephen Rollnick the co-founder of MI in Cardiff medical school before conducting the trial. MI is a focused, patient-centred counselling approach for provoking behaviour change. MI is used to engage with patients' health problems and discuss their strengths and weaknesses. The core purpose of MI was to prompt their inner motivation and solve their ambivalence, hence, promoting patient's autonomy of decision making. During the course of MI, the HCP maintains the direction of the consultation when providing any necessary information related to a specific behaviour, and at the same time, ensures that the patient preserves the responsibility over the change. MI was commonly applied in various healthcare settings with people who required assistance in behavioural change. It showed a great efficacy with patients who had an uncontrolled diabetes, alcohol and drug addiction problems (Rollnick et al., 2010 , West et al., 2007) . Indeed, a systematic review conducted by Ekong and Kavookjian (2016) showed a promising results of MI to improve dietary behaviours and clinical outcomes. Therefore, it is believed that MI approach can be effective with patients with T2DM who are ambivalent to change their unhealthy DSCB behaviours.

2.2.2.2.1 Spirit of Motivational Interviewing (MI):

MI is not a technique and it is important to differentiate between the spirit of MI and the techniques that are used to show its spirit. MI spirits can be described in few points and they are; motivation to change should not be enforced rather to be provoked, solving the patients' ambivalence is not the HCP mission, direct confrontation needs to be avoided with them, MI counselling style is quite and passive approach, the HCP intention is to help them to resolve fluctuation to change, this fluctuation in readiness to change or resistance is a reflection of therapist behaviour and not an inherited attribute of patients, and lastly, the therapist-patient relationship is partnership or comradeship rather than sender-receiver relationship.

HCPs who used Motivational Interviewing (MI) style practised specific skills and most importantly focused on active listening during the communication process with patients. According to MI, it is recommended to use open-ended questions to understand the situation and their surroundings through active listening, showing acceptance and affirmation, reinforcing their concerns and intention to change through reflective listening, monitoring their responses and willingness to change known as "change talk" without generating resistance, the more change talk and less resistance talk the highly likely of subsequent behavioural change (Hettema et al., 2005). Lastly, summarising by respecting their choices and self-determination.

Amrhein (2004) stressed the importance of the content and strength of change talk, thus, those who plan to utilise MI should be trained how to exercise MI during the change talk and this could be seen as burden. When patients' speak about a specific behaviour, the HCP needs to focus on problem recognition and tries to bring to light

or read up on the clients' ambivalence, and then, providing the opportunity to assess for themselves what they need next and how they think they can achieve it. This way gives the responsibility of self-management daily work to be done by them where the HCP can offer some help and practical advice to overcome real life obstacles during the performance of a specific self-management behaviour. To support clients toward their responsibility, it was stressed by (Burt et al., 2014) on the importance of documenting patient-centred plans and goals. For that reason, a technique called Brief Action Planning (BAP) was used in this trial used to support clients to make behavioural changes that can be implemented in their practical life.

2.2.2.2.2 Brief Action Planning (BAP):

BAP is a structured self-management technique that comprises of three main questions and five skills. BAP integrated principles and practice of MI to facilitate patient-centred goal settings and action planning to enhance self-efficacy in managing their chronic condition. This technique was developed into this current version by Gutnick et al. (2014). and was consistent with MI style that was described as the spirit of MI in the previous section. BAP technique allowed those who received the IMBDSME intervention the opportunity to express what self-care behaviours they need help with and what they can do about them once engagement was established. This was the first question of BAP to provoke patients' interest in self-care or behaviour change. Once they were ready to change, they generally were used to respond by either they had an idea and knew what they needed, or they did not know what to do afterwards. For those who were not sure what they wanted to do, three main skills were used after answering the first question of BAP. In the first skill, they

were asked for their permission to discuss and share some ideas on three Diabetes Self-Care Behaviours (DSCBs); diet, physical activity and medications management. Those behaviours were offered on table to provide participants with the opportunity to choose which one they wished to start and work on. At that point, they were required to choose one self-care behaviour which was frequently a behaviour that they were more familiar with or in other words easy task for them to enhance their self-efficacy toward diabetes self-management daily task as was recommended by Lenz and Shortridge-Baggett (2002). They stated that patients were more likely to succeed with easy task than complicated task until eventually practicing the complete management of T2DM. Experiences of success can provide patients the proof that they can succeed while negative experiences can disrupt the feeling of self-efficacy. Previous experiences whether successes or failures can greatly attribute to persons' self-efficacy (Bandura et al., 1999). Then, it was proceeded to the second skill where they were offered to create an action plan that had Specific, Measurable, Achievable, Relevant and Time-lined (SMART) goals. To help creating those SMART goals, researcher used to probe patients with questions that were related to the plan such as what, when, where, how frequent and how long, and utilized the answers to inform SMART elements. Consequently, the discussion used to end up with eliciting a commitment statement, and this was the third skill. After that, it was important to ask the patient to repeat back the action plan and commitment statement to prop up an inner self-reflection about the feasibility of its implementation. Repeating backs skill smoothed the way to ask the second question of BAP where researcher asked patients to express how confident/ sure they felt to achieve the SMART goal

they had committed to perform. They were asked to choose a number on a scale from zero to ten where ten was “totally confident” and zero was “not confident at all”. Those who scored less than seven had a problem-solving discussion to come up with any ideas that could assist to overcome the low confidence level (skill four), otherwise, researcher would have referred back to the behavioural menu again, while those who scored with a confidence level of seven and over were asked to allow the researcher to revise action plan and goals with them on a later date, which was the last question of BAP. At that instant, patients knew their SMART goals and they were highly likely sure to practice them afterwards, they were informed that their progress about following the proposed action plan and their SMART goals is going to be revised during the next intervention phone call. Klinkner et al. (2017) showed that exercising goal-setting documentation was statistically highly likely associated with an increase in the amount of support received from nurses in their study. Therefore, and to support reporting their progress and goal achievements, patients were provided with twelve copies of weekly logs to document their progress over the intervention period as it is presented (3.11.2). The fifth skill of BAP was following up the patients’ self-care behaviours plan either by modifying their BAP or making new BAP, and this was originated as part of the clinical trial design as presented in (3.11).

2.2.2.3 Behavioural skills determinant:

Although most of the required knowledge and information for diet, physical activity and medications management self-care behaviours were documented in the Arabic-translated PRIDE version as mentioned in (2.2.2.1), behavioural skills were portrayed alongside as well. Behavioural skills were necessary to enhance patients' self-efficacy to support the implementation of each self-care behaviours. Those skills were explained and discussed with patients during the interventional phone calls and were not necessarily required to be discussed face to face.

Multiple behavioural skills for diet were portrayed in the educational toolkit. Skills such as "Dividing the Plate" helped patients to learn how to control their carbs intake during lunch and dinner. A pictogram of 9-10 inches plate was used to show the user how to divide the plate into three parts to put together the three main types of food as well as a pictogram to show the palm of hand to teach them what counts as one serving as illustrated in Figure 4.

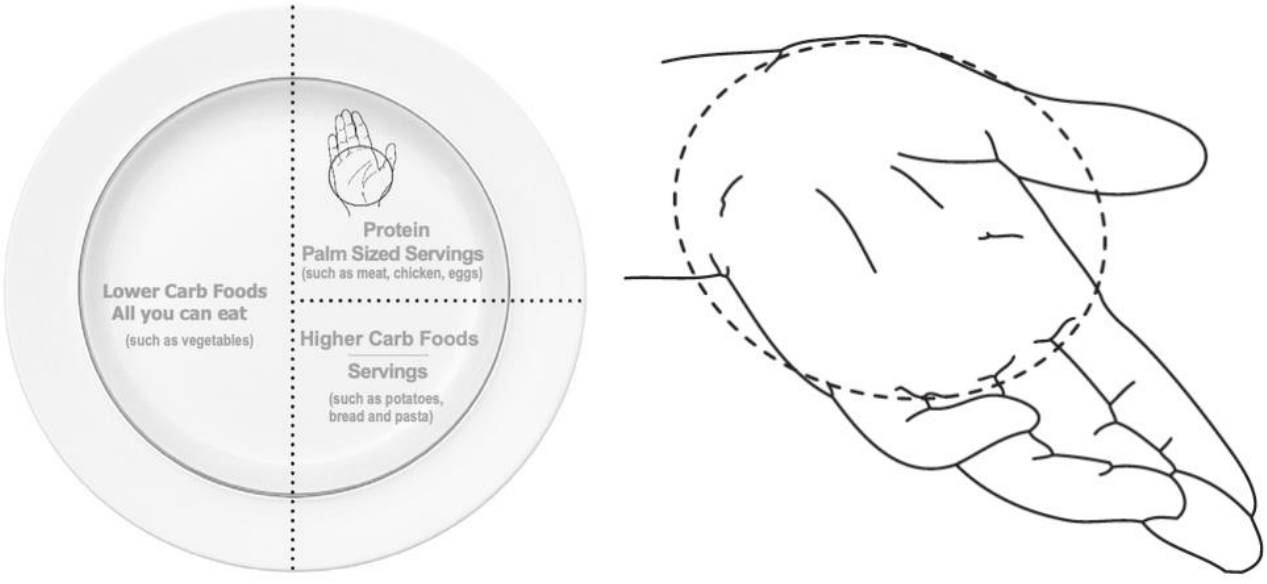


Figure 4 A 9-10 inches Divided Plate and Palm of Hand to teach Diet Behavioural Skills (Source: PRIDE toolkit).

For physical activity self-care behaviours, the introduced skills helped patients to prevail over the difficulties of practicing the recommended healthy walking. Examples of those skills that were suggested, chair exercises for those who complained about knee or joint pain, stairs instead of lifts for those who had place and time restrictions due to their job nature and practicing with a company such as family member or friend if they felt lonely or bored during physical activity.

For medications management behavioural skills, appendix for insulin dose adjustment was discussed with patients who experienced a fluctuation in their daily blood glucose level if they were prescribed insulin. Those appendixes helped patients to manage their daily doses to receive the right amount of insulin according to their health condition and base on their blood glucose reading as they usually receive a fixed set of doses from their treating physician. The appendix is presented in the appendices (8).

2.2.2.4 Constructing the IMBDSME intervention:

Although it can be seen that researcher defined all determinants of IMB model for the trial self-care behaviours, this did not mean that IMBDSME intervention was ready to be delivered. As part of Intervention Mapping (IM), it was required to construct the three determinants together to form the intervention and plan for the implementation. While delivering those determinants could have been done using different approaches, the aim was to use the best evidence available and implement the IMBDSME intervention using evidence-base techniques. Therefore, and to build up the intervention, various effective techniques were utilised from the literature above in section (1.7) as well as from key DSME systematic reviews that were conducted by (Dube et al., 2015 , Norris et al., 2001 , Clement, 1995). Those DSME techniques were recommended by different scholars who stressed the importance of including them in future DSME interventions. Out of all, sensible and culturly acceptable techniques were discussed with the research team concerning the feasibility aspect as well as the barriers of implementation of those techniques within the treatment regimen of T2DM in outpatient clinics in Jordan, which is explained later in (3.9.4).

The delivery of IMBDSME using MI style and BAP was lengthy process because MI approach requires active listening and this required considerable time to interact with those receiving DSME intervention. Adding to this, delivering the intervention all at once targetting three self-care behaviours could cause information misintrepretation as a result of overloading patients with information about self-care behaviours that could act as barrier to the adherence to DSME (Rushforth et al.,

2016). Other barriers that could have jeopardized attending DSME sessions on several occasions such as work commitments, forgotfulness, weather conditions as well as the burden of travelling from different and distanced parts of the governerate as were published by (Lawal et al., 2018). These barriers need to be addressed to increase the uptake of DSME interventions. Therefore, other remote ways of delivering DSME interventions were at the sight. In literature, DSME was delivered over telephone and in some cases they applied MI style, and their results were promising and supportive to the fact that MI style has the potential to improve the adherence to therapeutic regimen, patients' self-efficacy and clinical outcomes (Dale et al., 2007 , Welch et al., 2006 , Krishna and Boren, 2008). Therefore, it was agreed by the team that delivering IMBDSME intervention need to be distributed on several occasions using an acceptable way of communication that do not necessarily requisite their physical presence at the clinic such as phone calls. However, due to the difficulties of sending chapters of PRIDE to patients separately on several occasions, the idea of handing a complete PRIDE toolkit at the beginning was more realistic. To simplify, the main idea was to discuss knowledge and skills related to a specific self-care behaviour from the PRIDE educational toolkit using MI style and BAP over phone calls, which are called as Interventional Phone Calls (IPCs) in this trial.

2.2.2.5 Interventional Phone Calls (IPCs):

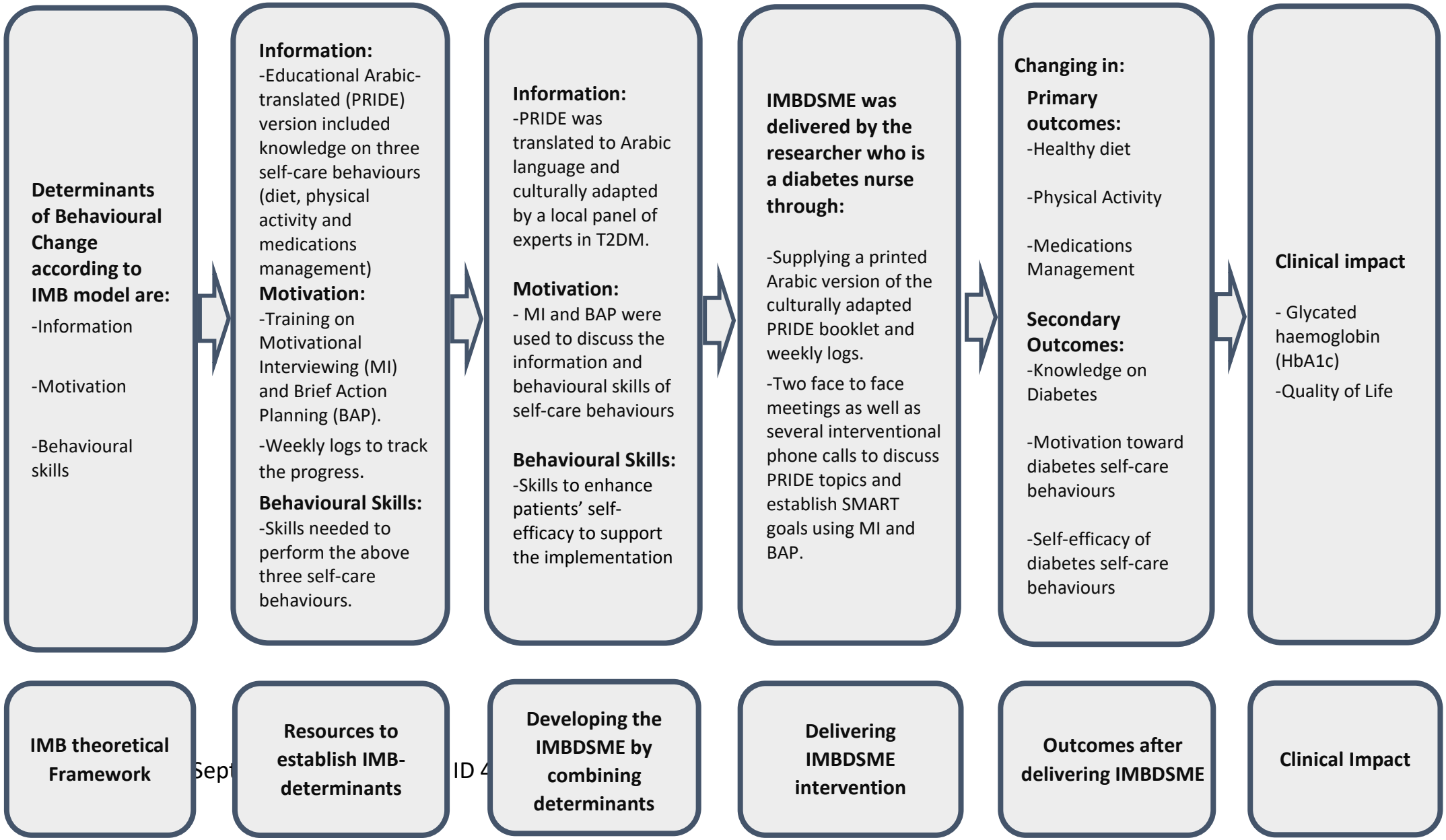
IPCs were the place where the interaction between the patients and researcher occurred for intervention delivering purposes, which was defined by Norris et al. (2002) as the patients' contact time in their meta-analysis. The length and frequency of IPCs can be defined by the patients' contact time that was required to deliver

IMBDSME intervention to produce a behavioural change. They pointed out that an average of 23.6 hours of interaction of DSME between patient and therapist was the only clinically significant predictor to lower HbA1c by 1%. Although their calculations targeted HbA1c as a clinical outcome, it was a strong indication to estimate the amount of time required to produce a behavioural change that might eventually decrease their HbA1c. Having mentioned that estimation, on the other hand, Osborn et al. (2010) claimed that their 1.5 hours of IMB model-based DSME intervention lowered participants' HbA1c by 0.48% and proceeded to presume that their dose was equal to 11.8 hours of patients' contact time in comparison to Norris et al. (2002) calculations. Based on these calculations, it was proposed that an interaction of three hour-time (180 minutes) using IMB model-based DSME could be adequate to lower participants' HbA1c by roughly 1% to match the clinically significant prediction of Norris et al. (2002). Therefore, 180 minutes were estimated to be adequate and was planned to deliver IMBDSME over at least six phone calls, 30 minutes each. IPCs were proposed to range from at least six to eight IPCs and were distributed over three-month intervention period as described in (3.11.2). Over IPCs, patients were encouraged to complete the weekly logs along with delivering the IMBDSME and were able to start with a self-care behaviour of their interest over the first IPC.

2.2.3 Logic model of IMBDSME development:

Logic modelling was used to visually present the steps of developments and relationships between needs, IMB behavioural determinants, behavioural outcomes and methods or strategies (resources) in a chronological systematic order (Hayes et al., 2011 , Savaya and Waysman, 2005). The logic model is presented below in Figure 5.

Figure 5 Logic model of the development IMBDSME intervention



2.3 Conclusion:

In this chapter, it was explained the theoretical framework of IMB model and its fundamental assumption. It was explained that IMB model determined that information and motivation of a health-related behaviour are expressed through the deployment of behavioural skills, in which they were found to directly influence and initiate the performance of that behaviour (Fisher and Fisher, 2000). By utilising IMB model procedures as well as intervention mapping approach, essential determinants of IMB model were defined considering the targeted self-care behaviours in this trial; healthy diet, physical activity and medications management. Furthermore, relevant evidence-based methods and strategies were selected to construct an individualised IMBDSME intervention and planned for the implementation and delivery. To conclude, all IMB determinants were placed together where the related knowldege and skills for the trial self-care behaviours were mainly demonstarted in the Arabic-translated PRIDE, and Motivational Intervieiwing (MI) and Brief Action Planning (BAP) were the medium in which those determinants were carried to patients over the Interventional Phone Calls (IPCs).

3 Evaluating the IMBDSME intervention (RCT):

3.1 Overview:

At chapter one, the evidence for the effectiveness of DSME interventions and the need for a tailored, individualized and multicomponent programs was presented. Indeed, those programs need to be underpinned by appropriate behavioural change theories. Systematic reviews and other studies in the literature revealed how the IMB model was effective among clients with high HIV risk. They have emphasized that IMB model can be utilized across health promoting programs and was consistent with the required determinants to promote diabetes management. Very few studies have used IMB model among patients with diabetes and there were no studies in which patients have been followed up after delivering the DSME intervention. Developing educational programs and modelling them with outcomes using the IMB model have been discussed in chapter two. In this chapter, methodological factors and other design matters that were well-thought-out were called to develop an appropriate research design. The narrative shows how an approach to design an experimental trial was constructed to evaluate the effectiveness of IMB model based DSME intervention for patients with T2DM.

3.2 Pre-trial and Design considerations:

Designing a research trial depends on the type of the research question. Our research question was looking to know the answer of whether IMBDSME intervention can make an effect on self-care behaviours among patients with T2DM. The answer for that question can provide a causal explanation and description of the relationship

between the intervention as an independent variable and the self-care behaviours as dependent variables. It is generally classified as relational research question that investigate cause-and-effect relationship (Privitera, 2017). The experimental, quasi - experimental and non-experimental research designs can all be used to answer our relational research question. They are distinguished by the level of control instituted in the design. The level of control in a design describes the manipulation of a variable while holding the other variables constant. A crucial asset of the experimental design that it is competent to explain cause and effect relationship, enabling researcher proficiently to control the conditions of the participants adequately. This means, to demonstrate how the intervention causes a change in the trial outcomes variables, researcher should be able to adequately control the conditions of the participants by choosing the experimental design (Polit, 2008).

3.2.1 Choosing the Experimental Trial design:

The notion of applying control was illustrated in a hierarchy of evidence pyramid that indicates which research design gives the highest weight and classifies the evidence during evaluating an intervention, see the pyramid of hierarchy of evidence in Figure 6. Rigorous scientific methodologies increase as long we are moving from the bottom of the pyramid upwards. On the other hand, the risks of bias inherited in trial design increase as long we are moving downwards within the pyramid (Akobeng, 2005). The pyramid was adopted from Golden and Bass (2013) article and they acknowledged that it is permitted to use any part of their work as long as it is cited properly for educational purposes.

Figure 6 Pyramid of Hierarchy of Evidence

Overall, Randomized Controlled Trial (RCT) was recognized to be the gold standard and known to provide the most reliable evidence when evaluating the effectiveness of the interventions. The included controlling measures during the conduct of an RCT minimize the risk of affecting the results by the confounding factors. The level of control in trials refers to the validity or in other words it is the extent of the trial design to allow the researcher to draw a true cause and effect relationship (Bondemark and Ruf, 2015).

3.2.2 Why Randomized Controlled Trial?

During RCT, participants are randomly allocated to the trial groups to distribute participants' characteristics such as disease duration and severity, socioeconomic status and sex between trial groups. Accordingly, it creates a status of balance of baseline systematic differences that might affect the outcome, so that any difference

in the outcome can be rationalized by the trial intervention (Sibbald and Roland, 1998). A true experiment or RCT characterized by applying control using three essential elements: **Randomization** , **Manipulation** and **Comparison (Control)** that allow researcher to draw cause-and-effect conclusion (Polit and Beck, 2008 , Privitera, 2017). In this trial, researcher will be referred to those elements in sections (3.3), (3.3) and (3.4) respectively.

3.2.3 Validity of the RCT results:

Validity refers to the accuracy of the results and considered whether the effectiveness of the intervention reported in the trial stands for the actual magnitude or directions of the intervention effect. It can be demonstrated in answering the following question "Do these results represents an unbiased evaluation of the effectiveness of the intervention? Or have they been affected in a methodical fashion leading to a false inference?" Many factors may act as a source of threats to validity whether internal or external validity. Therefore, a criteria of a previously developed critical appraisal tool such as CASP tool was considered during the process of designing this experiment to increase the level of control in the trial design to safeguard the validity of the trial results, as well as, following CONSORT statement that entails a transparent reporting of randomised clinical trial (CASP, 2017 , Schulz et al., 2010). Entail

3.2.3.1 Threats to internal validity:

The greater control in a trial design, the higher is the internal validity and RCT design has the greatest control, and therefore, has the highest interval validity. However,

threats to internal validity such as bias, significance level and power are potential confounders that need to be practically controlled in this trial.

3.2.3.1.1 Bias:

Bias can be defined to be any trend in sampling process, collection, analysis, interpretation of data that may generate a deviated conclusion from the truth. Generally, bias is any influence that produces a misrepresentation in the trial results randomly or systematically. The result of bias in a trial might underestimate or overestimate the effectiveness of the intervention when it really does not. Several types of bias can influence trial results such as selection bias, performance bias, detection bias and attrition bias (Juni et al., 2001). Those types are addressed throughout this trial design and within the randomisation section below.

3.2.3.1.2 Significance level, power and sample size calculation:

Significance level α should be defined at the planning stage to be able to reject or accept the null hypothesis after completing the trial analysis. Usually, α is known as 0.05 or 5%. If p-value larger than 0.05 then we fail to reject the null hypothesis and conclude that the difference between trial groups is not statistically significant. On the other hand, if p-value is smaller than 0.05, we can reject the null hypothesis and conclude that there is a statistically significant difference between trial groups. A p-value of 0.02 means that the likelihood of obtaining a positive trial results when the null hypothesis is in fact true is 2 in 100. However, there is still risk of rejecting the null hypothesis when it is in fact true. In this case, it will lead to type I error or alpha error where there is no real difference between trial groups.

The power of a significance test is the probability that a test yields a statistically significant results when the null hypothesis is truly not true, enabling researcher to detect a small difference between trial groups when there is a real difference existed. Several factors may determine the power of the trial including the frequency of the outcome being studied, the size of the effect, sample size and trial design. However, the feasibility of recruiting enough participants to detect the smallest statistically significant difference that considers clinically important is a crucial aspect. In other words, power should be high enough to calculate a sample size that is large and represent the population adequately to detect a small difference between the trial groups. On the other hand, an under-power trial means that calculation of sample size will yield a small sample that might not allow the researcher to detect a statistically significant difference between trial groups where it really exists. In this situation, we fail to reject the null hypothesis when it is in fact not true and make a type II error (or false-negative) and the probability of this is presented by the symbol β. The probability of type II error is related to the power of the trial; which is (1-power). Both, type I error and type II error, are due to a term called random sampling error and illustrated in Table 2 below.

State of nature	**Experimental conclusion**	
	Accept null hypothesis	Reject null hypothesis
Null hypothesis true	Correct conclusion	Type I or α error
Null hypothesis false	Type II or β error	Correct conclusion

Table 2 Types of Random Sampling Error (Type I or α error and Type II or β error)

In the light of the above discussion, and to calculate sample size for this trial, researcher referred to an earlier RCT conducted to examine the effectiveness of diabetes education program in one of the royal medical services hospitals in Jordan (Jarab et al., 2012). In their trial, the mean difference in the primary outcome which was the Summary of Diabetes Self-Care Activity (SDSCA) scale score was 0.7 higher in the intervention group than control group at six-month endpoint with a Standard Deviation (SD) of 2.0 and alpha (α) level was 0.05. Moreover, they had a dropout's rate of 13.5 % of eligible participants during trials' follow up. As a result, it was assumed that 15% of participants will be lost to follow up during the trial to address the attrition bias. All in all, in coordination with the school's statistician, a statistical software for professional STATA version 13 was used to calculate the trial sample size and was based on a level of power of (0.8) to compute a feasible sample size and avoid falling in type II error (Jones et al., 2003). Consequently, calculation resulted in recruiting 100 participants per group to detect 0.7 mean difference between two trial groups at six-month endpoint. Therefore, a sample size of 230 participants for both trial groups was decided to be the trial sample size adding the proposed attrition rate.

3.2.3.2 Threats to External validity:

External validity refers to the degree of which the relationship observed in a trial can be generalized beyond the specific constrains or manipulation in the trial. The lower constrains in a trial design, the higher external validity. External validity is a matter of judgements and depends on several factors such as the characteristics of the participants and different treatment regimens across trial settings. These factors

make trial results sometimes difficult to interpret and elucidate a precise component of the intervention that can be generalised to the wider setting. RCT may be more rigorous in the recruitment process and may not reflect the real clinical practice. To address this point, pragmatic eligibility criteria was utilized to choose patients with T2DM as participants to reflect the real clinical practice. For example, participants have been choosing from a wide age range regardless of any comorbidities, psychological problems or diabetes-related medications. Moreover, exclusion criteria were minimized to take account of any condition that may impact participants' compliances with trial protocol or trial intervention as well as recruiting two trial sites to increase the external validity while maintaining the internal validity of the trial results. Thus, criteria to follow for choosing participants was developed and is described below.

3.2.4 Eligibility criteria

Patients with T2DM were eligible if:

1- They were aged between 18 and 65 years old. According to Selvin et al. (2006), patients who are older than 65 years old considered as elderlies and distinct from middle aged patients with diabetes who are 18-65 years old. The distinction is clear regarding the burden of diabetes and other comorbidities such as hypertension, thus, possibly the need for different treatment goals.

2- They have been diagnosed with type 2 diabetes for at least six months. This term was to ensure that hyperglycaemia is primarily related to type 2 diabetes. Hyperglycaemia as a sign may occur by multiple disorders such as auto-immune diseases or hypothyroidism etc. Clinically, we cannot judge that initial sign of

hyperglycaemia is related to T2DM unless patient undertake several lab tests to confirm that insulin resistance is the cause behind hyperglycaemia. Therefore, leaving six months after being diagnosed with T2DM increase the chance of being diagnosed accurately.

3- They have been experienced an uncontrolled glycaemic level (HbA1c >8%) within two weeks prior the day of visiting the clinic. According to Duke et al. (2009), patients with high glycaemic level (HbA1c >8%) were responded and benefitted from DSME significantly more than patients who had HbA1c < 8%.

4- They are attending the outpatient clinic regularly once each 3-month for the last two appointments. It was decided to recruit patients who attended their previous appointments on time and according to their treatment plan. This point aimed to increase the chance of attending their prospects appointments which were used to follow them up according to trial requirements. In fact, any patient with diabetes is free to attend any of the trial sites for a consultation. However, using this criterion meant to recruit patients who are being treated for their diabetes condition and have a medical record at that trial site.

5- Taking any form of diabetes medications (pills or injections such as insulin). One of this trial outcomes was to improve the management of diabetes medications. Some patients usually are not prescribed any form of diabetes-related medications and were given a chance to reverse their hyperglycaemic symptom by following a tight diet plan or physical activity regimen. This was in accordance with the diabetes treatment universal regimen to control diabetes and they were out of the scope of this trial.

By referring to a previously collected data in Jordan for patients with T2DM who attended the National centre for Diabetes, Endocrinology and Genetics (NCDEG) during researchers' master's degree in 2012, it was estimated to recruit 68.4% of all patients with T2DM when applying the criteria. This proportion of almost two third of patients was justified because the other third had a relatively controlled glycaemic level (HbA1c < 8). Neither data nor the research study were published.

3.2.4.1 Inclusion criteria:

Once patients with T2DM meet the eligibility criteria, they were checked if they were compatible with the trial inclusion criteria by asking them during the recruitment interview whether:

1- They have had access to a telephone whether mobile or landline in order to be contactable.
2- They were capable to give informed consent for themselves as well as being able to communicate, read, write and understand Arabic language to complete self-report outcomes questionnaires and interpret the trial booklet.

More details on the recruitment interview are presented in (3.12.2).

3.2.4.2 Exclusion criteria:

Patients with T2DM who were eligible to participate were excluded if:

1- They were suffering from any cognitive impairment or taking medication that affects their memory (self-reported by patient and/or companion).

In this trial, researcher depends heavily on participants' involvement and compliance with the trial protocol. Trial parameters were assessed and evaluated using self-report measurements, and this require mentally healthy volunteers.

2- Patients with terminal illnesses such as cancer, pregnant women and patients who were scheduled for a major surgical operation

Those patients have different treatment goals and different targets in terms of glucose levels pre and post prandial. Indeed, terminal illnesses affect the way that patients should control their diabetes condition. Therefore, they were excluded as they need different treatment approach.

3- They were attending or had attended a diabetes education program within six months prior enrolment.

Patients who attended a different diabetes education program in that period may affect the trial outcomes as researcher solely intended to examine the effectiveness of IMBDSME.

3.3 Manipulation (the trial intervention):

Researcher should develop the trial intervention (the independent variable) that will be administered to one of the trial group to observe a change in the trial outcomes (or dependent variable). The manipulation of the intervention occurs to some participants and withholding it from the others by the researcher using random assignment as researcher will describe shortly. As a result, researcher is deliberately producing multiple groups in the trial to observe the variation in the dependent variable between the groups occurred by the independent variable. For this reason

and to examine the intervention in an experimental design, the design of the intervention should be appropriate to the problem, theoretically rationalized and sufficiently intense to expect a sensible effect. Furthermore, to allow replicability in future trials, the intervention design should be clearly described. This trial intervention was mapped to the IMB theoretical framework and trial outcomes to cause a change. Mapping process was described in detail in section2.0).

3.4 The Control Condition:

Manipulation is not always enough to obtain an evidence about cause-and-effect relationship. Because manipulation alone cannot explain the relationship between the independent and dependent variables. A control group was important to make at least one comparison. A control group was defined to be those participants who did not receive the trial intervention or their act on the dependent variable was used to evaluate the act of the intervention group on the same dependent variable. Without control group, it is impossible to isolate the effectiveness of the intervention from those who are in the intervention group. In this trial, participants in the control group received the Treatment As Usual (TAU) during data collection period. However, since it is unethical that control group receive nothing at all during an experiment (Nardini, 2014), participants in the control group were given the educational booklet after completing the trial.

3.5 Sampling procedure (Randomization):

One of the distinguished features of RCTs is the randomization sampling procedure. Randomization refers to the method of randomly selecting a sample (random sampling) from a population of patients to be recruited in a trial and assigning them

randomly to trial groups (random assignment or random allocation). Random sampling is being conducted in RCTs to avoid sampling bias that is considered as a type of selection bias and a weakness in other research designs such as case-control and cohort studies (Mann, 2003). So, each participant has an equal chance of being selected to participate in the trial and an equal chance to be assigned to one of the trial groups. This will help to eliminate bias of selecting participants based on certain characteristics to create a difference in specific trial group. (Kim and Shin, 2014). It improves the sense of balance by distributing participants' characteristics equally and sufficiently among trial groups as well as to create a control group that is highly capable to be utilized as a comparator to the intervention group (Roberts and Torgerson, 1999). In this trial, several measures that are explained below in the trial's procedure section have been employed to form a randomization list. The list was uploaded to an online randomization platform to warrant a random assigning of participants to two trial groups within each trial sites (Kim and Shin, 2014).

3.5.1 Online randomization:

The process of assigning participants was conducted through an online randomisation platform via internet during the recruitment interview. Nowadays, randomizations software and internet services have facilitated the maintenance of the process of randomization and allocation. Researchers are able to allocate participants to different trial groups within multiple trial centres. They allow researcher to exercise control over the different aspects of randomization including blocks design, sizes and its sequences, trial strata, providing of codes or unique

identifiers and control over the way of delivering the randomization outcome (Saghaei, 2004).

3.5.1.1 Trial's Procedure:

An independent colleague who neither was involved in data collection nor in the delivery of intervention used a randomization website to create a sequentially numbered list that consisted of simple randomized blocks prior conducting the trial. The list was established using two strata according to trial sites, each was comprised of different blocks sizes of four, six and eight to allocate participants to two trial groups on 1:1 basis. Each participant on the list had a number for their turn, and each number had a code. Once baseline data has been collected, the researcher manually used the software to enter the participant number according to their turn and received a message via internet service indicating which group the participant should be allocated to. Indeed, due to the nature of the intervention that required researcher interaction with participants in the intervention group, participant allocation concealment was not possible.

3.5.1.2 What is Simple Randomization?

Simple randomization is a basic procedure that allows researcher to assign each participant in one of trial groups completely by a chance. If researcher is interested to examine the effectiveness of an intervention between two groups, a method of coin flipping for each participant can be used. If the coin turns to give "head", participant will be assigned to control group; but if the coin turns to give "tail", participant will be assigned to intervention group. This procedure preserves group balance in terms of the number of participants and their characteristics to be

assigned to each group if the trial sample is large. However, if the trial has a small sample size, other strategies such as block randomization and stratification are preferred to be utilised to ensure a balance between groups in numbers and patient characteristics.

3.5.1.3 What is Block Randomization?

Block randomization means that participants are considered in blocks. It can be used to try to equalize the number of participants among trial groups. For example, using a block size of six for two trial groups (Intervention and Control) will lead to 6 possible arrangements of 2Is and 2Cs blocks, each participant will be assigned into trial groups according to their predetermined allocation in the blocks by using a sequential numbered list respectively. To illustrate this, the table below show the random allocation of 20 participants to two trial groups using five blocks with a size of four participants for each. See (Table 3).

Block number	1	2	3	4	5
Participant's sequence	1-2-3-4	5-6-7-8	9-10-11-12	13-14-15-16	17-18-19-20
Allocation	I-I-C-C	C-C-I-I	I-C-I-C	C-I-C-I	I-C-C-I

Table 3 Random Allocation Using Blocks

As such, participant number 1 will be assigned to Intervention group, participant number 2 will be assigned to Intervention group and participant number 3 will be assigned to control group and so forth. In this example where the block size is small, it allows researcher to predict the allocation of the 4th participant in the first block, which is the control group. In this case, researcher is recommended to use the random permuted block sequence or (Hadamard randomization).

3.5.1.4 What is Stratified Randomization?

Stratification or stratified block sampling is used to ensure that groups are as much as possible identical to produce separate block randomization list for specific or multiple prognostic variables. This strategy is used when important predefined prognostic factors are aware of before the trial. For example, a block randomization list can be generated stratified by gender or disease duration or trial site to ensure that variations in those factors are sufficiently distributed within the randomization blocks.

3.6 Trial Hypothesis and purpose:

The purpose of this trial was to examine the effectiveness of IMBDSME among Jordanian patients with T2DM on diabetes self-management behaviours: diet, physical activity and medications management. In this trial, researcher hypothesised that participants who received the IMBDSME intervention should have experienced a greater improvement in performing the self-management behaviours than patients who received usual care at three-month and six-month visits.

3.7 Primary outcomes:

Primary outcomes were to evaluate the performance of diabetes-self-management behaviours after delivering IMBDSME intervention to examine its effectiveness among patients with T2DM. Those behaviours were diet modification, physical activity and medications management at three-month and six-month endpoints. Those outcomes were measured by the Summary of Diabetes Self-Care Activities

Scale (SDSCA) and the Medication Adherence Rating Scale (MARS). Both are explained in detail later in section (3.13.2).

3.8 Secondary outcomes:

Secondary outcomes were designed to examine the effectiveness of delivering IMBDSME intervention on the main three elements of IMB model (Information-Motivation-Behaviour skills), glycaemic level and quality of life among patients with T2DM. Those outcomes were measured at three-month and six-month endpoints using Spoken Knowledge in Low Literacy in Diabetes scale (SKILLD), Diabetes Empowerment Scale (DES), Medical Outcomes Study (MOS), Perceived Diabetes Self-Management Scale (PDSMS), glycated haemoglobin blood test (HbA1c) and Audit of Diabetes Dependent Quality of Life (ADDQOL). Details on those scales are described in section (3.13.3).

3.9 Recruitment of Trial-settings:

Before choosing the trial settings, the health care system in Jordan was screened to identify the appropriate health care centres that were high likely feasible to recruit the required sample size in a limited recruitment and follow up periods in accordance with PhD program.

3.9.1 The public health care system in Jordan:

The Jordanian health care system is formed of six sectors according to the Ministry of Health (MoH) and they are:

1- Ministry of Health that consist of some hospitals and health centres distributed over the country and serve all Jordanian citizens whether covered by national health insurance or not.
2- Royal Medical Services is principally developed to treat the military staff and their family members additionally to be used by civilians who have been granted referrals by the Royal Hashemite Council (RHC).
3- Government university medical institutions such as Jordan University Hospital in Amman city and King Abdullah University Hospital in Irbid city. These hospitals serve mainly government university staff and their dependents, civilians covered with national health insurance (special categories) or have been granted referrals by the RHC.
4- The National Centre for Diabetes, Endocrinology and Genetics (NCDEG) serves mainly civilian sectors' employees and their family members and civilians who have been granted referrals by the RHC to be treated there. The centre is affiliated by the Higher Council for Science and Technology and developed initially for research purposes and manage patients' conditions who suffer from any disorders related to endocrinology especially diabetes.
5- United Nations Relief and Works Agency (UNRWA) runs and administers health care centres that serves the registered Palestinian refugees who are living in Jordan.
6- Various private hospitals.

The High Health Council (HHC) coordinates all these sectors. Any patient who doesn't fall under the national health insurance or any of the above categories can apply for

the RHC to be exempted from treatment costs at any of those sectors (Alhadidi and Alkurdi, 2013).

3.9.2 Managing Diabetes in Jordan:

Patients with diabetes in Jordan are treated by attending outpatient clinics whether they are in primary care centres or available at MoH hospitals. A considerable proportion of patients who are covered by private health insurance attend private diabetes consultants for treatment. Few patients who can afford the treatment fees choose to attend private diabetes consultants by their own. Generally, patients with T2DM are treated by family physicians as long as they can manage their condition within governmental sectors. Once their condition is difficult to manage, and their HbA1c is uncontrolled, they are referred to diabetes consultant who are available only in MoH hospitals. While this is not the case at the NCDEG, patients are seen by a family physician and a treatment plan agreed upon with an endocrinology consultant who reside in the centre.

The National Centre for Diabetes, Endocrinology and Genetics is the largest centre to treat and manage diabetes in Jordan and located at the capital Amman. It has the highest attendance rate. Many patients with diabetes tend to try to apply for full health coverage to be treated at the centre through RHC to be exempted from treatment fees. Whilst it might have been the most obvious context for the research, it has been contacted to seek approval of conducting the trial, but this was not available due to the high number of trials that were conducted at that period. Therefore, other centres were investigated which included diabetes outpatients' clinic, have high attendance rate of patients with T2DM, covered with MoH health

insurance and preferably managing T2DM in parallel with the treatment regimen of the NCDEG such as Jordan University Hospital (JUH) and Prince Hamzah Hospital (PHH).

3.9.2.1 Jordan University Hospital (JUH):

JUH is the most specialized and advanced teaching medical centre in the public sector. It contains of 534 beds and includes several outpatient clinics; one of them is the outpatients' endocrinology clinic (see Figure 7). Around 60-150 patients are attending the endocrinology clinic to treat and manage their endocrine disorders such as diabetes, thyroid diseases and conditions each Sunday, Monday and Wednesday of the week. The treatment regimen in the endocrine clinic for patients' with T2DM is parallel to the one in NCDEG. Patients who start insulin therapy are usually referred to the diabetes educator to be educated on administering insulin injections or pens. Not every patient is referred to dietitian or diabetes educator who are available within the department, only obese patients or those who expresses his/her willingness to make counselling visit. Generally, patients with T2DM should attend the clinic to manage and follow up their diabetes condition once each three months regularly and should attend the pharmacy each month to receive their medications that cover one-month period.

Figure 7 Jordan University Hospital

3.9.2.2 Prince Hamza Hospital (PHH):

Prince Hamza Hospital is one of the largest Ministry of Health (MOH) hospitals in Amman and holds 434 beds distributed on nine floors (see Figure 8). The hospital has several outpatient clinics to treat and manage chronic conditions such as cardiovascular diseases, neurological and endocrinology disorders. Around 30-70 patients with chronic diseases attend the internist clinic to manage and treat their health condition on each Sunday, Tuesday and Thursday of the week and receive their medications once a month. In PHH, around 10-25 patients with T2DM attend the internist clinic to follow up their diabetes condition and its complications. The clinic doesn't have nutritional or diabetes educational services for patients with diabetes.

Figure 8 Prince Hamza Hospital

3.9.3 Rational for choosing trial settings

The Jordan University Hospital (JUH) and Prince Hamza Hospital (PHH) have been chosen to be the trial sites. JUH is affiliated by the University of Jordan and PHH is one of the largest governmental hospital in Amman. Each one of them serves different populations as have been described earlier in this section, and a 20 minute distance trip by car separates them (Figure 9). Patients do not routinely receive behavioural change strategies and theoretically informed educational interventions at both sites. The utilization of two hospitals as trial sites served to enhance the credibility and the reliability of trial results, improve the external validity and increase the heterogeneity of patients' characteristic. Multicentre trial improves the basis for subsequent generalization of trial findings, since the effectiveness of the DSME intervention is not dependant on a specific centre; thus, allow to be reproducible at other centres (Friedman, 2010).

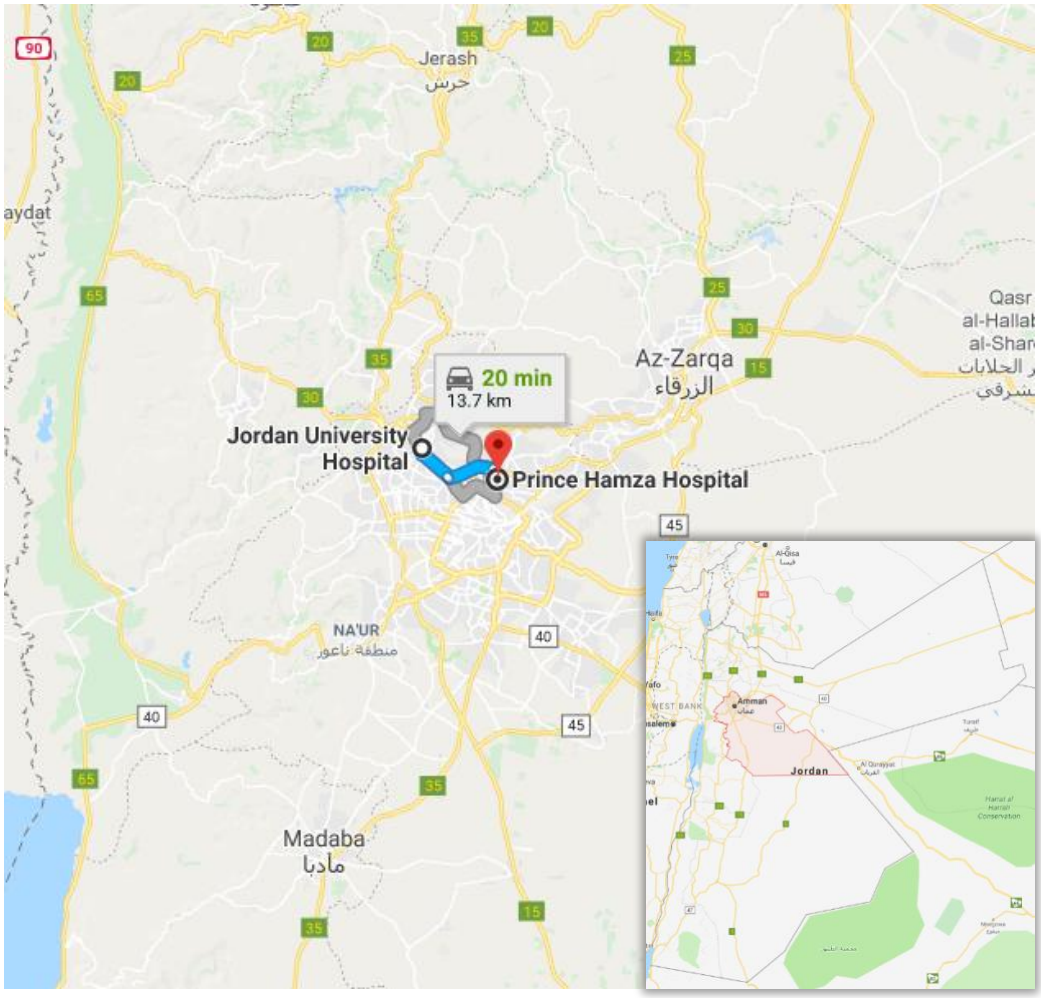


Figure 9 Location of Trial Sites in Amman

3.9.4 Treatment regimen in outpatient clinics in trial sites:

On each clinic day, patients who are supposed to attend the clinic are recorded and listed on computerized medical records. All patients should attend the clinic either in the morning session for the morning clinic, which starts at 8:00 am, or afternoon for the afternoon clinic which starts at 12:00 pm. Therefore, most of the patients who used to attend those clinics usually arrive at those two sessions every day. Once they arrive, they go to the receptionist to confirm their attendance to generate a confirmed list of patients that appears on the computer screen inside the physician room. Each one of the trial sites differs in terms of patients' health investigations and

examinations prior the consultation. To describe the routine treatment regimen, usual clinical visit procedure at both JUH and PHH is outlined in below.

Trial Sites	
JUH	**PHH**
Patients who confirm their attendance are invited as part of their routine care to measure blood glucose level and HbA1c if they did not measure them in advance of two-week period. A small laboratory located at the same department is dedicated to obtaining HbA1c result. It needs approximately 20-30 minutes waiting period to provide blood sample and analyse it. Once they finish laboratory routine, they return to waiting area and wait 15-20 minutes to attend the physical examination room.	Patients who confirm their attendance should wait for their physician consultation turn. This waiting period may take 60-120 minutes prior their consultation according to the number of patients who are attending that day and the available physicians who are providing consultations.
As soon they are called for physical examination, a qualified and trained nurse examines patients physically and measures their anthropometric parameters (weight, height and blood pressure) that takes approximately 5-10 minutes.	As soon it is their turn for consultation, a qualified and trained nurse invite them for the consultation and measure patients' blood pressure as a

Following physical examination, patients return to the waiting room and wait for their physician consultation turn. This waiting period may need 45-75 minutes prior their visit according to the number of patients attending at that day or the available physicians who are providing consultations.	part of the routine care. If the physician needs a weight reading, patients are asked to measure the weight in another clinic room with an accompanied nurse

Table 4 Usual care description in both trial sites

After finishing the consultation that varies in time between patients from 15 to 25 minutes according to their condition, they visit the pharmacy to collect a sufficient quantity of diabetes-related medication that is enough medication to last for one month. The pharmacy visit might also need 30-40 minutes waiting period for them to receive their diabetes-related medications and pay for the expenses if applied. The whole treatment visit in the outpatient clinics might entails 2.5-3.5 hours for the participant if all procedures happened according to planned time schedules, which is not common, and patients usually spend longer time in waiting rooms. It was therefore feasible to recruit patients and collect research data during their waiting period within scheduled visit day, which is approximately 110 – 165 minutes. Appointments are usually every three months.

3.10 Trial Management:

This trial was managed by the researcher at the trial sites under the supervision of the PhD supervisors. The researcher put together a printed copy of PRIDE educational toolkit, which was presented in section (2.2.2.1), three copies of the outcome measurements as well as 12 copies of weekly logs. See Appendix 13 Weekly Logs. Prior the day of visiting clinic, the educational toolkit and the Case Report Forms (CRFs) was prepared for the recruitment interview. The detail statistics of patients who were assessed, eligible, recruited, excluded, declined and could not be approached were recorded on the recruitment follow up sheet to be used in data analysis see Appendix 7 Recruitment follow up sheet.

During the recruitment interview, randomisation procedure was generated online via the internet using www.sealedenvelope.com . Each participant was assigned a trial unique identifier at the time of randomisation and was used on their Case Report Forms (CRFs), on trial documents and on the electronic database. Information that could identify participants such as participants' real personal data (name and telephone number), date of birth, medical file number and randomization code were recorded on a separate register see Appendix 4 Participants Personal Information Sheet. The register was developed to permit identification of all participants enrolled in the trial for follow-up and reference purposes. In addition, another sheet was developed to record the dates of participant's second and third visits and the conducted laboratory examinations such as HbA1c and lipid profile see Appendix 5 Follow up Information Sheet. Independent assessors were trained and supervised by the researcher with overall guidance from the research supervisors. They used to

hand in the completed outcome measures personally to the researcher and then to be attached to their CRFs.

Data collection occurred mainly throughout the working hours of the clinics, while interventional phone calls took place on every working day afternoon. On several occasions, researcher received phone calls from participants in the control group and were managed briefly and instructed to follow the medical advice given during the consultation. In case they asked for more information and could not attend the clinic due to travel distance, researcher used to refer them to the nearest pharmacist.

A diary was used to record dates and timings of all conducted phone calls whether they were for delivering the intervention or collecting the outcomes. The delivered intervention over the phone calls was concisely transcribed on a purposely developed chart to follow the participant progress with the educational toolkit content and to document the phone calls' length and frequencies see Appendix 6 Interventional phone calls contents. Any unexpected events occurred during the trial were recorded on the researcher diary. Similarly, any adverse events were managed according to the adopted policy at trial sites and by informing the trial chief investigator and the available supervisor at the department.

3.10.1 Research governance and ethical considerations

The trial was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005. Each trial needs a sponsor and this trial was sponsored by the

University of Nottingham who cover their researchers, research participants and research protocols with both public liability insurance and clinical trials insurance.

Ethical approval was pursued from the Faculty of Medicine and Health Sciences Research Ethics Committee (REC) and from the Institutional Review Board (IRB) at the original trial site the National Centre for Diabetes, Endocrinology and Genetics (NCDEG) in Jordan. The trial received approvals from trial sites and favourable opinion from REC on respecting and following all ethical and regulatory permissions in accordance with all Jordanian laws and those required by the host institution; ethics reference no: OVS18012016 SoHS. Ethical approvals letters are presented at appendices (see Appendix 8 and Appendix 9).

As a result of changing the original trial site which was described earlier in section (3.9), a notice of amendment was submitted to REC to include the new trial sites. The amendment received approval and is attached in appendices. See Appendix 10. Ethical approvals were sought from JUH and PHH and were granted on April 2016. Approval letters from both JUH and PHH are presented in appendices. See Appendix 11 and Appendix 12.

3.10.2 Informed Consent, Confidentiality and Data Protection:

The process for obtaining participant informed consent was in accordance with the REC guidance, Good Clinical Practice (GCP). The researcher and the participant both signed and dated the Informed Consent Form (ICF) before the person can participate in the Trial.

Patients who agreed to participate were given a copy of ICF, one was kept by the researcher, and a third was retained in the patient's records to notify each participants' treating physician of their patients' willingness to participate in the trial. It has been explained that in the event of their withdrawal, their data collected could not be erased because their data were entered onto the University of Nottingham secure network and it was not possible to be traced and erased. All completed documents and CRFs have been kept and treated with confidentiality in a folder that was placed in a locked filing cabinet, and was stored and will be kept for seven years in accordance with the regulations (Data Protection Act, 1998, and local hospital regulations); as there is no data protection law in Jordan (Privacy, 2018).The locked filling cabinet was secured by a lock and the trial database were protected by a password.

3.10.3 Registering the trial in Clinicaltrial.gov:

Web-based databases of clinical trials are acting as clinical trials registries that serve ethical and scientific purposes. Publicly, they serve as a source of information about ongoing and previously conducted trials to ensure the ethical considerations. While they also provide scholars and journal editors by a complete list of trials regardless of the results status. They are distinct by the sponsor, scope and type of information about trials. International Committee of Medical Journal Editors (ICMJE) recommends that clinical trials registries should be administered by a non-profit organization and provide a free of charge service for users and registrants (Krleza-Jeric et al., 2005). Presently, one of the largest international clinical trials registries that meet the former criteria is the ClinicalTrials.gov web-based register. It is

managed by the U.S. National Library of Medicine of the National Institutes of Health (NIH) and contains approximately over a quarter million of registered research trials nowadays (Zarin and Keselman, 2007). Only two conditions needed to be existed at the time before registering our research trial. Firstly, it had to be approved by the University of Nottingham faculty Research Ethical Committee (REC) or Institutional Review Board (IRB), and secondly, it should follow the regulations of the related health authority which is the Jordanian MoH (Zarin et al., 2005). Once this trial received ethical approval, researcher registered the trial before starting data collection process to avoid any possibility of retrospective data analysis or fishing expeditions that look for significant outcomes. The unique identifier for this trial on ClinicalTrials.gov is: NCT02699541 (https://clinicaltrials.gov/ct2/show/NCT02699541?cond=Diabetes+Type+2&cntry=JO&city=Amman&rank=4).

3.11 Trial design:

In the third phase of the MRC framework, authors recommended that randomised controlled trial is the most rigorous way to evaluate complex interventions. Two main designs of RCT can be chosen to evaluate the effectiveness of the IMBDSME intervention and compare outcomes with a group who received the TAU; individualised design or clustered design. So, due to the nature of the developed IMBDSME intervention, the approach of delivering the intervention cannot be in a group setting and need to be individualised, as a result, individualised design was sought to be more appropriate.

The trial was designed to be consistent with the Consolidated Standards of Reporting Trials CONSORT statement (Moher et al., 2012) as well as the general treatment regimin of busy diabetes outpatient clinics in Jordan. The majority of patients with T2DM attend outpatients' clinics for follow up once each three-month to manage their disease condition and to renew or change the prescription of diabetes-related medications. Participants in this trial were assessed at baseline, three-month (second visit) and six-month (third visit) in both groups through self-reported questionnaires, medical records and interviews. Overall, and in order to collect the primary trial outcome which was the frequency of performing the participants' self-care activities, phone calls were initiated by two qualified independent assessors, once at the end of each month during the intervention and follow up periods to complete the outcomes measurements and to remind them about their next appointment.

3.11.1 First visit (baseline):

At first visit, patients with T2DM who attended the outpatients clinics were screened and eligible patients were invited to a recruitement interview, which is explained in more details in section (3.12). During the interview, those who agreed and consented to particpate were invited to complete the baseline assessment where possible. Following this, the randomisation took place and participants have been allocated to either the intervention group or control group. Intervention group participants received the TAU plus the intervention booklet additionally with the explanation on how the intervention will be delivered on phone calls using the educational toolkit during the following three months (Intervention period). Subsequently, if they were free and available, they have had the choice to immediately receive the first 20-30 minutes individualised face-to-face orientation session. It included some facts about T2DM and statistics on the prevalence of T2DM in Jordan and world-wide. Those facts were cited from Jordanian scholars' publications as well as WHO facts sheets about Jordan and worldwide. Indeed, the schedule of the interventional phone calls was agreed with the participant and was documented in the researcher trial's diary. On the other hand, control group participants received the TAU and have been asked to adhere with their usual assigned treating physician's instructions and did not receive any intervention from the researcher.

Participants in both groups were provided with all necessary information related to follow-up through PIS, then, were free to leave the room. Participants who did not have sufficient time either to complete the baseline assessment or to receive the intervetion were followed up using phone calls during the intervention period and

within 48 hours from the first visit. Baseline measurements are mentioned in (3.13.2) and (3.13.3).

3.11.2 Intervention period (Month one to three)

Durng this period, participants in the intervention group have been receiving the interventional phone calls from the researcher, while those who are in the control group did not receive any intervention. Both have been contacted by the independednt assessors to complete the main trial outcome on phone calls and to be reminded about their next appointment. Those who had to leave the clinic due to time constraints have been called to deliver the first orientation session within two weeks period of the first visit.

After finishing the delivery of the interventional phone calls, participants were reminded about their next appointment to bring the completed weekly logs. If the participant was not available when it was the time to be contacted by telephone for the first time, they were further contacted by phone call two times at different times and days of the week. When they failed to answer, they were considered as being lost to follow up unless they had actively indicated their preference to withdraw from the trial by contacting the researcher.

3.11.3 Second visit (post-intervention):

At second visit, participants in both groups who attended their regular appointments in the outpatients' clinics and were expected to show up were invited by trained independent assessors for a follow up interview and to complete the measurements of the trial outcomes and they are mentioned in (3.13.2) and (3.13.3).

. Those who did not attend their predefined appointments were contacted by the researcher to determine whether they were able to complete the outcomes measurements on phone calls with the independent assessors. Based on the researcher availability at the trial site, the earlier delivered intervention was summarized in a 20-30 minutes face-to-face meeting, otherwise, they received a phone call for the same purpose. All participants were asked to complete the three months assessment. Then, only control group participants were free to leave. While intervention group participants were asked to hand in the completed weekly logs and were invited to complete other tasks regarding process evaluation.

3.11.4 Follow up period (Month four to six):

Durng this period, participants in both groups did not receive any intervention from the researcher. They have been only contacted by the independent assessors to complete the main trial outcomes and to be reminded about their next appointment.

3.11.5 Third visit (post-follow up):

At the third visit (post follow up), participants in both groups who attended their regular appointments in the outpatients' clinics and were expected to show up were invited by a trained independent assessor for post-follow up interview to complete the assessment of the six months. Those who did not attend their predefined appointments were contacted by the researcher to know if they were able to complete the primary and secondary outcomes measurements on phone calls with an independent assessor. The measurements are mentioned in (3.13.2) and (3.13.3).

The diagram below describes each period in the trial. See Diagram 1 Trial Flow and table below briefly demonstrates the trial design in points see Table 5.

Clinic visit	Procedure
First visit (baseline assessment)	1- Patients screening for eligibility early at the morning (20 minutes). 2- Eligible patients were invited to participate (10 minutes maximum). 3- Participants' baseline assessment (30-35 minutes). 4- Participants were allocated randomly to one of trial groups (2 minutes). 5- Participants in the intervention group received first face-to-face session with the intervention booklet (20-30 minutes). While participant in the control group received TAU.
Intervention period (month one to three)	1- Participants in the intervention group received the rest of the intervention through phone calls at preferred frequency and followed up for weekly logs (approx. 30 minutes per call). 2- Participants in the control group did not receive any intervention from the researcher. 3- Participants in both groups were called to collect the trial outcome using phone calls by two qualified independent assessors, once at the end of each month and to be reminded about their next appointment.
Second visit (post intervention)	1- Participants in both groups were invited by trained independent assessors for a follow up interview to complete the assessment of the three months. 2- A 20-30 minutes face-to-face meeting was conducted with participants in the intervention group to summarize the delivered intervention. 3- They were asked to hand in the completed weekly logs and were invited to complete other tasks related to process evaluation.
Follow up (month four to six)	1- All participants have been contacted by the independednt assessors to complete the main trial outcome and to be reminded about their next appointment.

Third visit (Post-follow up)	1- Participants in both groups were invited by the trained independent assessors for a post-follow up interview to complete the assessment of the six months.

Table 5 Brief Trial Procedure

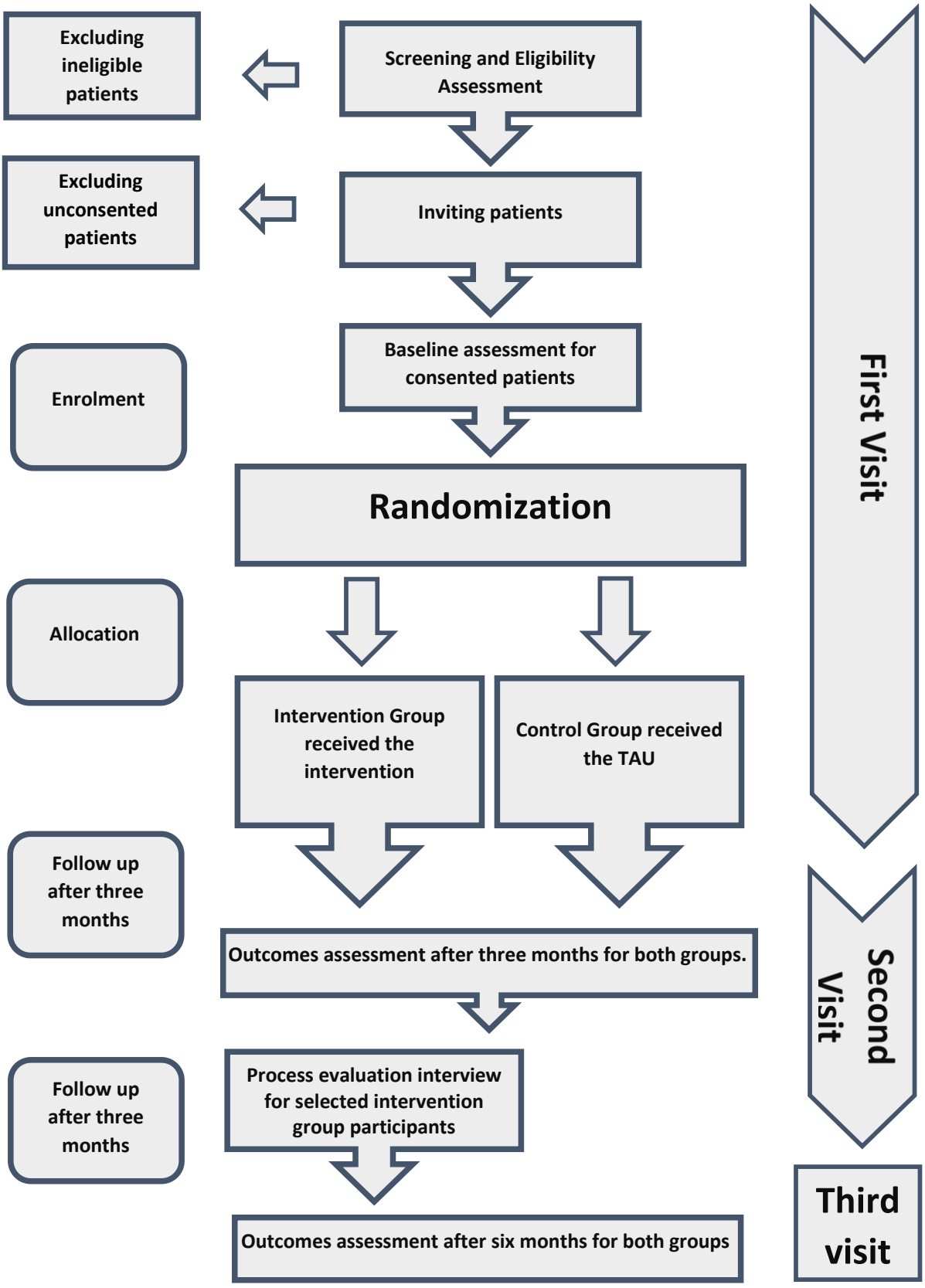


Diagram 1 Trial Flow

3.12 Recruitment of individuals-participants:

Participants were recruited from the outpatient clinics in both participating hospitals through consecutive sampling within a three-month recruitment period that started on the 1st April 2016 and ended on 30th June 2016. Recruiting participants in PHH started two weeks earlier than JUH and was attended on Sunday, Tuesday and Thursday, while attending JUH on Monday, Tuesday and Wednesday to recruit participants. On each clinic day, all patients who were supposed to attend and registered on the medical record list were screened for eligibility, initially through accessing the electronic medical records and then verified in a face-to-face recruitment interview. Patients who met the eligibility criteria were recorded on the researchers' list of potential participants and have been invited verbally to a recruitment interview at one of the empty clinic rooms.

3.12.1 Approaching participants:

Approaching eligible participants formed a challenge to the researcher in this trial. Advertisements about the trial were posted at the department waiting area and clinics' corridors. See **Error! Reference source not found.**. Patients were screened, checked for eligibility, generated a list of potential participants and invited them for a short interview prior recruitment on the same day. That day was considered as first visit once they were recruited. The efforts spent to recruit potential participants would not be constructive without the assistance of the physicians and nurses at both trial sites. They were provided with the Personal Information Sheet (PIS) before commencing the trial and were acknowledged through informal meetings about the trial purpose and the characteristics of the eligible participants see Appendix 3. They

have informed and encouraged eligible participants to take part in the trial and referred them to the researcher. Once they have been referred by any Healthcare professionals, they were asked to return to the waiting area until researcher finishes with the engaged participant if possible. On few occasions at JUH, researcher have had the chance to use a spacious meetings room located at the same department to meet and recruit a number of patients concurrently.

3.12.2 Recruitment interviews:

Eligible patients were called from the waiting area and invited for a recruitment interview in a clinic room to check if they meet the inclusion criteria through a face to face conversation. Patients who met inclusion criteria were invited to participate in the trial verbally and were provided with PIS. Those who did not meet the inclusion criteria were free to leave. Patients who agreed to participate have been asked to sign an informed consent prior to completing baseline assessment. It was explained to the potential participant that entry into the trial is entirely voluntary, and they were free to withdraw at any time. On the other hand, patients who wanted to leave either to discuss participation with other family members or have not had sufficient time to consent have been given a period of 48 hours to consider their participation. They could have opted to take part by calling the researcher, or the researcher should have followed them up by phone call after 48 hours. If patient has verbally consented to participate by phone call, the researcher should have elaborated on all aspects and procedures pertaining to their participation in trial. Upon the final verbal agreement, the researcher should have organized a face-to-face meeting at the outpatient clinic at a time convenient to the patient. This had to be within 48 hours,

and the patient should have required to sign the ICF and complete baseline questionnaires assessment prior randomization. Researcher has proposed that all participants who will be attending the outpatients' clinics again for any research-related purposes will be reimbursed for travel costs.

3.13 Data collection and Outcomes Measurements

As presented in recruitment interviews as was described in section (3.12.2), participants were asked to complete the baseline assessment questionnaires following randomisation procedure. CRFs contents was briefly described and they were asked to respond to all questions if possible. Any clarification was provided when they had any questionnaires-related inquiries during the recruitment interviews. Those who had eyesight complications have been assisted by the researcher who had to read the questionnaires and write their responses. However, participants who consented during the recruitment interview and have not had sufficient time to complete the baseline assessment questionnaires were offered to choose either to complete them on phone or to attend the clinic to complete the baseline assessment questionnaires.

3.13.1 Participant's demographics and clinical characteristics:

Participant's demographics and clinical characteristics were collected at the recruitment interviews. Demographics were gender, age, marital status, level of education, income and occupation status. Other clinical characteristics such as latest readings of lipid profile, weight, blood pressure, fasting glucose level, HbA1c, being diagnosed with other chronic diseases or diabetes complications such as retinopathy, duration of diabetes and diabetes-related medications were collected by the

researcher from the electronic medical records. If any information was missed in the record, it was gathered by asking patients to self-report the missing details, and this was noted as self-reported information. These measures were collected again at the second visit and at the third visit without asking again for their demographics again.

3.13.2 Primary outcomes:

As mentioned in section (3.7), the trial primary outcomes were evaluated using two scales; the Summary of Diabetes Self-Care Activities Scale (SDSCA) to measure the diet and physical activity performance, and Medications Adherence Rating Scale (MARS) to assess T2DM Medications adherence. Total score of performing Diabetes Self-Care Behaviours (DSCB) was computed by summing all three scales after weighting adjustments (Bethlehem, 2019). Both scales are described in detail as follow:

3.13.2.1 Summary of Diabetes Self-Care Activities Scale (SDSCA):

This is a multidimensional, well validated, self-reporting instrument measuring the occurrence of diabetes behaviours and asking participants to recall their self-care activities in the last seven days at six areas: diet, physical activity, Self-Monitoring Blood Glucose (SMBG), foot care, medications and smoking (Toobert et al., 2000). Only diet and physical activity subscales were used to collect the performed self-care activities. SDSCA was used in previous intervention studies among patients with T2DM (Glasgow et al., 1996 , Glasgow and Toobert, 2000 , Glasgow et al., 1992 , Wagner et al., 2001). These studies showed that means and SDs for each subscale in these studies showed a significant consistency among patients who reported higher levels of dietary healthy habit than physical activity. Toobert et al. (2000) calculated

means across the studies for each subscale to calculate the average inter-item correlations within scales and they were high (mean *r* = 0.47); test-retest correlations over 3-4 months were moderate (mean *r* = 0.40). In addition, correlations with other measures of diet and physical activity behaviour supported the validity of subscales within SDSCA (mean *r* = 0.23).

3.13.2.2 Medication Adherence Rating Scale (MARS):

Thompson et al. (2000) developed a medication compliance questionnaire to be used among psychiatric patients and used Item Response Theory (IRT) as a tool for developing the scale. The development of Medication Adherence Rating Scale (MARS) was based on two existing self-report measures of compliance; the Drug Attitude Inventory (DAI) scale and Medication Adherence Questionnaire (MAQ) (Hogan et al., 1983 , Morisky et al., 1986). The new emerged scale consisted of 10 questions with a response of Yes/ No answer. An answer with "No" rated as one and an answer with "Yes" rated as zero except for questions seven and eight which have been reversely rated as one for "Yes" and zero for "No". MARS score was calculated to be the total of ten responses. Thus, the total score will then reflect a greater degree of compliance if it is high, and non-compliance if it is low. The reliability analysis of the MARS using Cronbach's alpha was 0.75 compared to 0.76 and 0.77 for the MAQ and the DAI respectively.

Two independent assessors have contacted all participants in both groups to complete 2 copies of (SDSCA) and (MAS) questionnaires on phone call 2 times, once at the end of each month during the delivery of intervention period.

3.13.3 Secondary outcomes:

As mentioned in section (3.8), trial secondary outcomes were evaluated by several measurements to examine the effectiveness of IMBDSME intervention on the main three elements of IMB model (Information-Motivation-Behavioural skills). *Information;* to measure the level of diabetes self-management knowledge, *Motivation*; to measure the level of motivation toward diabetes self-management behaviours, *Behavioural skills* was measured by evaluating the perceived self-efficacy to perform those behaviours, glycaemic level (HbA1c) and quality of life among patients with T2DM at three-month and six-month endpoints. Those outcomes were evaluated using several measurements as follows:

3.13.3.1 Knowledge of diabetes self-management behaviours:

Patients' knowledge level about diabetes self-management was measured using an adjusted version of the Spoken Knowledge in Low Literacy in Diabetes scale (SKILLD) (Rothman et al., 2005). The original SKILLD scale consisted of ten items assessing patients' knowledge about diabetes self-care, including glucose management, lifestyle modifications, treatment of acute complications, and appropriate activities to prevent long-term complications of uncontrolled diabetes. The coefficient of internal reliability was 0.72, proposing adequate reliability.

The original version was adjusted by merging some items and extra questions were added to assess aspects that were related to trial purposes and outcomes such as diet and medications management. Participants were required to self-report the answers for the ten open-ended questions by handwriting. If they answered an item correctly, a score of one was accounted. While if they answer part of the question

correctly, a score of 0.5 was accounted. The adjusted scale was ten items and was weighted equally to calculate as total of ten if all answers were correct and zero if all answers were not correct.

3.13.3.2 Motivation toward Diabetes self-management behaviours:

Motivational level of patients with diabetes was measured using two scales, one for personal motivation and the other for social support. Firstly, Diabetes Empowerment Scale (DES) was used to measure the personal psychosocial self-efficacy. It was developed by Anderson et al. (2000) and comprised of 28 items representing and distributed into three domains: managing psychosocial aspects of diabetes (9 items), dissatisfaction and readiness to change (9 items) and setting and achieving goals (10 items). DES scores were significantly correlated with both subscales of Diabetes Care Profile (DCF); the validated Positive Attitude scale (coefficient ranged from 0.32 to 0.59) and with the validated Negative Attitude scale (coefficient ranged from 0.38 to 0.59). All participants were required to respond to each item of DES by stating how much do they agree or disagree with the statement in each item apply to their condition. An item checked “strongly agree” received five points; “agree” received four points; “neutral” received three points; “disagree” received two points; and “strongly disagree” received one point. Total score for DES was calculated by summing all of the items scores and dividing by 28 and ranged from one to five.

Secondly, social support was measured by a brief, self-report multidimensional questionnaire developed by Sherbourne and Stewart (1991) and used with patients in the Medical Outcomes Study (MOS). It consisted of 19 items demonstrating four main dimensions (emotional/informational, tangible, affectionate, and positive social interaction), alpha reliability was more than 0.91 in MOS. All participants were required to respond to each of the 19 items by stating how much time they were offered social support for each statement in all items. Each item had five options;

each option received a score. An item checked “all of the time” received five points; “most of the time” received four points; “some of the time” received three points; “a little of the time” received two points; and “none of the time” received one point. To generate an overall score, researcher used both scales (DES) and (MOS) to create a dummy variable, which was generated to represent the total score of personal and social motivation for patients with T2DM. Therefore, and as long as both were scored from one to five, both scales were summed and divided by two to approach a range score from one to five similar to the original scoring system.

3.13.3.3 Diabetes self-management self-efficacy:

Diabetes patients’ self-efficacy in managing their health status was measured by the Perceived Diabetes Self-Management Scale (PDSMS) developed by Wallston et al. (2007). It derived from the Perceived Health Competence Scale (PHCS) where the word “condition” in the original instrument was replaced with “diabetes”. The derived version was used in several investigations and found to be a reliable and valid measure (Smith et al., 1995). PDSMS is an 8-item scale that assesses the degree to which patients with T2DM feel competent or self-efficacious in managing their disease condition. All participants were asked to respond to each item, and they ranged from one “‘Strongly Disagree’’ to five “Strongly Agree”. Four of the items were phrased such that high agreement indicates low self-efficacy or perceived skill. Consequently, these four items were reverse scored prior to being added to the other four items. Then, the total PDSMS score was divided by 8 and ranged from 1 to 8, with higher scores indicating more confidence in self-managing one’s diabetes.

The scale indicated internal consistency with a Cronbach's alpha of 0.83. PDSMS scores were significantly correlated with SDSCA subscales in the psychometric validation trial (Wallston et al., 2007).

3.13.3.4 Glycaemic level (HbA1c)

Glycaemic level for trial participants was measured using the widespread glycated haemoglobin blood test that called (HbA1c). It is a specific form of glycated haemoglobin formed through the irreversible binding of glucose particle to the N-terminus of the haemoglobin β-chain (Marshall and Barth, 2000). HbA1c reflects average glycaemia over approximately three months period. The test is the main tool for assessing glycaemic control and has strong predictive value for prospects diabetes complications (ADA, 2019).

Although different approaches were available to measure patients' glycaemic level, HbA1c was chosen for several reasons. First, it was considered and used in clinical research by the representatives of several medical bodies such as the Association of Clinical Biochemists, Association of British Clinical Diabetologists, British Diabetic Association and Royal College of Physicians. Second, the decision of using HbA1c helped in limiting the lack of standardisation and heterogeneity in the implemented approaches to measure patients' glycaemic level within this area of clinical research in literature. Consequently, it improved the interpretation of trial results and the comparison with other trials. Third, using HbA1c made it possible to estimate the risk of developing diabetes complications for an individual through the harmonization of HbA1c results in this trial with UK Prospective Diabetes Study (UKPDS) and Diabetes Control and Complications Trial (DCCT) results. Those trials demonstrated an

association between the development of different diabetes complications and HbA1c values. Finally, it is the only measure for which a considerable amount of data is available on the risk of subsequent diabetic complications.

In both trial settings, several blood tests including HbA1c were ordered by their treating physician for health check purposes every three months. On some cases, treating physicians were ordering HbA1c blood test each six-month if they had a controlled level of HbA1c, which might be less than 7% or 7.5%. The results and readings of HbA1c were made available by the laboratory technician and was accessible on the electronic record of each patients who attended PHH and JUH.

3.13.3.5 Audit of Diabetes Dependent Quality of Life (ADDQOL):

Diabetes patients' quality of life was measured using an Audit of Diabetes-Dependent Quality of Life (ADDQOL) scale. ADDQOL is an instrument designed to measure patients' perceptions of the impact of diabetes on their quality of life. Bradley et al. (1999) reported that factor analysis and Cronbach's alpha coefficient of internal consistency during the development stage was 0.85 for all items, which supported that all of them need to be combined in one scale.

It consisted of two items regarding their quality of life in general at the beginning, and an additional 18 items asking about certain aspects related to their DM. The two overview questions were developed to inquire about the generic present status of their quality of life and the second was asking about how their quality of life would be without diabetes. Participants were required to respond to the first item by choosing a number on a seven-point scale and they ranged from "excellent" received score of +3 to "extremely bad" received score of -3. The second required participants to choose a number on a five-point scale and they ranged from "very much better" received score of -3 to "worse" received score of +1. The additional 18 items were designed to ask participants to express the impact of diabetes on certain aspects of life such as enjoyment of food, holidays or leisure activities and ease of travel by choosing a number on a five-point scale and they ranged from "very much more or better" received score of -3 to "less or worse" received score of +1. Then, participants were asked to respond on each item by stating how important that item was in their life by choosing a number on a four-point scale that ranged from "very important" received a score of +3 to "not at all important" received a score of zero. Each item's

score was calculated by multiplying their score of response with the score of importance for each specific item to produce scores ranging from -9 to 3. Total score of the 18 items was calculated by summing their scores and divide the total by 18.

All of the measurements were administered in Arabic language. SKILLD, DES MOS, and PDSMS questionnaires were translated to Arabic language using translation and back translation method (Sperber, 2004). All translated measurements were not tested as they have sort of credibility in their original languages. All questionnaires were made available in Arabic language as have been provided by the original authors. The following Table 6 is briefly describing the timing of administering each instrument in this trial. The questionnaire in is presented in the Appendix14 .

Variables	**Baseline**	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**	**Month 6**
Demographics	X						
Contact Details	X						
Anthropometric Measurements	X			X			X
Disease Duration	X						
Next Clinic Appointment	X			X			
Group Allocation	X						
Diabetes Self-Management Knowledge	X			X			X
PDSMS	X			X			X
DES and MOS-SSS	X			X			X
SDSCA and MARS	X	X	X	X	X	X	X
HbA1c (Medical Records)	X			X			X
ADDQOL	X			X			X

Weekly Logs*¥[2]	X	X	X	X	X

Table 6 Brief description about the timing of administering trial instruments and tools

[2] *For intervention group participants only, ¥ Developed for Trial purposes

3.14 Data handling:

Once data collection ended, the completeness of the clinical and demographical data was checked by the researcher. Any detected missing data were collected again by researcher from the electronic medical records at trial sites where possible. Indeed, any empty or blank responses on CRFs were considered as missing raw data. Data collected throughout the trial such as participants' responses on the CRFs and trial sheets were numerically coded and entered onto a Software Package for Social Sciences (SPSS) database version 24.0. For analysis purposes, SPSS datasets were transferred and exported to Stata format due to the robusteness of STATA over SPSS as was advised by the school statistician. All electronic databases were protected by a password and original CRFs and trial sheets were stored in a locked filling cabinet, while the real participants' information sheet was stored separately.

3.14.1 Data cleaning:

Two types of errors can happen during data entry, random and systematic. Random errors can occur as a result of typing wrong value or coding the variable's value with an erroneous value, while systematic errors can occur due to a misunderstanding on how data should be recorded, and they are more easily to be detected. Theoretically, random errors are evenly distributed among trial groups and are more difficult to be discovered. However, an increase rate of random errors may reduce the power of the trial (Polit, 1999). After entering the coded data onto a computer by the researcher, data on the electronic database were verified visually with the original documentation to detect any systematic errors that were inevitable made. Until that point, data were not ready for analysis because they are not cleaned. Therefore, data

cleaning was initiated by checking data for outliers or wild codes and internal consistency. To find the outliers within database, and depending on the level of measurements of variable, frequency distributions, central tendency and range checks of trial variables were carried out to inspect variables for implausible errors. The detected errors were compared with the original documentation to determine whether errors were an entry errors or coding errors. Missing data were not coded and left blank to reduce the chance of using missing codes in statistical calculation (Roberts et al., 1997).

Data internal consistency was checked by testing whether a relation between two variables is compatible. For example, a response for the Body Mass Index (BMI) should be consistence with weight and height responses.

3.14.2 Handling missing data

As is the case with many clinical epidemiological research, missing data are inevitable during data collection process and are often constitute a considerable challenge during analysis and interpretation of the results and can negatively affect and may compromise the validity of the conclusions. Missing values are presented across most trials' datasets and can reduce trial sample size and the trial power (Jakobsen et al., 2017). If attrition rate was higher in one of the trial arms due to participants drop out, it may generate group imbalance and bias (Vickers and Altman, 2013).

They are due to number of reasons such as being in short supply of trial equipment or participant failing to provide data for trial measures. It is commonly happening because they may have died, hospitalized, declined the participation, lost to follow up and cannot be approached again because it is impossible to trace them. In order

to reduce missing values in this trial, several actions were proposed by researcher during designing the trial:

- At recruitment interviews, researcher was available to answer participants inquires on the CRFs. In addition, they were assisted if they had eyesight complications. CRFs then was reviewed to be certain that they have answered all questions.
- Consented participants had the choice to return to the clinic to continue the recruitment interview or to complete CRFs on phone call if they have not had sufficient time to do so.
- Participants who were not able to attend the second or third visit were contacted to complete the outcome measures on phone calls by independent assessors.
- On every occasion where participants have been contacted by researcher or independent assessors, they were reminded about their next appointment and were followed up if they have changed it. Moreover, intervention group participants were reminded to complete the weekly logs whenever it is possible, and it was short and formatted to be on one paper and wording was kept to the minimum for easiness.

These actions were adopted in an attempt to be vigilance and decrease the number of missing values, but some loss of data could not be avoided. Missing values can be handled by several accepted methods such as “Complete Case Analysis”, “Last Observation Carried Forward” or “Multiple Imputation”. The selection of such a method depends on the patterning and distribution of the missing data across the

dataset variables. As Stata handles missing data by a “listwise deletion” which is usually called “Complete Case Analysis” approach, it was inappropriate to use it for some statistical tests such as regression due to the risk of introducing bias within outcomes (Pedersen et al., 2017). Therefore, data were analysed using complete case analysis approach after imputing missing data. However, type of missingness across RCTs is commonly Missing Completely At Random (MCAR) where the estimate of the mean remains unbiased and can best be treated using the mean imputation, but it biases the standard error. Therefore, and in order to solve the problem of having either large or small standard errors, multiple imputation was used to provide unbiased and valid estimates of associations based on the available data (Pedersen et al., 2017).

3.14.3 Multiple Imputation:

Multiple imputation (MI) is a general approach to handle incomplete dataset and is existed in many statistical packages. This approach allows for the uncertainty about missing data by predicting multiple different plausible imputed datasets and then combined together to produce an overall estimated association. Rubin’s rules that consider the variability in results between the imputed datasets, are reflecting the implausibility associated with the missing values to calculate the standard errors and confidence intervals (Rubin, 1987 , Sterne et al., 2009). In contrast to the statistically invalid general approaches, such as mean substitution or last value carried forward, the technique of MI requires the researcher to model the distribution of each variable with missing values based on the observed responses. It includes a random element as a reflection that imputed values are estimated rather than known with

certainty. As a result, MI has the potential to enhance the validity and generate more likely accurate measures of standard errors and variances of the means than other approaches of imputations (McKibben et al., 2012).

3.15 Data analysis:

3.15.1 General consideration:

Data were analysed using STATA software package version 15.0. A statistical significance level was two sided tested at 0.05. Descriptive statistical tests were used to summarize clinical and sociodemographic data. In order to calculate the mean, median and standard deviation for continuous variables, and frequency distributions to describe categorical variables.

3.15.2 Assessing data distribution:

Data were assessed for normality by visual inspection of the shape of the variables' distribution using histograms or plots. Categorical variables were described using frequencies of distribution. While continuous variables were assessed for normality using visual inspection of histogram, skewness and kurtosis statistical tests, and Shapiro-Wilk test (Ghasemi and Zahediasl, 2012). By using skewness and kurtosis tests, a probability of (>0.05) for any measure indicates that data distribution is not violating the assumptions of normal distribution. If the probability was less than 0.05 in one of them, a joint probability was used to decide on normality. If the joint probability was significant, Shapiro-Wilk statistical test was used for the same purpose due to its high power for testing the correlation between the data and the corresponding normal values in comparison to Kolmogorov-Smirnov (K-S) test for

normality. As a result, Shapiro-Wilk was used to test all continuous variables and they were defined as normally distributed if the probability of z was statistically non-significant, otherwise, they were considered as non-normally distributed (Brzezinski, 2012). In addition, summary statistics of skewness and kurtosis were calculated to examine whether the distribution indicated any significant skewness or kurtosis (Rose et al., 2014).

Another way was used is check that sample data are drawn from a normally distributed population through Kolmogorov-Smirnov and the Shapiro-Wilk statistical tests. Those tests compare trial responses against those that should be expected from a normally distributed population. Both were check in conjunction with the former measure above (Ghasemi and Zahediasl, 2012). If the distribution has had any abnormality such as skewed or leptokurtic, then assumptions of normality were not valid. In that case, researcher used to transform data by using logarithmic transformation where possible. This procedure was used to normalise the data by manipulating the magnitude of the variance of the non-normally distributed variables. Several types of transformations were used to change the shape of a distribution or relationship. Stata offer the *gladder* statistical command that uses a graphical approach and produces an array of nine possible histograms, one for each ladder-of-power transforms (Kirkwood and Sterne, 2010 , Becketti, 1994).

3.15.3 Intention to treat analysis (ITT):

Primarily, data were analysed using intention to treat analysis and included all participants who were randomly allocated to trial groups. Intention to treat (ITT) approach is a strategy that is commonly used to analyse RCTs that compares

participants according to the treatment groups they were originally allocated at Randomisation procedure. It includes all participants who were enrolled in the trial regardless of the treatment they actually received, lost to follow up, complied with the trial intervention or any deviation from the protocol. If trial results were obtained without an intention to treat analysis, clinical effectiveness of the studied intervention maybe overestimated (Craig et al., 2008).

To begin with, ITT approach sustains trial groups that are alike irrespective from random disparity, which is the main rationale behind randomisation. For example, patients with uncontrolled glucose level are more likely to die from advanced complications such as Myocardial Infarction or renal failure. If those patients were assigned to an intervention and died during the implementation period, intervention seems to be attributed to death events. If these deaths are included using an ITT analysis, intervention might have a falsely high mortality. Secondly, it allows for exceptional aberration from the policy by practitioners because it may occur only within the trial setting. To clarify this point, in a trial comparing a phone calls educational intervention with the TAU service, intervention provider might incorrectly educate a control group participant on one of the intervention contents through a phone call before identifying the condition of that participants' assignment, but this will not happen in a real-life situation and, therefore, it needs not to be considered for a potential effectiveness. Thus, Intention to treat approach is the most appropriate way for trials of effectiveness, and emphasizes a considerable accountability for all recruited patients in the trials (Hollis and Campbell, 1999)

Nevertheless, many arguments put forward in favour of the invalidity of ITT. To explain, if a participant was allocated to intervention group and did not actually receive the intervention, it may underestimate the effectiveness of the intervention. Intervention impact is generally conventional due to heterogeneity of participant where compliant, non-compliant and lost to follow are included in the analysis. However, although ITT minimize type I error, it has been criticized for being very vigilant and more vulnerable to type II error (Gupta, 2011).

3.15.4 Data transformation

A process of data transformation was initiated if a variable was non-normally distributed. Data transformation is a mathematical function to convert data from one format to another. It can help to improve the homogeneity of variable's variance, so that robust parametric statistical tests can be applied (Manikandan, 2010). Several methods of transformation were utilized to improve the assumption of normality such as log, square root and reciprocal transformations. Therefore, if data transformation changed the variable variance to be normally distributed, mean and standard deviation was used to describe the data, otherwise, median and interquartile range was applied.

3.15.5 Measuring IMBDSME effectiveness:

Comparing trial groups can be done in different ways. Trial groups can be compared at the end of the trial to show which group has improved more, or a change score can be calculated by deducting the follow up score from the baseline score to show which group has the higher/ lower change score. However, using the change scores in analysis takes account of the chance of imbalances at baseline but does not control it (Vickers and Altman, 2001). In RCTs, randomisation is used to reduce the probability of generating an imbalance in baseline measurements between trial groups. Although this is the case in most trials with high number of participants, it may happen within small trials. In fact, there is no recommendation within CONSORT statement about which analysis should be used in RCTs and whether or not an adjustment for baseline measurements is preferred.

Baseline imbalances can occur as a result of chance when choosing participants randomly (Nash et al., 2014). This imbalance may have an impact on the outcomes of the trial during analysis because baseline measurements are negatively correlated with the difference in the scores before and after the treatment. For example, participants with low score at baseline may improve greater than participants with higher score whether they were allocated to control or IMBDSME group. This can lead to creating an artificial underestimation or overestimation in the treatment effect due to the regression to the mean, which has a confounding role since both trial groups are from the same population. Therefore, it is strongly recommended to adjust for the baseline values of the outcome variable regardless having a statistically

significant differences between trial groups or not at baseline (J et al., 2018 , de Boer et al., 2015).

Different methods are existed in the literature that are being used to estimate treatment effect within RCTs. J et al. (2018) used four common methods in their educational article to estimate the effectiveness of a treatment intervention in reducing systolic blood pressure. They concluded that using longitudinal analysis of covariance is strongly advised to estimate treatment effect between trial groups rather than using regular repeated measures analysis and the regular analysis of changes which both are unable to secure proper adjustment for baseline value of the outcome variable during performance. While longitudinal analysis of covariance takes into account the fact that the repeated observations of the outcome variable for each participant are adjusted for the baseline value. However, analysis of covariance can be applied under the assumption of the independency between the independent variable and covariates within subjects where there is no interaction between them. This is a common problem for analysis of covariance because in longitudinal data, observations are collected repeatedly across subjects and a structure of correlation could have been be generated. This assumption, in addition that analysis of covariance support only well-balanced data without any missing values, are big disadvantages to this method (Locascio and Atri, 2011). Therefore, a more flexible advanced approach was chosen to deal with longitudinal data analysis such as Generalized Estimating Equations (GEE).

3.15.5.1 Generalized Estimating Equations method:

GEEs cover the generalized linear model and extend to analyse the repeated correlated measurements. This method is considered a marginal longitudinal approach that attempts -through two equations- to draw a conclusion of how the mean of the dependent variable changes across visits, while at the same time, is eliminating the nuisances of covariances among the observations within subjects separately in order to validate the regression coefficient estimates significantly. It has more power to detect an association of interest, either at population level or individual level, can deal with missing values and with a small number of equally distanced visits (homogeneously separated) as well as does not require dependent variable to be normally distributed. GEEs are "pooled" analyses of within-subject and between-subject relationships, both of which represent imperative aspects to estimate IMBDSME effect. Lastly, GEE method was used to estimate the treatment effect for each single outcome (Zeger et al., 1988).

Analysis were performed through several models to estimate the effect size of IMBDSME intervention on primary and secondary outcomes. Basically, all models used model 1 where the outcomes' score was the dependent variable and the interaction between trial groups and trial visits was the independent variable (unadjusted to the baseline). Then, adjustments were considered for baseline values of the outcome score by adding the trial visits to model 1 (model 2); as in model 2 with adjustments for age and gender (model 3); as on model 3 with the adjustments for HbA1c (model 4); as in model 4 with the adjustments for diabetes-related medications (model 5).

4 Results:

4.1 Recruitment:

The electronic records of 2786 patients who attended the trial sites were screened. Those who did not meet the eligibility criteria were 2384 (85.6%) as large proportion were diagnosed with different disorders and chronic conditions apart from T2DM due to the diverse range of patients who attend both trial sites as was explained in (3.9.2.1) and (3.9.2.2). What is more, those who were diagnosed with T2DM were supposed to meet the eligibility of having an uncontrolled level of HbA1c as was listed in section (3.2.4). Of those who were eligible, 402 (14.4%) potential participants, 215 (53.5%) were unobtainable and only 187 (46.5%) were approached and invited to participate. Of those who were approached, 36 (19.2%) patients declined to participate where 151 (80.8%) agreed to participate and were recruited in the trial. All in all, the overall recruitment rate in this trial was 151/187 (80.8%). However, despite the flexibility of offering the completion of baseline assessment on phone at a time convenient for participants, three participants 3/151 (2%) withdrew during baseline assessment due to lengthy assessment which they perceived to be a burden. The rest 148 (98%) were randomised and allocated to two trial groups. Moreover, during follow up period, seven participants were lost for different reasons mentioned in the following section (4.1.1). The statistics of patients who were screened, excluded, invited and agreed to participate or declined within each stratum are presented in Table 7.

Recruitment stages	Total (%) n=2786	Std. Err.	95% CI[3]
Assessed n= 2786			
PHH	808 (29%)	70.1	667.6 to 948.3
JUH	1978 (71%)	151.4	1674.8 to 2281.1
Excluded n= 2384			
PHH	694 (29.1%)	60.1	573.6 to 814.3
JUH	1690 (70.9%)	128.0	1433.8 to 1946.1
Eligible n= 402			
PHH	114 (28.4%)	14.2	85.50 to 142.4
JUH	288 (71.6%)	28.6	230.7 to 345.2
Couldn't be Invited n= 215 (215/402= 53%)			
PHH	54 (25.1%)	5.7	42.5 to 65.4
JUH	161 (74.9%)	18.4	124.1 to 197.8
Invited n= 187 (187/402=47%)			
PHH	60 (32.1%)	6.3	47 to 72
JUH	127 (67.9%)	16.6	97 to 156
Results of invitation of n=187	**Declined n= 36 (36/187=19.2%)**		**Recruited n= 151 (151/187=80.8%)**
PHH	17 (47.2%)		43 (28.5%)
JUH	19 (52.8%)		108 (71.5%)

Table 7 Statistics of Recruitment stages across trial settings

[3] CI: Confidence Interval

Principally, randomisation was designed to equalize the number of participants within both trial groups. Nevertheless, due to different sizes of randomization blocks in the randomization list, it resulted in the intervention group being slightly larger (n=77) than the control group (n=71), representing 51% and 47% of the sample respectively. CONSORT flow diagram of recruitment stages and allocation of eligible participants within RCT arms is presented below in Figure 10. At second visit, data were unobtainable from two participants (2.6%) in intervention group because researcher was unable to approach, contact or meet them at clinic. While in the control group, data were unobtainable from one participant (1.4%) due to the same reason. In the third visit, the percentages of lost to follow up increased within intervention group and control group, standing at 6.5% (5/77) and 2.8% (2/71) respectively. Further two participants were unapproachable, and one participant died during follow up period, therefore, their data were unobtainable in the intervention group. While in the control group, another participant was unapproachable. All in all, ten participants were lost in trial after signing the consent from and those represented no more than 6.6% of those who were recruited.

4.1.1 CONSORT Flow Diagram of recruitment process and allocation within RCT:

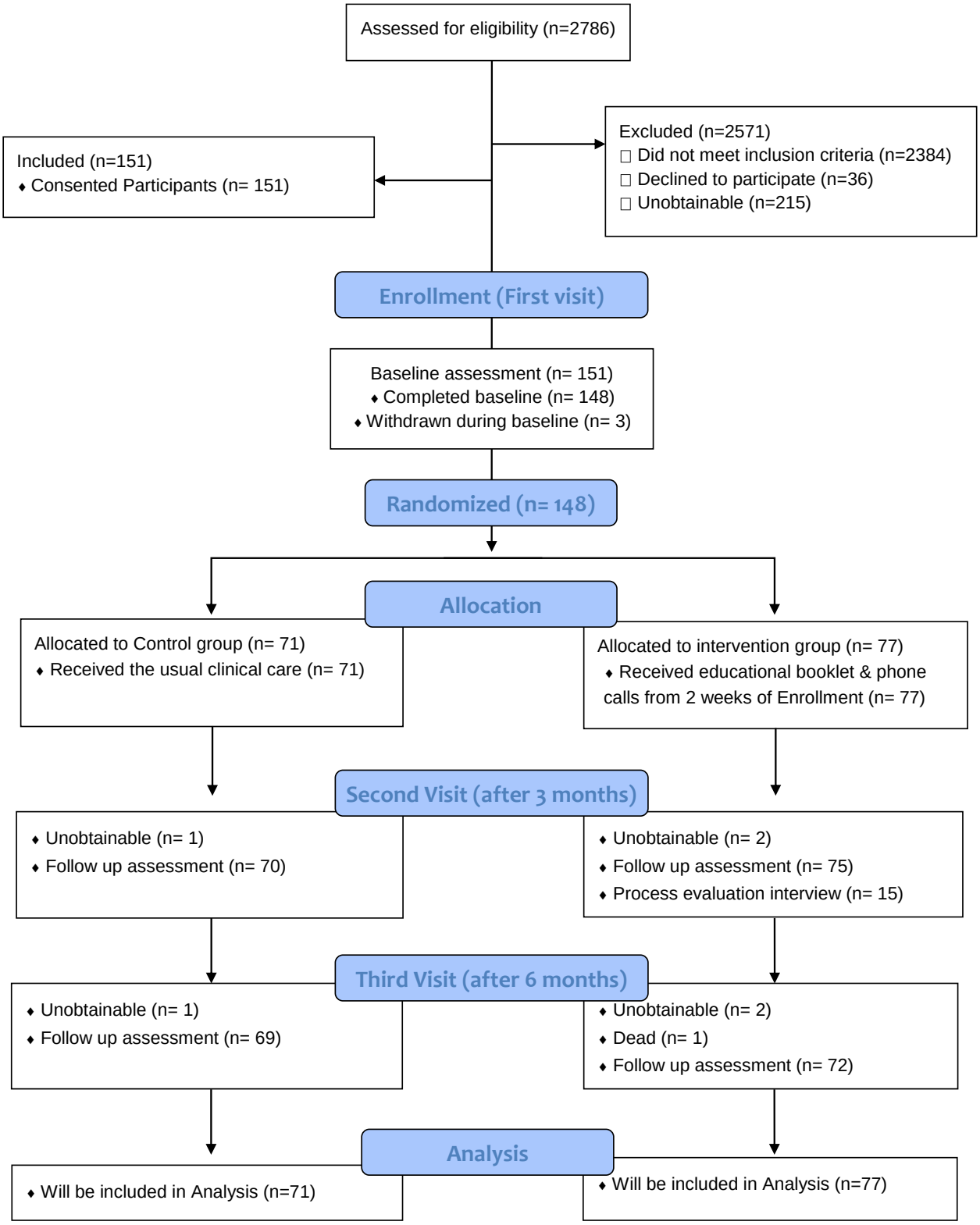


Figure 10 CONSORT Flow Diagram of recruitment process and allocation within RCT

4.2 Data and randomisation list check:

4.2.1 Data check:

The entered raw data on the electronic SPSS database were checked with the original documentation using the anonymised Case Report Forms (CRFs). There were 151 cases with approximately 665 responses for each case. All of them were checked by researcher who found 256 single input mismatching the original documentation. The mismatched responses were corrected. Entry error rate was 0.26% with 95% CI (0.17 - 0.38%) using 256/100415 for the whole dataset. The error rate was less than 0.5% and this means that any difference between the trial groups of 0.5% may be accounted for the entry error. Nevertheless, this difference is unlikely to affect the clinical effect size.

4.2.2 Randomisation outcome check:

The numbered randomisation list contained a block identifier number, stratum of two sites, participant number, unique randomisation code for each participant and his/her allocation in a trial group. Moreover, the list was developed based on different sizes of even blocks of four, six and eight to recruit a total of 464 participants from two trial sites; 232 participants from each This long list was generated in case researcher could not secure a second trial site for individual recruitment purposes. The sequence of 148 participants who were allocated according to the outcome of the randomisation online service was compared with the initially uploaded randomisation list and were identical.

4.3 Participants' allocation:

As seen in Table 8 below, participants were allocated to both trial groups equally within each trial site stratum according to the process of randomisation. Recruited participants from JUH were (70.2%) of the whole trial sample, while (29.8%) were recruited from PHH due to the low number of patients with T2DM who attended PHH. Participants who withdrew during baseline assessment were attending JUH and they are described under pre-randomisation group.

Allocation within Trial Arms / Trial Settings	Intervention group n (%)	Control Group n (%)	Pre-randomization n (%)	Total n (%)
Jordan University Hospital	53 (35%)	50 (33 %)	3 (2%)	106 (70.2%)
Prince Hamza Hospital	24 (16%)	21 (14%)	0	45 (29.8%)
Total	77 (51%)	71 (47%)	3 (2%)	151 (100%)

Table 8 Allocation of eligible participants within Trial arms across trial settings

4.4 Baseline data:

4.4.1 Demographic characteristics:

Demographic characteristics for all participants and by trial groups are presented at Table 9. The data of the three participants (2%) who chose to withdraw before the procedure of randomisation are described under pre-randomization trial group. Median of age of participants in this trial sample was 56 (IQR[4], 50 – 61) and the mean was 55 ± (7.58). Of those, 86 participants were females who constituted the majority (57%) of the sample. As a result, 78 participants were housewives, which was the highest among job categories (51.7%). Similarly, housewives were the majority in each trial group; 38 participants in TAU group (53.6%) and 40 participants in IMBDSME group (52%). Fifth of the sample 34 participants (22.5%) were retired and did not have a specific job at the point of recruitment. Regarding marital status, 116 participants (76.8%) of the sample were married. Another figure, 61 participants (40.4%) of the sample finished their elementary education. Furthermore, active smokers were almost third (29.8%) of the sample whom more than two third of them were males. Lastly, all participants have a median of income of 350 (IQR, 250 – 500) Jordanian Dinars JD[5]. Researcher used significance statistical tests to compare baseline characteristics whether demographics or comorbidities between IMBDSME group and TAU group, and based on the statistically non-significant results, researcher concluded that trial groups were homogenous and comparable at the point of recruitment.

[4] IQR: Inter Quartile Range
[5] 1 JD = 1.41 USD

Demographic characteristics	All Participants	TAU Group	IMBDSME group	Pre-randomization	Statistical test
Age Median (IQR[6])	56 (50 – 61)	56 (50 – 61)	56 (50 – 62)	60 (54 – 65)	Wilcoxon Rank-Sum test P=0.91
Gender					
Male	65 (43%)	31 (44%)	31 (40.3%)	3 (100%)	Chi-square test
Female	86 (57%)	40 (56%)	46 (59.7%)	-----	P=0.121
Job					
Employed	11 (7.3%)	6 (8.5%)	5 (6.5%)	------	
Professional worker	13 (8.6%)	6 (8.5%)	7 (9.1%)	------	Chi-square test
Manager or Employer	13 (8.6%)	6 (8.5%)	7 (9.1%)	------	
Housewife	78 (51.7%)	38 (53.6%)	40 (52%)	------	P=0.988
Retired	34 (22.5%)	15 (21%)	18 (23.4%)	1 (33.3%)	
Marital Status					
Married	116 (76.8%)	54 (76.1%)	61 (79%)	1 (33.3%)	Chi-square test
Single	12 (7.95%)	5 (7.1%)	7 (9.1%)	------	
Widow	16 (10.6%)	10 (14.1%)	6 (7.8%)	------	P=0.63
Divorced	5 (3.1%)	2 (2.8%)	3 (3.9%)	------	

[6] Inter Quartile Range (75%-25%)

Education level					
Below elementary level	5 (3.3%)	4 (5.6%)	1 (1.3%)	------	Chi-square test
Elementary level	61 (40.4%)	30 (42.3%)	31 (40.3%)	------	
Secondary Level	40 (26.5%)	14 (19.7%)	25 (32.5%)	1 (33.3%)	P=0.18
University level	43 (28.5%)	23 (32.4%)	20 (26%)	------	
Smoking status					
Non-smoker	85 (56.3%)	41 (57.8%)	44 (57%)	------	Chi-square test
Smoker	45 (29.8%)	21 (29.6%)	23 (30%)	1 (33.3%)	
Ex-smoker	19 (12.6%)	9 (12.7%)	10 (13%)	------	P=0.99
Income					Wilcoxon Rank-Sum test
Median (IQR[7])	350 (250 – 500)	350 (200 – 500)	350 (280 – 500)	600	P=0.48

[7] Inter Quartile Range

Medications					
Metformin only	4 (2.65%)	2 (2.8%)	2 (2.6%)	------	
Metformin + Sulfonylureas	20 (13.25%)	8 (11.3%)	12 (15.6%)	------	
Metformin + Sulfonylureas + Pre-Mixed insulin	2 (1.3%)	1 (1.4%)	1 (1.3%)	------	
Metformin + Sulfonylureas + Long acting	13 (8.6%)	4 (5.6%)	9 (11.7%)	------	Chi-square test
Metformin + Short acting insulin + Long acting	38 (25.2%)	21 (29.6%)	17 (22.1%)	------	
Metformin + Pre-Mixed insulin	32 (21.2%)	18 (25.4%)	13 (16.9%)	1 (33.3%)	P=0.19
Metformin + Sulfonylureas + DPP-4 inhibitor[8]	19 (12.6%)	10 (14.1%)	8 (10.4%)	1 (33.3%)	
Metformin + Pre-Mixed insulin + DPP-4 inhibitor	8 (5.3%)	3 (4.2%)	5 (6.5%)	------	
Metformin + Sulfonylureas + Pre-Mixed inhibitor	1 (0.7%)	1 (1.4%)	0	------	
Metformin + Sulfonylureas + Long acting	13 (8.6%)	3 (4.2%)	10 (13%)	------	

Table 9 Demographic Characteristics for all Participants and by Trial Groups

[8] Inhibitors of Dipeptidyl Peptidase 4

4.4.2 Comorbidities and Anthropometric measurements:

The presence of comorbidities and measurements of anthropometric parameters within trial sample and trial groups are demonstrated in detail in Table 10. In terms of comorbidities, and although the variations between trial groups were not statistically significant, more participants in the IMBDSME group were diagnosed with retinopathy and lipoedema than of those who were in the TAU group. Whereas in the TAU group, more participants were diagnosed with hypertension and nephropathy than participants in the IMBDSME group.

The glycaemic level (HbA1c) was slightly more controlled in TAU group 9.73 ± (1.51) than participants in IMBDSME group 9.82 ± (1.7), whom have been diagnosed with T2DM longer than participants in TAU, standing at median of 10 (IQR, 5-16) years and median of 9 (IQR, 5-15) years respectively. In contrast, participants in TAU group have had uncontrolled and higher level of lipoedema such as triglycerides and cholesterol levels, standing at median of 181 (IQR, 134 – 219) and mean of 185.7 ± (53.2) respectively, than participants in the IMBDSME group who had median of 162 (IQR, 104 – 272) and mean of 178.2 ± (50.2) respectively. Lastly, systolic and diastolic blood pressure readings and body mass index were similar between trial groups.

Comorbidities characteristics	All Participants	TAU Group	IMBDSME group	Pre-randomization	Statistical test
HbA1c (Glycaemic level) Mean ± (SD)	9.75 ± (1.60)	9.73 ± (1.51)	9.82 ± (1.7)	8.8 ± (0.77)	Independent t test P=0.75
Hypertension					
Yes	108 (71.5%)	56 (78.9%)	51 (66.2%)	1 (33.3%)	Chi-square test
No	41 (27.1%)	15 (21.1)	26 (33.8%)	------	P=0.09
Lipoedema					
Yes	122 (80.8%)	57 (80.3%)	64 (83.1%)	1 (33.3%)	Chi-square test
No	27 (17.9%)	14 (19.7%)	13 (16.9%)	------	P=0.66
Heart Diseases					
Yes	66 (43.7%)	31 (43.7%)	34 (44.2%)	1 (33.3%)	Chi-square test
No	83 (55%)	40 (56.3%)	43 (55.8%)	------	P=0.95
Nephropathy					
Yes	19 (12.6%)	12 (16.9%)	7 (9.1%)	------	Chi-square test
No	130 (86.1%)	59 (83.1%)	70 (90.9%)	1 (33.3%)	P=0.15
Retinopathy					
Yes	104 (68.9%)	18 (25.4%)	27 (35.1%)	1 (33.3%)	Chi-square test
No	45 (29.8%)	53 (74.6%)	50 (64.9%)	------	P=0.19

Neuropathy Yes No	69 (45.7%) 80 (53%)	34 (47.9%) 37 (52.1)	34 (44.2%) 43 (55.8%)	1 (33.3%) ------	Chi-square test P=0.65
Diabetes Duration (before transformation) Median (IQR[9]) **Diabetes Duration (Square root Transformation)** Mean ± (SD[10])	10 (5 – 15) 3.11 ± (1.23)	9 (5 – 15) 3.01 ± (1.2)	10 (5 – 16) 3.17 ± (1.24)	10 5.47	 Independent t test P=0.42
Body Mass Index (Before transformation) Median (IQR) **Body Mass Index (After log transformation)** Mean ± (SD)	31 (26.4 – 35) 3.43 ± (0.22)	31 (25.3 – 35.2) 3.42 ± (0.23)	31 (27.2 – 35) 3.45 ± (0.21)	29 (24.8 -33.4) 3.36 ± (0.21)	 Independent t test P=0.57
Systolic Blood Pressure Mean ± (SD)	134.4 ± (19.3)	134.3 ± (20.9)	134.6 ± (18.3)	130 ± (21.2)	Independent t test P=0.57
Diastolic Blood Pressure Mean (SD)	76.1 ± (11.6)	76.8 ± (13.3)	76 ± (9.9)	60	Independent t test P=0.72
Triglycerides (Before transformation) Median (IQR) **Triglycerides (After log transformation)** Mean ± (SD)	174 (121 – 255) 5.16 ± (0.60)	181 (134 – 219) 5.2 ± (0.50)	162 (104 – 272) 5.12 ± (0.62)	235(229 – 242) 5.5 ± (0.04)	 Independent t test P=0.41

Cholesterol Mean ± (SD)	182.3 ± (51.6)	185.7 ± (53.2)	178.2 ± (50.2)	226 ± (59.4)	Independent t test P=0.46
Low Density Lipoprotein (LDL) Mean ± (SD)	118.2 ± (41.8)	120.8 ± (42.0)	114.8 ± (40.7)	204	Independent t test P=0.49
High Density Lipoprotein (HDL) Mean ± (SD)	40.9 ± (12.4)	41.1 ± (14.1)	40.7 ± (11.3)	44 ± (9.9)	Independent t test P= 0.88

Table 10 Comorbidities and Anthropometric measurements for all Participants and by Trial Groups at Baseline

[9] IQR: Inter Quartile Range (75%-25%)
[10] SD: Standard Deviation

4.4.2.1 Differences between trial sites:

As mentioned in (3.9.4), trial sites differ in treatment regimen and sponsors. This fact may explain the variations in the prescribed diabetes-related in both trial sites (JUH and PHH). In details, more than third (36.1%) of participants who attended JUH were treated for T2DM using the combination of metformin plus the short and long acting insulin, whereas it was not prescribed to any of participants who attended PHH. On the other hand, more than quarter (26.7%) of participants who attended PHH were treated using the combination of metformin and pre-mixed insulin, whereas 19.1% of participants who attended JUH were prescribed this combination.

Without a doubt, the result of HbA1c is greatly informed by the treatment plan that includes diabetes-related medications where patients with T2DM are commonly treated by different regimens (Hirst et al., 2014). Those medications lower HbA1c in different ways, which explain the need for different regimens to achieve an individually tailored HbA1c goal. This may explain the statistically significant difference (P value = 0.015) in HbA1c between trial sites where participants who attended PHH had higher mean of HbA1c 10.2 ± (1.8) than participants who attended JUH 9.5 ± (1.5). All details are presented in Table 11.

Medications	PHH[11] n=45 (29.8%)	JUH[12] n=105 (70.2%)	Total n=150 (100%)
HbA1c	10.2 ± (1.8)	9.5 ± (1.5)	9.8 ± (1.6)
Metformin only	4 (8.9%)	0	4 (2.7%)
Metformin + Sulfonylureas	12 (26.7%)	8 (7.4%)	20 (13.3%)
Metformin + Sulfonylureas + Pre-Mixed insulin	1 (2.2%)	1 (1.0%)	2 (1.3%)
Metformin + Sulfonylureas + Long acting	1 (2.2%)	12 (11.3%)	13 (8.7%)
Metformin + Short acting insulin + Long acting	0	38 (36.1%)	**38 (25.3%)**
Metformin + Pre-Mixed insulin	12 (26.7%)	20 (19.1%)	**32 (21.3%)**
Metformin + Sulfonylureas + DPP-4 inhibitor	9 (20.0 %)	10 (9.4%)	19 (12.7%)
Metformin + Pre-Mixed insulin + DPP-4 inhibitor	4 (8.9%)	4 (3.7%)	8 (5.3%)
Metformin + Sulfonylureas + Pre-Mixed inhibitor	1 (2.2%)	0	1 (0.69%)
Metformin + Sulfonylureas + Long acting	1 (2.2%)	12 (11.4%)	13 (8.7%)
Total	**45 (100%)**	**105 (100%)**	**150 (100%)**

Table 11 Medications and HbA1c level for all participants across Trial sites

[11] PHH (Prince Hamza Hospital)
[12] JUH (Jordan University Hospital)

4.4.3 IMB components, quality of life and self-care behaviours:

IMB components, diabetes-dependent quality of life, and self-care behaviours were measured at baseline and are presented from Table 12 to Table 15. As mentioned before in section (2.1), "I" letter stands for information (knowledge), "M" for motivation whether social or personal and "B" for related-behaviour self-efficacy. Participants in the TAU group tended to have higher scores in all IMB components than participants in the IMBDSME group, except personal motivation where both trial groups had nearly similar scores. The variations in baseline scores between trial groups were not statistically significant as shown in Table 12, Table 13 and Table 15. Using the Audit for Diabetes-Dependent Quality of Life (ADDQOL) scale, participants in both groups had a median of 1 (0 – 2) in the first question, a median of -2 (-2 -- -1) in the second question and a median of -2.1(-3.3 - -1.2) for the diabetes-specific 18-items. According to the ADDQOL scale responses, a middle score of one for the first question means they averagely chose a "good" level of quality of life in general, while for the second question, a score of -2 means they averagely chose that their lives would be "much better" without T2DM. Total score of ADDQOL that measured the impact of T2DM on particular life aspects through 18-items was higher within participants in the TAU group than participants in the IMBDSME group. Moreover, the level of participants' satisfaction on the received TAU did not statistically significantly vary between trial groups, whereas it statistically significantly varied between trial sites. Regardless of the trial groups allocation, participants who attended PHH had a lower level of satisfaction (23.1) compared to participants who attended JUH (26.1) with P value < 0.004.

Overall, mean score of measuring the performance of self-care behaviours such as diet modification, physical activity and medications management were broadly comparable in both trial groups. Those scales have been summed after weighting adjustments for each scale and the total is presented in a dummy variable called total of Diabetes Self-Care Behaviours (DSCB). Generally, participants in TAU group scored higher in performing diet modification 3.14 ± (1.3) and lower in performing physical exercise 1.14 ± (1.1) than IMBDSME group who scored 2.8 ± (1.3) and 1.32 ± (1.37) respectively at baseline.

Characteristics of diabetes knowledge, motivation and self-efficacy (n=148)	All Participants n=151 (100%)	TAU Group, n=71 (47%)	IMBDSME group, n=77 (51%)	Statistical test
SKILLD Mean ± (SD)	6.63 ± (1.2)	6.75 ± (1.0)	6.5 ± (1.3)	Independent t test P=0.22
DES Mean ± (SD)	3.4 ± (0.4)	3.39 ± (0.4)	3.41 ± (0.5)	Independent t test P=0.22
MOS Median (IQR)	0.77 (0.6 – 0.9)	0.78 (0.6 – 0.9)	0.75 (0.6 – 0.8)	Wilcoxon Rank-Sum test P=0.66
DES+MOS Mean ± (SD)	3.64 ± (0.45)	3.65 ± (0.45)	3.62 ± (0.46)	Independent t test P=0.74
PDSMS Mean ± (SD)	2.87 ± (0.57)	2.89 ± (0.48)	2.85 ± (0.64)	Independent t test P=0.72

Table 12 Baseline Data of Diabetes Knowledge, Motivation and Self-Efficacy. SKILLD: Spoken Knowledge in Low Literacy in Diabetes scale; DES: Diabetes Empowerment Scale; MOS: Medical Outcomes Trial; DES+MOS: Total score of combining DES with MOS.PDSMS: Perceived Diabetes Self-Management Scale.

Diabetes-Dependent Quality of Life (n=148)	All Participants n=151 (100%)	TAU Group, n=71 (47%)	IMBDSME group, n=77 (51%)	Statistical test
ADDQOL (Q1) Median (IQR)	1 (0 – 2)	1 (0 – 2)	1 (0 – 2)	Wilcoxon Rank-Sum test P=0.9
ADDQOL (Q2) Median (IQR)	-2 (-2 -- -1)	-2 (-2 - -2)	-2 (-2 - -1)	Wilcoxon Rank-Sum test P=0.35
ADDQOL Total Median (IQR)	-2.1(-3.3 - -1.2)	-2(-3.1 - -1.2)	-2.2(-3.3 - -1.2)	Wilcoxon Rank-Sum test P=0.83
DTSQs Median (IQR)	26 (21.5 – 30)	26 (22 – 30)	26 (21 – 29)	Wilcoxon Rank-Sum test P=0.80

Table 13 Baseline Data of Audit of Diabetes Dependent Quality of Life (ADDQOL) and Diabetes Treatment Satisfaction Questionnaire (DTSQs)

DTSQs	Total n=148 (100%)	PHH n=45 (30.5%)	JUH n=103 (69.5%)	Statistical test
DTSQs at Baseline Mean ± (Standard Deviation)	25.2 ± (5.9)	23.1 ± (6.7)	26.1 ± (5.4)	Independent t test P=0.01

Table 14 Differences between participants across Trial settings in their satisfaction about the perceived treatment

Diabetes Self-Management Behaviours (n=148)	All Participants n=151 (100%)	TAU Group, n=71 (47%)	IMBDSME group, n=77 (51%)	Statistical test
Diet (SDSCA) Mean ± (Standard Deviation)	3 ± (1.3)	3.14 ± (1.3)	2.8 ± (1.3)	Independent t test P=0.13
Physical Activity (SDSCA) Mean ± (Standard Deviation)	1.24 ± (1.24)	1.14 ± (1.1)	1.32 ± (1.37)	Wilcoxon Rank-Sum test P=0.64
Medications Adherence (MARS) Mean ± (Standard Deviation)	8 ± (1.3)	8.0 ± (1.41)	8.1 ± (1.3)	Independent t test P=0.76
Total of DSCB Mean ± (Standard Deviation)	10.67 ± (3.02)	10.66 ± (2.70)	10.67 ± (3.6)	Independent t test P=0.86

Table 15 Baseline Data of Diabetes Self-Management Behaviours. SDSCA; Summary of Diabetes Self-Care Activities Scale; MARS, Medications Adherence Rating Scale; DSCB, Diabetes Self-Care Behaviours.

4.4.4 Missing Data:

Table 16 below shows the percentages of missing data across baseline variables in this trial. At baseline, and as part of the routine clinic practice, weight was not measured for 24.3% of this sample, and researcher was unable to calculate BMI for 43.7% of the sample due to the absence of height measurements in the medical records. Moreover, blood pressure was not measured for 31.8% of all participants, while lipid profile such as HDL, LDL, triglycerides and cholesterol were not measured for 36.5%, 38.5%, 27.7% and 27.7% respectively. All other parameters were collected for all participants (148) who finished baseline assessment and allocated to one of trial groups. Anthropometric measurements such as weight, height and blood pressure were not always measured either due to the unavailability of equipment or were not requested by the treating physician. Likewise, many results of blood tests at baseline such as lipid profile and glycaemic indicators did not exist in the electronic database due to various technical difficulties. According to Pedersen et al. (2017), this type of missing data is a clear example of the Missing Completely At Random (MCAR) and supported the notion of using multiple imputation as researcher proposed in section (3.14.2).

Variable	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Gender	0	151	0.0%	2	0	1
Job	2	149	1.4%	5	1	5
Age	1	150	0.7%	28	30	65
Marital Status	2	149	1.4%	4	0	3
Educational level	2	149	1.4%	4	0	3
Smoking status	2	149	1.4%	3	0	2
Income	2	149	1.4%	39	50	3000
Alcohol	2	149	1.4%	1	0	0
Diabetes Duration	2	149	1.4%	32	0.5	35
Hypertension	2	149	1.4%	2	0	1
Lipoedema	2	149	1.4%	2	0	1
Heart Disease	2	149	1.4%	2	0	1
Nephropathy	2	149	1.4%	2	0	1
Retinopathy	2	149	1.4%	2	0	1
Neuropathy	2	149	1.4%	2	0	1
weight	36	115	24.3%	68	49	150
BMI	66	85	43.7%	84	20	55.8
Systolic pressure	47	104	31.8%	20	90	190
Diastolic pressure	47	104	31.8%	13	50	115
Blood sugar	57	94	38.5%	80	97	492
HDL	54	97	36.5%	46	17	94
LDL	57	94	38.5%	69	45	213
Triglycerides	41	110	27.7%	99	47	630
Cholesterol	41	110	27.7%	83	70	312
Medications	1	150	0.7%	10	1	16
HbA1c	0	151	0.0%	47	8.1	15.1
SKILLD	2	149	1.4%	14	3.5	9.5
DES	2	149	1.4%	130	1.86	5
MOS	3	148	2.0%	26	1.62	5
PDSMS	3	148	2.0%	24	9	38
SDSCA Diet	3	148	2.0%	25	0	6.25
SDSCA activity	3	148	2.0%	11	0	6.5
MARS	3	148	2.0%	7	4	10
ADDQOL 1st Question	3	148	2.0%	7	-3	3
ADDQOL 2nd Question	3	148	2.0%	5	-3	1
ADDQOL Total	3	148	2.0%	107	-8.2	0
DTSQs	3	148	2.0%	26	9	36
DTSQs 2nd Question	3	148	2.0%	7	0	6
DTSQs 3rd Question	3	148	2.0%	7	0	6

Table 16 Percentages of MCAR Missing Data at Baseline for all Participants (n=151) before Randomisation.

Data on weight was available to 83% of participants who attended JUH, while only 60% of those who attended PHH have been measured for weight. Moreover, systolic and diastolic blood pressure readings were available for 75.5% of participants who attended JUH, and available only for 53.3% of participants who attended PHH. This variation was due to the availability of equipment and facilities. In JUH, the required equipment and a dedicated registered nurse were available for anthropometric measurement purposes, whereas in PHH, none of the attendees were measured for anthropometrics unless it was asked by the treating physician because the equipment were not available in the clinic and were shared with other clinics. Details and percentages are presented in Table 17 below.

Variables	Prince Hamza Hospital n=45 (29.8%)	Jordan University Hospital n=106 (70.2%)	Total in trial settings n=151 (100%)
Weight			
Available	27 (60%)	88 (83%)	115 (76.2%
Missing	18 (40%)	18 (17%)	36 (23.8%)
Height			
Available	26 (57.8%)	61 (57.5%)	87 (57.6%
Missing	19 (42.2%)	45 (42.5%)	64 (42.4%)
BMI[6]			
Available	25 (55.6%)	60 (56.6%)	85 (56.3%)
Missing	20 (44.4%)	46 (43.4%)	66 (43.7%)
SBP[6]			
Available	24 (53.3%)	80 (75.5%)	104 (68.9%)
Missing	21 (46.7%)	26 (24.5%)	47 (31.1%)
DBP[6]			
Available	24 (53.3%)	80 (75.5%)	104 (68.9%)
Missing	21 (46.7%)	26 (24.5%)	47 (31.1%)[13]

Table 17 Percentages of Missing data of Anthropometric Measurements across trial settings at Baseline

[13]BMI: Body Mass Index
SBP: Systolic Blood Pressure
DBP: Diastolic Blood Pressure

4.5 Missing data within trial outcomes:

In this trial, primary and secondary outcomes were measured at three-month (second visit) and six-month (third visit) after collecting baseline data as was described in section (3.11). As is the case in many clinical trials, missing data were presented repeatedly across all trial visits due to several reasons such as not attending, or the unavailability of the blood tests results in the medical records and anthropometric measurements equipment in the clinic. All missing data regardless of the quantity of missingness were treated using multiple imputation as explained in section (3.14.2).

It was key factor for this trial that participants should attend their clinic appointments for data collection purposes, and in order to collect primary and secondary outcomes by the independent assessors. Although it was also clinically relevant, participants who attended all the pre-planned clinical appointments were diagnosed with T2DM for a mean duration of 11.61 ± (8.06) years while who did not attend the pre-planned clinic appointments tend to have T2DM for a mean duration of 9.52 ± (7.06) years, this relationship was not statistically significant. However, participants who attended JUH were statistically significant (P=0.026) more likely to attend their clinic appointments (83%), whereas (33.3%) of participants who attended PHH did not attend their clinic appointment as presented in Table 18.

Variables	Did not attend their clinic appointments n=33 (21.9%)	Attended their clinic appointments n=118 (78.1%)	Total n=151 (100%)
Prince Hamza Hospital, n (%)	15 (33.3%)	30 (66.7%)	45 (29.8%)
Jordan University Hospital, n (%)	18 (17.0%)	88 (83.0%)	106 (70.2%)
Duration of T2DM by years at baseline, mean ± (SD)[14]	9.52 ± (7.06)	11.61 ± (8.06)	11.2 ± (7.9)

Table 18 Characteristics of Participants who attended their clinic appointments versus who did not

In this trial, as mentioned before in trial management section (3.10), independent assessors collected the primary and secondary outcomes at three-month and six-month visits. Both (two assessors) managed to attend trial settings to meet the recruited participants from trial groups to collect outcomes face to face. However, some participants did not show up for their clinic appointments and assessors were advised by the researcher to contact those participants by phone to collect the trial outcomes if they were willing to continue voluntarily with the trial. Independent assessors chose and prioritised to collect the primary outcomes over the secondary outcomes due to time constraints as secondary outcomes scales were longer and consumed considerable time and efforts. Overall, percentages of missing data within primary outcomes were less than of those within secondary outcomes.

Statistics of all participants and their status according to the trial visits and by trial groups are presented in Table 19. In general, 97.2% and 93.5% of TAU group and

[14]T2DM: Type 2 Diabetes Mellitus
SD: Standard Deviation

IMBDSME group respectively completed their primary outcomes either face to face or on phone at three-month or six-month.

Percentages of participants who completed their primary outcomes on phone are presented in Table 20. From the details, 32 participants (21.6%) of the trial sample were called on phone to collect their primary outcomes; nine participants (6.1%) at three-month and 23 participants (15.6%) at six-month points because they were not approachable at the clinic on the pre-planned appointment. Of those who were called at three-month point, six of them were allocated at IMBDSME group. Whereas, of those who were called at six-month time point, 14 of them were allocated in TAU group. Using chi-square statistical tests, the relationship of being allocated to a certain trial group and participants' status according to trial visits or the fact of collecting their primary outcomes on phone was not statistically significant different.

Status of Participants according to trial visits	TAU Group, n=71 (47%)	IMBDSME group, n=77 (51%)	Pre-randomisation group, n=3 (2%)	Total, n=151 (100%)
Completed the trial either face to face or on phone	69 (97.2%)	72 (93.5%)	0	141 (93.4%)
Withdrawn at First Visit before Randomisation	0	0	3 (100%)	3 (2%)
Can't be reached at Second Visit	1 (1.4%)	2 (2.6%)	0	3 (2%)
Can't be reached at Third Visit	1 (1.4%)	2 (2.6%)	0	3 (2%)
Deceased at Third Visit	0	1 (1.3%)	0	1 (0.6%)

Table 19 Percentages of participants and their status according to the trial visits for all participants and by trial groups.

Participants who completed primary outcomes on phone and didn't complete secondary outcomes	TAU Group, n=71 (47%)	IMBDSME group, n=77 (51%)	Total, n=148 (100%)
At three-month visit	3 (4.2%)	6 (7.8%)	9 (6.1%)
At six-month visit	14 (19.7%)	9 (11.7%)	23 (15.6%)
Total	17 (24%)	15 (19.5%)	32 (21.6%)

Table 20 Percentages of participants who completed their primary outcomes on phone for all participants and by trial groups

4.5.1 Primary outcomes:

Percentages of missing data of primary outcomes for all participants and across trial groups at three-month and six-month are presented below in Table 21, Table 22 and Table 23. It is notable that the highest percentage of drop out was among IMBDSME group at six-month because five participants (6.5%) could not be approached by the independent assessors whom one of those participants were female and died during the trial data collection period.

Primary outcomes for all participants (n=148)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three -month						
SDSCA Diet	3	145	2.0%	21	1	6.25
SDSCA Activity	3	145	2.0%	9	0	4
MARS	3	145	2.0%	6	5	10
Six-month						
SDSCA Diet	7	141	4.7%	20	1	6.3
SDSCA Activity	7	141	4.7%	10	0	5
MARS	7	141	4.7%	6	5	10

Table 21 Percentages of Missing Data of primary outcomes at for all Participants SDSCA; Summary of Diabetes Self-Care Activities Scale; MARS, Medications Adherence Rating Scale.

Primary outcomes of TAU group (n=71)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three -month						
SDSCA Diet	1	70	1.4%	20	1	6.25
SDSCA Activity	1	70	1.4%	7	0	3.5
MARS	1	70	1.4%	6	5	10
Six-month						
SDSCA Diet	2	69	2.8%	17	1.25	6.25
SDSCA Activity	2	69	2.8%	7	0	3.5
MARS	2	69	2.8%	6	5	10

Table 22 Percentages of Missing Data of primary outcomes at for Participants of TAU group. SDSCA; Summary of Diabetes Self-Care Activities Scale; MARS, Medications Adherence Rating Scale.

Primary outcomes of IMBDSME group (n=77)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three -month						
SDSCA Diet	2	75	1.4%	16	1.75	6.25
SDSCA Activity	2	75	1.4%	9	0	4
MARS	2	75	1.4%	4	7	10
Six-month						
SDSCA Diet	5	72	6.5%	17	1	5.5
SDSCA Activity	5	72	6.5%	10	0	5
MARS	5	72	6.5%	4	7	10

Table 23 Percentages of Missing Data of primary outcomes at for Participants of IMBDSME group. SDSCA; Summary of Diabetes Self-Care Activities Scale; MARS, Medications Adherence Rating Scale.

4.5.2 Secondary outcomes

Percentages of missing data of secondary outcomes for all participants and across trial groups are presented below from Table 24, Table 25 and Table 26. Similar to baseline missing data, several blood tests and anthropometric measurements data were the highest compared to other variables to be missed. At three-month, BMI and blood pressure readings were missed in more than 85% of the trial sample, whereas lipid profile results were missed in more than 55%, and glycaemic level was the least missing, standing at 30% of the whole sample. Indeed, all other outcomes measurements that measured diabetes patients' knowledge, motivation, self-efficacy, satisfaction on the perceived treatment and their quality of life were missed in 15 participants (10.1%) of the sample because they did not show up during their clinic appointment. At six-month, the percentages of missing data increased moreover to approach 100% among BMI and blood pressure readings. While lipid profile results were not available in around 65% of the trial sample whom almost 40% of them have not had any glycaemic indicators readings such as HbA1c and fasting glucose level. While missing data doubled for those other secondary measurements to reach up to 20.3% of the trial sample.

Secondary outcomes for all participants (n=148)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three-month						
Weight	127	21	85.8%	19	50	156
BMI	134	14	90.5%	14	20.8	41.4
Systolic pressure	127	21	85.8%	9	105	190
Diastolic pressure	127	21	85.8%	8	60	100
HbA1c	45	103	30.4%	56	4.9	16
Blood sugar	62	86	41.9%	79	51	716
HDL	93	55	62.8%	31	22	103
LDL	101	47	68.2%	39	44	249
Triglycerides	84	64	56.8%	61	45	736
Cholesterol	83	65	56.1%	54	81	346
Medications	11	137	7.4%	10	1	16
SKILLD	15	133	10.1%	13	4	10
DES	15	133	10.1%	69	2.65	4.67
MOS	15	133	10.1%	21	1	5
PDSMS	15	133	10.1%	19	17	38
ADDQOL 1st Question	15	133	10.1%	5	-1	3
ADDQOL 2nd Question	15	133	10.1%	5	-3	1
ADDQOL Total	15	133	10.1%	113	-7	.17
DTSQc	15	133	10.1%	21	-4	18
DTSQc 2nd Question	15	133	10.1%	6	-2	3
DTSQc 3rd Question	15	133	10.1%	6	-2	3
Six-month						
Weight	148	0	100.0%	0	.	.
BMI	148	0	100%	0	.	.
Systolic Pressure	148	0	100.0%	0	.	.
Diastolic Pressure	148	0	100.0%	0	.	.
Hba1c	57	91	38.5%	53	5.1	13.5
Blood Sugar	70	78	47.3%	69	77	455
HDL	99	49	66.9%	33	21	120
LDL	107	41	72.3%	35	49	195
Triglycerides	95	53	64.2%	45	47	970
Cholesterol	95	53	64.2%	46	96	273
Medications	16	132	10.8%	9	1	16
SKILLD	30	118	20.3%	12	4.5	10
DES	30	118	20.3%	55	2.5	4.5
MOS	30	118	20.3%	20	1.6	5
PDSMS	30	118	20.3%	23	15	40
ADDQOL 1st Question	30	118	20.3%	6	-2	3
ADDQOL 2nd Question	30	118	20.3%	5	-3	1
ADDQOL Total	30	118	20.3%	97	-6.6	.24

Table 24 Percentages of Missing Data of Secondary outcomes at for all Participants

According to trial groups, percentages of missing data between trial groups in all secondary outcomes were nearly parallel of those for the whole sample. Nevertheless, the percentages of missing data at three-month in secondary outcomes such as diabetes patients' knowledge, motivation, self-efficacy, satisfaction on the perceived treatment and their quality of life for TAU group was lower 7.6% in comparison to 12.9% in IMBDSME group. In contrast, the percentages of missing data in the aforementioned measurements at six-month for TAU group was higher 22.5% in comparison to 18.2% in IMBDSME group. All the previous variations between trial groups in terms of missing data were not statistically significant. All details are illustrated in Table 25 and Table 26 below.

Secondary outcomes for TAU group (n=71)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three-month						
Weight	60	11	84.5%	11	61	156
BMI	64	7	90.1%	7	22.95	41.4
Systolic pressure	60	11	84.5%	7	105	190
Diastolic pressure	60	11	84.5%	4	65	100
HbA1c	21	50	29.5%	34	4.9	16
Blood sugar	29	42	40.8%	38	65	543
HDL	45	26	63.3%	21	22	103
LDL	50	21	70.4%	19	44	221
Triglycerides	40	31	56.3%	30	86	467
Cholesterol	40	31	56.3%	28	81	317
Medications	5	66	7.04%	10	1	16
SKILLD	5	66	7.6%	10	4	8.5
DES	5	66	7.6%	49	2.6	4.4
MOS	5	66	7.6%	18	1	4.8
PDSMS	5	66	7.6%	13	17	32
ADDQOL 1st Question	5	66	7.6%	5	-1	3
ADDQOL 2nd Question	5	66	7.6%	5	-3	1
ADDQOL Total	5	66	7.6%	61	-6.5	-0.4
DTSQc	5	66	7.6%	18	-4	17
DTSQc 2nd Question	5	66	7.6%	5	-2	3
DTSQc 3rd Question	5	66	7.6%	5	-1	3
Six-month						
Weight	71	0	100.0%	0	.	.
BMI	71	0	100.0%	0		
Systolic pressure	71	0	100.0%	0	.	.
Diastolic pressure	71	0	100.0%	0	.	.
Hba1c	26	45	36.6%	36	5.1	13.5
Blood Sugar	34	37	47.8%	34	77	455
HDL	46	25	64.7%	17	26	120
LDL	50	21	70.4%	18	49	195
Triglycerides	45	26	63.3%	23	47	523
Cholesterol	45	26	63.3%	25	112	273
Medications	9	62	12.6%	8	1	16
SKILLD	16	55	22.5%	10	4.5	9.5
DES	16	55	22.5%	34	2.5	4.4
MOS	16	55	22.5%	18	1.6	5
PDSMS	16	55	22.5%	16	15	33
ADDQOL 1st Question	16	55	22.5%	5	-1	3
ADDQOL 2nd Question	16	55	22.5%	4	-3	0
ADDQOL Total	16	55	22.5%	50	-6.5	0.23

Table 25 Percentages of Missing Data of Secondary outcomes at for TAU group Participants

Secondary outcomes for IMBDSME group (n=77)	n =.	n ≠.	%of missing data	Unique Values	Minimum	Maximum
Three-month						
Weight	67	10	87.0%	10	50	104
BMI	70	7	90.9%	7	20.8	38.2
Systolic pressure	67	10	87.0%	5	110	155
Diastolic pressure	67	10	87.0%	7	60	100
HbA1c	24	53	31.1%	36	5.4	12.7
Blood sugar	33	44	42.8%	42	51	716
HDL	48	29	62.3%	22	23	73
LDL	51	26	66.2%	23	50	249
Triglycerides	44	33	57.1%	33	45	736
Cholesterol	43	34	55.8%	31	98	346
Medications	6	71	7.7%	8	7	16
SKILLD	10	67	12.9%	8	6.5	10
DES	10	67	12.9%	44	2.6	4.6
MOS	10	67	12.9%	15	2.3	5
PDSMS	10	67	12.9%	18	18	38
ADDQOL 1st Question	10	67	12.9%	4	0	3
ADDQOL 2nd Question	10	67	12.9%	5	-3	1
ADDQOL Total	10	67	12.9%	60	-7	0.17
DTSQc	10	67	12.9%	16	0	18
DTSQc 2nd Question	10	67	12.9%	6	-2	3
DTSQc 3rd Question	10	67	12.9%	6	-2	3
Six-month						
Weight	77	0	100.0%	0	.	.
BMI	77	0	100%	0	.	.
Systolic pressure	77	0	100%	0	.	.
Diastolic pressure	77	0	100%	0	.	.
Hba1c	31	46	40.2%	31	5.6	12
Blood Sugar	36	41	46.7%	39	110	420
HDL	53	24	68.7%	20	21	76
LDL	57	20	74.0%	17	55	132
Triglycerides	50	27	64.9%	25	87	970
Cholesterol	50	27	64.9%	23	96	251
Medications	7	70	9.0%	9	1	16
SKILLD	14	63	18.2%	8	6	10
DES	14	63	18.2%	35	3.0	4.4
MOS	14	63	18.2%	17	2.6	5
PDSMS	14	63	18.2%	18	16	40
ADDQOL 1st Question	14	63	18.2%	6	-2	3
ADDQOL 2nd Question	14	63	18.2%	5	-3	1
ADDQOL Total	14	63	18.2%	54	-4.6	0

Table 26 Percentages of Missing Data of Secondary outcomes at for IMBDSME group Participants

4.6 Statistics of primary and secondary outcomes

It is clear from the information in the sections above that percentages of missing data of primary outcomes were less than those of the secondary outcomes at three-month and six-month. As per CONSORT statement, all trial outcomes whether primary or secondary needs to be statistically summarized for each group using proportions or means and standard deviations together with the effect size using odds ratio and their confidence intervals. Thus, means and standard deviations of trial outcomes with missing data are presented within Table 27 and Table 29below and presented after imputing missing data within Table 28 and Table 30. Presenting outcomes before and after imputing missing data was recommended by (Altman, 2009). While effect size of IMBDSME for each outcome is presented separately within estimation models later in this chapter. Conducting sensitivity analysis is recommended to support conclusions based on the results from the planned analysis after handling missing outcomes.

Primary Outcomes Before Imputing Missing Data	Baseline Mean±(SD)		3-month Mean±(SD)		6-month Mean±(SD)	
	TAU n=71	IMBDSME n=77	TAU n=70	IMBDSME n=75	TAU n=69	IMBDSME n=72
Diet (SDSCA)	3.14 ± (1.3)	2.82 ± (1.3)	2.95 ± (1.1)	3.56 ± (1.10)	2.84 ± (1.1)	3.31 ± (1.02)
Physical Activity (SDSCA)	1.14 ± (1.1)	1.32 ± (1.37)	1.18 ± (0.94)	1.55 ± (1.15)	1.20 ± (0.78)	1.6 ± (1.07)
Medications adherence (MARS)	8.0 ± (1.41)	8.1 ± (1.3)	8.37 ± (1.29)	9.02 ± (0.92)	8.27 ± (1.25)	8.94 ± (0.9)
Total of DSCB	10.66 ± (2.63)	10.67 ± (3.36)	10.79 ± (2.27)	12.51 ± (2.90)	10.64 ± (2.21)	12.28 ± (2.64)

Table 27 Summary of Primary Outcomes before Imputing Missing Data.

Primary Outcomes After Imputing Missing Data	Baseline Mean±(SD)		3-month Mean±(SD)		6-month Mean±(SD)	
	TAU n=71	IMBDSME n=77	TAU n=71	IMBDSME n=77	TAU n=71	IMBDSME n=77
Diet (SDSCA)	3.14 ± (1.3)	2.82 ± (1.2)	2.95 ± (1.1)	3.55 ± (1.10)	2.84 ± (1.1)	3.30 ± (1.0)
Physical Activity (SDSCA)	1.14 ± (1.1)	1.32 ± (1.4)	1.18 ± (0.95)	1.55 ± (1.14)	1.21 ± (0.78)	1.6 ± (1.1)
Medications adherence (MARS)	7.99 ± (1.4)	8.1 ± (1.3)	8.4 ± (1.3)	9.02 ± (0.88)	8.28 ± (1.25)	8.95 ± (0.9)
Total of DSCB	10.66 ± (2.70)	10.67 ± (3.56)	10.78 ± (2.28)	12.49 ± (2.90)	10.65 ± (2.24)	12.26 ± (2.69)

Table 28 Summary of Primary Outcomes after Imputing Missing Data. SDSCA; Summary of Diabetes Self-Care Activities Scale; MARS, Medications Adherence Rating Scale; DSCB, Diabetes Self-Care Behaviours.

Secondary Outcomes Before Imputing Missing Data	Baseline Mean±(SD)		3-month Mean±(SD)		6-month Mean±(SD)	
	TAU n=71	IMBDSME n=77	TAU n=66	IMBDSME n=67	TAU n=55	IMBDSME n=63
Glycaemic level (HbA1c)	9.70 ± (1.5)	9.81 ± (1.7)	9.21 ± (2.4)	8.72 ± (1.59)	8.97 ± (1.85)	8.72 ± (1.55)
Diabetes Knowledge (SKILLD)	6.75 ± (1.0)	6.51 ± (1.34)	6.86 ± (1.1)	8.36 ± (0.81)	6.7 ± (1.03)	8.37 ± (0.86)
Social Motivation (MOS)	3.9 ± (0.79)	3.83 ± (0.83)	4.01 ± (0.7)	4.3 ± (0.66)	3.97 ± (0.68)	4.19 ± (0.56)
Personal Motivation (DES)	3.4 ± (0.43)	3.4 ± (0.46)	3.51 ± (0.44)	3.74 ± (0.52)	3.48 ± (0.50)	3.91 ± (0.38)
Total of DES+MOS	3.65 ± (0.45)	3.62 ± (0.46)	3.76 ± (0.43)	4.02 ± (0.43)	3.73 ± (0.43)	4.05 ± (0.34)
Self-Efficacy (PDSMS)	2.89 ± (0.48)	2.85 ± (0.64)	3.02 ± (0.44)	3.59 ± (0.57)	2.99 ± (0.47)	3.62 ± (0.59)
Quality of Life (Q1)	0.87 ± (1.3)	0.82 ± (1.2)	1.29 ± (1.15)	1.82 ± (0.76)	1.05 ± (1.06)	1.9 ± (0.95)
Quality of Life (Q2)	-1.7 ± (0.88)	-1.56 ± (0.98)	-1.97 ± (0.89)	-1.0 ± (1.0)	-1.84 ± (0.74)	-0.90 ± (0.96)
Quality of Life (ADDQOL)	-2.3 ± (1.4)	-2.38 ± (1.63)	-2.92 ± (1.38)	-1.98 ± (1.35)	-2.63 ± (1.82)	-1.99 ± (1.18)
DTSQs	25.4 ± (6.0)	25 ± (6.01)	7.52 ± (4.32)	11.4 ± (3.4)	------	-----

Table 29 Summary of Secondary Outcomes before Imputing Missing Data. *SKILLD: Spoken Knowledge in Low Literacy in Diabetes scale; DES: Diabetes Empowerment Scale; MOS: Medical Outcomes Study; PDSMS: Perceived Diabetes Self-Management Scale;* Audit of Diabetes Dependent Quality of Life (ADDQOL) and Diabetes Treatment Satisfaction Questionnaire (DTSQs).

Secondary Outcomes After Imputing Missing Data	Baseline Mean±(SD)		3-month Mean±(SD)		6-month Mean±(SD)	
	TAU n=148	IMBDSME n=148	TAU n=148	IMBDSME n=148	TAU n=148	IMBDSME n=148
Glycaemic level (HbA1c)	9.73 ± (1.32)	9.81 ± (1.67)	9.2 ± (2.4)	8.73 ± (1.57)	8.93 ± (1.85)	8.72 ± (1.55)
Diabetes Knowledge (SKILLD)	6.75 ± (0.89)	6.51 ± (1.27)	6.80 ± (1.05)	8.39 ± (0.79)	6.7 ± (1.01)	8.31 ± (0.85)
Social Motivation (MOS)	3.90 ± (0.78)	3.83 ± (0.86)	3.98 ± (0.66)	4.3 ± (0.65)	4.0 ± (0.68)	4.21 ± (0.56)
Personal Motivation (DES)	3.40 ± (0.5)	3.42 ± (0.47)	3.5 ± (0.43)	3.7 ± (0.52)	3.46 ± (0.49)	3.94 ± (0.38)
Total of DES+MOS	3.65 ± (0.45)	3.62 ± (0.46)	3.75 ± (0.43)	4.01 ± (0.43)	3.74 ± (0.43)	4.04 ± (0.34)
Self-Efficacy (PDSMS)	2.89 ± (0.48)	2.85 ± (0.64)	3.02 ± (0.44)	3.57 ± (0.57)	3.03 ± (0.47)	3.61 ± (0.59)
Quality of Life (Q1)	0.87 ± (1.3)	0.82 ± (1.2)	1.28 ± (1.1)	1.79 ± (0.81)	1.14 ± (1.1)	1.9 ± (0.94)
Quality of Life (Q2)	-1.7 ± (0.86)	-1.56 ± (0.97)	-1.95 ± (0.89)	-1.0 ± (0.99)	-1.79 ± (0.79)	-0.91 ± (0.95)
Quality of Life (ADDQOL)	-2.3 ± (1.54)	-2.37 ± (1.62)	-2.9 ± (1.14)	-1.97 ± (1.36)	-2.62 ± (1.75)	-1.96 ± (1.22)
DTSQ	25.2 ± (6.2)	24.69 ± (6.13)	7.5 ± (4.3)	11.6 ± (3.14)	------	-----

Table 30 Summary of Secondary Outcomes after Imputing Missing Data. *SKILLD: Spoken Knowledge in Low Literacy in Diabetes scale; DES: Diabetes Empowerment Scale; MOS: Medical Outcomes Trial; PDSMS: Perceived Diabetes Self-Management Scale;* Audit of Diabetes Dependent Quality of Life (ADDQOL) and Diabetes Treatment Satisfaction Questionnaire (DTSQs).

4.7 Primary outcomes:

As mentioned before in section (3.12.2), primary outcomes were measuring the performance of diet modification, physical activity and medications management. Subscales of SDSCA were used to measure diet and physical activity behaviours, and MARS was used to measure medications management. All three self-management behaviours were computed in one variable called Diabetes Self-Care Behaviours (DSCB). The differences in mean scores between each trial group at baseline, three-month and six-month visits as well as 95% confidence intervals and P values are presented in a table for each self-management behaviour and their total. Each one was modelled separately using GEE before and after imputation and results were almost similar. However, and due to the trivial variation in means between imputed and non-imputed data as shown above in Table 27, Table 28, Table 29 and Table 30, inferential statistics is presented for the imputed dataset in the following sections.

4.7.1 Diet Self-Care behaviour:

Participants in the IMBDSME group had higher mean scores 3.55 ± (1.1) and 3.30 ± (1.02) at three-month and six-month visits respectively than baseline mean score 2.82 ± (1.3). While participants in the TAU group had lower mean score 2.95 ± (1.1) and 2.84± (1.1) for the same time points than baseline score 3.14 ± (1.3). In fact, participants in TAU group had a higher baseline mean score by 0.32 (95% CI, -0.74 – 0.09) than IMBDSME group. However, at three-month time point, diet score increased by 0.6 (95%CI 0.24 to 0.96), and 0.46 (95% CI 0.11 to 0.81) at second and third visits respectively for participants in IMBDSME group than those in the TAU

group. These differences were statistically significant as all p-values were less than 0.01 – except baseline- and demonstrated in the table below and Figure 11.

Diet Self-Care Behaviour (SDSCA)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	3.14 ± (1.3)	2.82 ± (1.3)	-0.32 (-0.74 – 0.09)	0.13
Three-month	2.95 ± (1.1)	3.55 ± (1.1)	0.60 (0.24 – 0.96)	0.001
Six-month	2.84 ± (1.1)	3.30 ± (1.0)	0.46 (0.11 – 0.81)	0.01

Table 31 Diet Scale Score for both Trial Groups after Imputation across Trial Visits

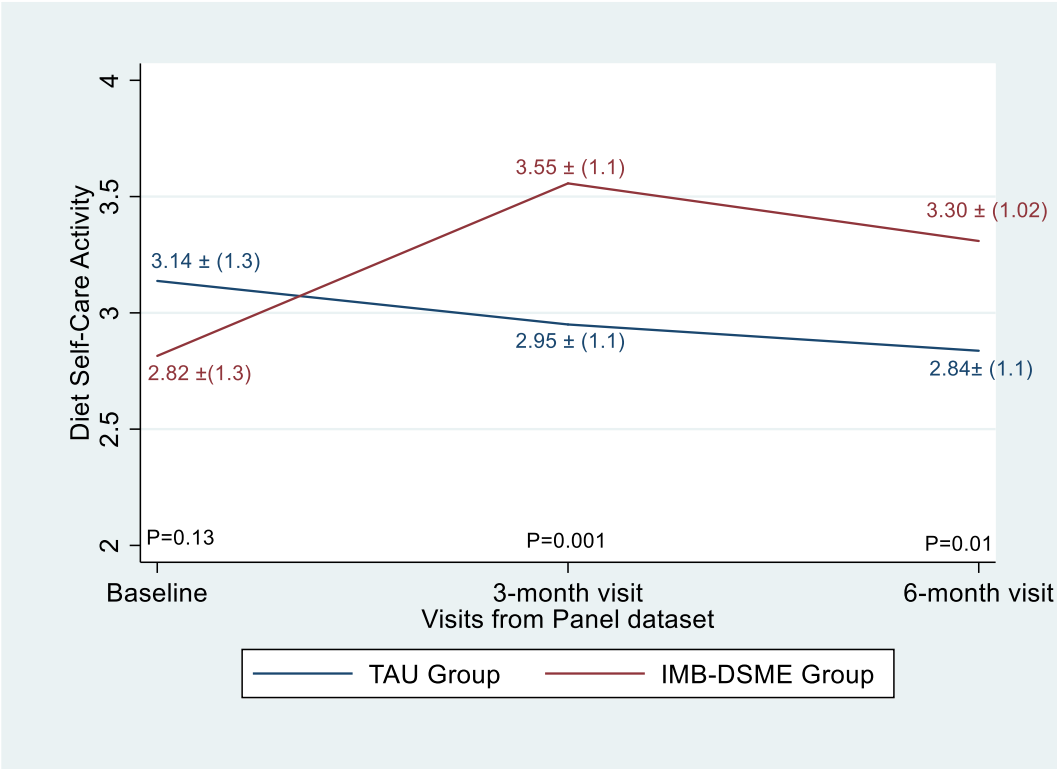


Figure 11 Mean Scores of Diet Self-Care behaviour for Trial Groups across Visits and their Values

4.7.1.1 Modelling GEE:

As mentioned before in section (3.15.5.1), analysis was performed through several models to estimate the effect size of IMBDSME intervention on diet score. P values, coefficients, risk ratios and their 95% CI of diet score for both trial groups for all models are presented below at Table 32.

From the details in the table below, it is clear that using model one produced an underestimated effect size of IMBDSME intervention at three-month and six-month visits due to the non-adjustment of the baseline values of diet score. While after adjustment in model two, the estimated coefficient increased to 0.92 (95%CI, 0.57 to 1.28) and 0.78 (95%CI, 0.40 to 1.17) statistically significant at three-month and six-month visits respectively. With further adjustments for other covariates as in model five, estimated points increased statistically significant to 0.97 (95%CI, 0.58 to 1.36) and 0.85 (95%CI, 0.31 to 1.39) at three-month and six-month visits respectively. All GEE models were statistically significant where P value of the models was less than 0.001. Participants who received IMBDSME intervention were 2.51 (95%CI, 1.76 to 3.59) and 2.19 (95%CI, 1.39 to 3.47) times more likely to have higher mean score in diet scale at three-month and six-month respectively when the score is adjusted to the baseline (model 2). This increase was statistically significant. While participants in the TAU group were high likely to have lower score in diet scale by 17% (95%CI, 7% to 36%) and 46% (95%CI, 1% to 46%) at three-month and six-month respectively before adjustment, and this change was statistically non-significant. However, after adjusting for the baseline scores, gender, age, HbA1c and diabetes-medications, participants who received IMBDSME intervention were 2.64 (95%CI, 1.65 to 4.20)

and 2.34 (95%CI, 1.37 to 4.01) times more likely to have higher score in diet scale at three-month and six-month respectively. The results were statistically significant. Nevertheless, participants in the TAU group were 19% (95%CI, 9% to 40%) and 35% (95%CI, 5% to 56%) likely to have lower score in diet scale at three-month and six-month respectively, and this change was only statistically significant at six-month visit.

Diet (SDSCA)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	-0.19 (-0.44 to 0.07)	0.83 (0.64 to 1.07)	0.15	0.73 (0.49 to 0.98)	2.08 (1.62 to 2.70)	0.001
	2	-0.19 (-0.44 to 0.07)	0.83 (0.64 to 1.07)	0.15	0.92 (0.57 to 1.28)	2.51 (1.76 to 3.59)	0.001
	3	-0.19 (-0.44 to 0.07)	0.83 (0.64 to 1.07)	0.15	0.92 (0.57 to 1.30)	2.52 (1.76 to 3.60)	0.001
	4	-0.24 (-0.53 to -0.05)	0.79 (0.59 to 1.05)	0.10	1.0 (0.60 to 1.40)	2.72 (1.82 to 4.06)	0.001
	5	-0.21 (-0.51 to 0.08)	0.81 (0.60 to 1.09)	0.16	0.97 (0.58 to 1.36)	2.64 (1.65 to 4.20)	0.001
6-month	1	-0.30 (-0.60 to 0.01)	0.74 (0.54 to 1.01)	0.57	0.48 (0.16 to 0.82)	1.62 (1.16 to 2.26)	0.005
	2	-0.30 (-0.60 to 0.01)	0.74 (0.54 to 1.01)	0.57	0.78 (0.33 to 1.24)	2.19 (1.39 to 3.47)	0.001
	3	-0.30 (-0.62 to 0.01)	0.74 (0.54 to 1.01)	0.57	0.78 (0.33 to 1.24)	2.19 (1.39 to 3.47)	0.001
	4	-0.43 (-0.81 to -0.05)	0.65 (0.44 to 0.95)	0.03	0.85 (0.32 to 1.37)	2.64 (1.78 to 3.90	0.002
	5	-0.44 (-0.83 to -0.05)	0.65 (0.44 to 0.95)	0.03	0.85 (0.31 to 1.39)	2.34 (1.37 to 4.01)	0.002

Table 32 Coefficients and Risk Ratios of Diet score of Trial Groups for all Models and their CI (Confidence Interval).
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.7.2 Physical Activity Self-Care behaviour:

Participants in the IMBDSME group reported higher scores 1.55 ± (1.14) and 1.60 ± (1.10) than baseline score compared to participants in the TAU group 1.18 ± (0.95) and 1.21 ± (0.78) at three-month and six-month respectively. Although participants in the IMBDSME group had a higher baseline score than participants in the TAU group, the increase across trial visits was higher among participants who received IMBDSME intervention. In details, mean score of physical activity increased by 0.37 (95% CI, 0.03 – 0.72) and 0.39 (95% CI, 0.07 – 0.71) at three-month and six-month respectively for participants in the IMBDSME group than those in the TAU group. Differences were statistically significant and p values were less than 0.05 except for baseline mean scores and presented in the table below and illustrated in Figure 12.

Physical Activity Self-Care Behaviour (SDSCA)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	1.14 ± (1.10)	1.32 ± (1.40)	0.18 (-0.22 – 0.59)	0.37
Three-month	1.18 ± (0.95)	1.55 ± (1.14)	0.37 (0.03 – 0.72)	0.04
Six-month	1.21 ± (0.78)	1.60 ± (1.10)	0.39 (0.07 – 0.71)	0.02

Table 33 Physical Activity score for both Trial Groups after imputation across all Trial Visits

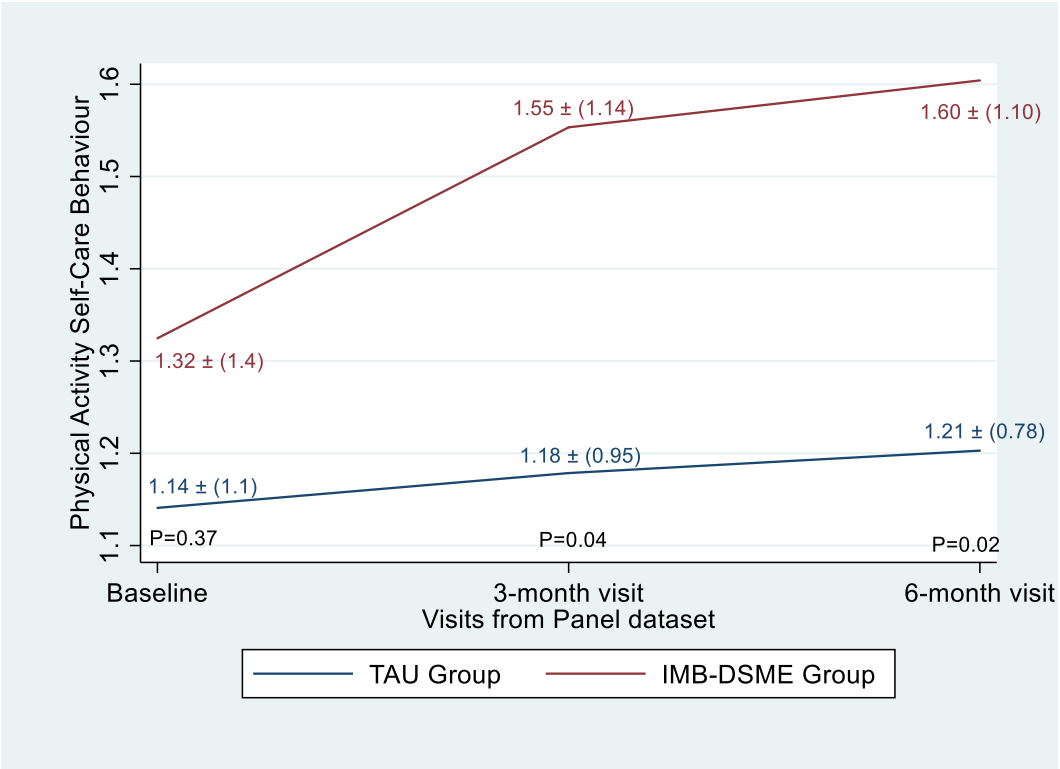


Figure 12 Mean Scores of Physical Activity Self-Care Behaviour for Trial Groups across visits and their values

4.7.2.1 Modelling GEE:

Similar to diet self-care behaviour, analysis was performed through several models to estimate the effect size of IMBDSME intervention on physical activity score. P values, coefficients, risk ratios and their 95% CI of physical activity score for both trial groups for all models are presented below at Table 34.

From the detail in the table belowabove, it shows that the only statistically significant coefficient was only within model 1 among participants in the IMBDSME group. Estimated coefficients were 0.23 (95%CI, 0.03 to 0.43) and 0.28 (95% CI, 0.06 to 0.50) compared to the estimated coefficients of those in the TAU group standing at 0.04 (95% CI, -0.18 to 0.25) and 0.07 (95% CI, -0.14 to 0.29) at three-month and six-month respectively. This means that the estimated coefficient was overestimated before adjustment at model 1 for IMBDSME group. While after adjustments to the baseline scores in model 2, the estimated coefficients for participants in the IMBDSME group were not statistically significant and decreased to 0.19 (95% CI, -0.10 to 0.48) and 0.21 (95% CI, -0.10 to 0.51) at three-month and six-month respectively. Nonetheless, estimated coefficients for participants in the TAU group in model 2 did not change from the estimates in model 1 at three-month and six-month, thus, risk ratios remained the same. All other GEE models were statistically not significant because P values were larger than 0.05 even after further adjustments for other covariates.

Indeed, in model 1 at three-month visit, participants in the IMBDSME group were 25% (95% CI, 3% to 53%) statistically significant more likely to improve their physical activity behaviour, whereas participants in the TAU group were 4% (95% CI, -16% to 29%) more likely to improve their physical activity behaviour, but this increase was

not statistically significant. However, after adjustment to the baseline score (model 2), the probability for participants in the IMBDSME group was not statistically significant and decreased from the value in model 1 to be 21% (95% CI, -10% to 62%) more likely to improve their physical activity behaviour, while the probability for participants in the TAU group was the same value in model 1. Similar trend was seen at six-month visit, in model 1, the probability for participants in the IMBDSME group was statistically significant and they were 32% (95% CI, 6% to 65%) more likely to improve their physical activity behaviour, whereas the probability for participants in TAU was 7% (95% CI, -14% to 34%) but was not statistically significant. After adjustment in model 2, the probability for participants in IMBDSME group was not statistically significant and decreased to be 23% (95% CI, -9% to 67%) more likely to improve their physical activity behaviour, while the probability for participants in the TAU group did not change and was the same in model 1.

Physical Activity (SDSCA)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.04 (-0.18 to 0.25)	1.04 (0.84 to 1.29)	0.74	0.23 (0.03 to 0.43)	1.25 (1.03 to 1.53)	0.026
	2	0.04 (-0.18 to 0.25)	1.04 (0.84 to 1.29)	0.74	0.19 (-0.10 to 0.48)	1.21 (0.90 to 1.62)	0.21
	3	0.04 (-0.18 to 0.25)	1.04 (0.84 to 1.29)	0.74	0.19 (-0.10 to 0.48)	1.21 (0.90 to 1.62)	0.21
	4	-0.01 (-0.27 to 0.25)	0.99 (0.76 to 1.28)	0.94	0.24 (-0.09 to 0.56)	1.27 (0.91 to 1.76)	0.16
	5	-0.004 (-0.27 to 0.26)	1.00 (0.76 to 1.30)	0.97	0.21 (-0.18 to 0.55)	1.24 (0.89 to 1.72)	0.21
6-month	1	0.07 (-0.14 to 0.29)	1.07 (0.86 to 1.34)	0.52	0.28 (0.06 to 0.50)	1.32 (1.06 to 1.65)	0.012
	2	0.07 (-0.14 to 0.29)	1.08 (0.87 to 1.34)	0.51	0.21 (-0.10 to 0.51)	1.23 (0.91 to 1.67)	0.18
	3	0.07 (-0.14 to 0.29)	1.08 (0.87 to 1.34)	0.51	0.21 (-0.10 to 0.51)	1.23 (0.91 to 1.67)	0.19
	4	0.16 (-0.09 to 0.41)	1.17 (0.91 to 1.51)	0.22	0.16 (-0.18 to 0.50)	1.17 (0.83 to 1.65)	0.36
	5	0.17 (-0.07 to 0.42)	1.19 (0.93 to 1.52)	0.17	0.13 (-0.21 to 0.47)	1.14 (0.81 to 1.60)	0.45

Table 34 Coefficients and Risk Ratio of Physical Activity score of Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.7.3 Medications Management Self-Care behaviour:

Participants in the IMBDSME group reported higher scores 9.02 ± (0.88) and 8.95 ± (0.90) than baseline scores compared to participants in the TAU group 8.40 ± (1.30) 8.28 ± (1.25) at three-month and six-month visits respectively. According to the baseline score, participants in IMBDSME group had a higher baseline score by 0.07 (95% CI, -0.37 – 0.5) than TAU group. However, after delivering IMBDSME, MARS score increased by 0.65 (95% CI, 0.28 – 1.01) and 0.67 (95% CI, 0.30 – 1.04) at second and third visits respectively for participants in IMBDSME group than those in the TAU group. These differences were statistically significant as all p-values were less than 0.01 – except baseline- and demonstrated in the table below and Figure 13.

Medications Self-care Behaviour (MARS)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	7.99 ± (1.40)	8.1 ± (1.30)	0.07 (-0.37 – 0.5)	0.76
Three-month	8.40 ± (1.30)	9.02 ± (0.88)	0.65 (0.28 – 1.01)	0.001
Six-month	8.28 ± (1.25)	8.95 ± (0.90)	0.67 (0.30 – 1.04)	0.001

Table 35 Medications' Management Scale Score for both Trial Groups after Imputation across Trial Visits

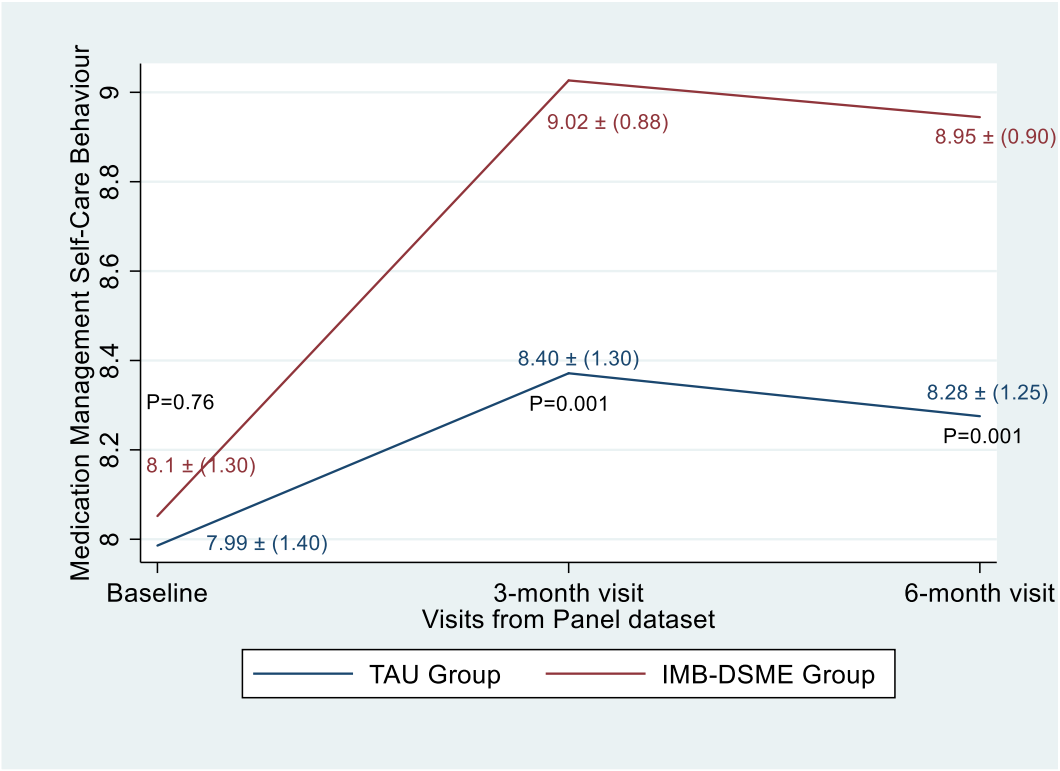


Figure 13 Mean Scores of Medications' Management Self-Care Behaviour for Trial Groups across Visits and their Values

4.7.3.1 Modelling GEE:

As mentioned before in section (3.15.5.1), researcher used several models to estimate the effect size of IMBDSME intervention on medications' management self-care behaviour. Coefficients, risk ratios and their 95% CI of MARS score for both trial groups for all models are presented below at Table 36. It shows that MARS score increased statistically significant for both trial groups at three-month and six-month visit before and after adjustment to baseline score.

Participants in the IMBDSME group had an estimated coefficient increase of 0.97 (95% CI, 0.69 to 1.24) and 0.90 (95% CI, 0.63 to 1.16) before adjustments (model 1) at three-month and six-month respectively. Where after adjustment to the baseline (model 2), the estimated coefficients for those who received IMBDSME intervention reduced at to be 0.58 (95% CI, 0.19 to 0.97) and 0.61 (95% CI, 0.23 to 0.99) at three-month and six-month visits respectively. Hence, the estimate coefficient was overestimated in model 1 for IMBDSME group. However, after adjustment for other covariates in model 5, participants who received IMBDSME intervention had the same coefficients of model 2 except for six-month visit where it statistically significant decreased to 0.46 (95% CI, 0.02 to 0.90).On the other hand, estimated coefficients for those in TAU group were statistically significant across all models at three-month and six-month visits except for model 4 and 5 at six-month time point. They did not change considerably across models and were around 0.39 to 0.37 at three-month visit, and from 0.29 to 0.27 at six-month visit.

Additionally, participants in the IMBDSME group in model 1 were statistically significant 2.63 (95% CI, 2.00 to 3.44) and 2.45 (95% CI, 1.88 to 3.18) times more likely

to practice medications management at three–month and six-month visits respectively. While those in the TAU group were only 1.47 (95% CI, 1.11 to 1.96) and 1.33 (95% CI, 1.01 to 1.76) times more likely to practice medications management at three–month and six-month visits respectively. While after baseline adjustment, the probabilities of IMBDSME group decreased to almost at 1.80 (95% CI, 1.21 to 2.64) and 1.84 (95% CI, 1.25 to 2.69) at three–month and six-month visits respectively and did not change for participants in TAU group from values before adjustments. After adjusting for all covariates, the probability for participants in IMBDSME group remained the same at three-month visit and decreased to 1.59 (95% CI, 1.02 to 2.49) at six-month visit where it was not statistically significant. While for participants in TAU group, the probabilities decreased to 1.45 (95% CI, 1.07 to 1.97) and 1.32 (95% CI, 0.96 to 1.81) at three-month and six-month visits respectively and was only statistically significant at three-month visit.

Medications Management (MARS)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.39 (0.10 to 0.67)	1.47 (1.11 to 1.96)	0.008	0.97 (0.69 to 1.24)	2.63 (2.00 to 3.44)	0.001
	2	0.39 (0.10 to 0.67)	1.47 (1.11 to 1.96)	0.008	0.58 (0.19 to 0.97)	1.80 (1.21 to 2.64)	0.004
	3	0.39 (0.10 to 0.67)	1.47 (1.11 to 1.96)	0.008	0.58 (0.19 to 0.97)	1.80 (1.21 to 2.64)	0.001
	4	0.36 (0.50 to 0.68)	1.44 (1.05 to 1.97)	0.02	0.60 (0.17 to 1.03)	1.82 (1.16 to 2.79)	0.006
	5	0.37 (0.07 to 0.68)	1.45 (1.07 to 1.97)	0.02	0.58 (0.17 to 0.99)	1.80 (1.18 to 2.70)	0.006
6-month	1	0.29 (0.01 to 0.57)	1.33 (1.01 to 1.76)	0.04	0.90 (0.63 to 1.16)	2.45 (1.88 to 3.18)	0.001
	2	0.29 (0.01 to 0.57)	1.33 (1.01 to 1.76)	0.04	0.61 (0.23 to 0.99)	1.84 (1.25 to 2.69)	0.002
	3	0.29 (0.01 to 0.57)	1.33 (1.01 to 1.76)	0.04	0.61 (0.23 to 0.99)	1.84 (1.25 to 2.69)	0.001
	4	0.29 (-0.02 to 0.60)	1.34 (0.98 to 1.82)	0.07	0.46 (0.03 to 0.90)	1.59 (1.03 to 2.46)	0.04
	5	0.27 (-0.04 to 0.59)	1.32 (0.96 to 1.81)	0.09	0.46 (0.02 to 0.90)	1.59 (1.02 to 2.49)	0.04

Table 36 Coefficients and Risk Ratio of MARS score of Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.7.4 Total of Diabetes Self-Care behaviours (DSCB):

Participants in the IMBDSME group reported higher scores 12.49 ± (2.90) and 12.26± (2.69) than baseline scores compared to participants in the TAU group 10.78 ± (2.28) and 10.65 ± (2.24) at three-month and six-month visits respectively. The difference between baseline scores for both groups were almost nil due to the fact that this variable were derived and computed from the three self-care behaviours after weighting adjustments for each one separately. To explain in detail, the mean score of the total of three self-care behaviours for IMBDSME participants increased statistically significant by 1.71 (95% CI, 0.84 – 2.59) and 1.61 (95% CI, 0.76 – 2.46) at three-month and six-month visits respectively than participants in the TAU group. All mean scores for trial groups at each trial visits and their CI are demonstrated in below and Figure 14.

Total of Diabetes Self-Care Behaviours (DSCB)	Mean±(SD)		Diff (95% CI)	P-value
	TAU	IMBDSME		
Baseline	10.66 ± (2.70)	10.67 ± (3.56)	0.007 (-0.98 – 0.99)	0.98
Three-month	10.78 ± (2.28)	12.49 ± (2.90)	1.71 (0.84 – 2.59)	0.001
Six-month	10.65 ± (2.24)	12.26± (2.69)	1.61 (0.76 – 2.46)	0.001

Table 37 Mean Score of the Total of Diabetes Self-Care Behaviours for both Trial Groups after Imputation across Trial Visits and their Confidence Intervals (CI)

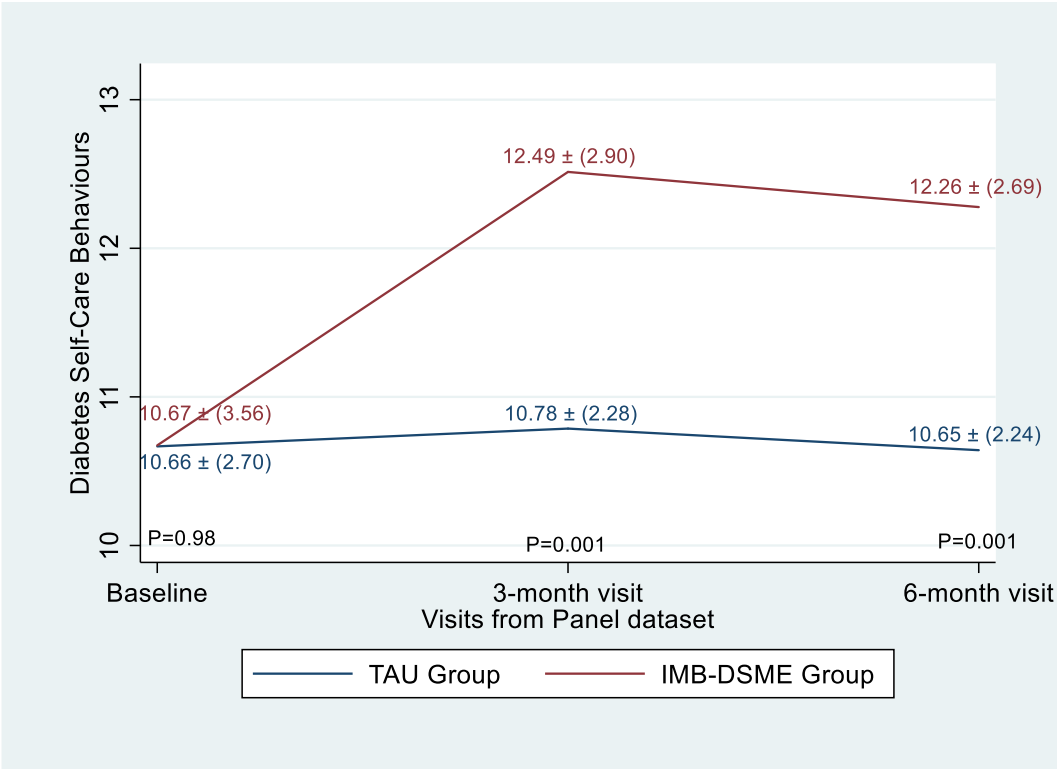


Figure 14 Mean Scores of the Total of Diabetes Self-Care Behaviours for Trial Groups across visits and their P values

4.7.4.1 Modelling GEE:

The same approach of estimating IMBDSME intervention effect size on previous primary outcomes was used with the total of diabetes self-care behaviours. Researcher performed GEE using five models to estimate the coefficients among participants in the IMBDSME group. Coefficients, P values, risk ratios and their 95% CI of MARS score for both trial groups for all models are presented below at Table 38. It shows that estimated coefficients, and accordingly, risk ratios in all models increased statistically significant in the IMBDSME group, whereas those in the TAU group changed minimally and were not statistically significant. At three-month visit, the increase in DSCB score among IMBDSME group was overestimated due to being modelled before the adjustment of the baseline score. However, after adjustment, the point estimate decreased to be 1.70 (95% CI, 0.90 to 2.51) instead of 1.82 (95% CI, 1.26 to 2.39) that was in model one. While after the adjustment for other covariates, estimates increased to be 1.87 (95% CI, 1.01 to 2.73) in model four and 1.78 (0.93 to 2.62) after adjustment for the diabetes-related medications. With this, participants in IMBDSME group were statistically significant 5.5 (95% CI, 2.46 to 12.27)) times more likely to perform all self-care behaviours after baseline score adjustment (model two) than participants in TAU group. This probability increased to 5.91 (95% CI, 2.53 to 13.8) after adjustment for all other clinically related covariates (model five). At six-month visit, the increase in DSCB score among IMBDSME group was 1.61 (95% CI, 0.74 to 2.47) after the adjustment of the baseline score which did not change hugely from the point estimate before the adjustment 1.59 (95% CI, 0.93 to 2.25). Whereas after adjustment for other covariates, the point estimate

decreased to be 1.50 (95% CI, 0.55 to 2.44) and 1.48 (95% CI, 0.54 to 2.42) in model four and five respectively. Lastly, participants in IMBDSME group were statistically significant 4.98 (95% CI, 2.1 to 11.85) times more likely to perform all self-care behaviours after baseline score adjustment (model two) than participants in TAU group. This probability decreased to 4.38 (95% CI, 1.71 to 11.2) after adjustment for all other clinically related covariates (model five).

Diabetes Self-Care Behaviours	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.11 (-0.45 to 0.69)	1.13 (0.63 to 2.00)	0.69	1.82 (1.26 to 2.39)	6.19 (3.53 to 10.9)	0.001
	2	0.12 (-0.46 to 0.69)	1.13 (0.63 to 2.00)	0.69	1.70 (0.90 to 2.51)	5.5 (2.46 to 12.27)	0.001
	3	0.12 (-0.46 to 0.69)	1.12 (0.63 to 2.00)	0.69	1.70 (0.90 to 2.51)	5.5 (2.47 to 12.27)	0.001
	4	-0.04 (-0.70 to 0.62)	0.96 (0.50 to 1.85)	0.90	1.87 (1.01 to 2.73)	6.50 (2.74 to 15.4)	0.001
	5	0.001 (-0.68 to 0.68)	1.00 (0.51 to 1.97)	0.99	1.78 (0.93 to 2.62)	5.91 (2.53 to 13.8)	0.001
6-month	1	-0.014 (-0.57 to 0.54)	0.99 (0.56 to 1.72)	0.96	1.59 (0.93 to 2.25)	4.91 (2.54 to 9.50)	0.001
	2	-0.014 (-0.57 to 0.54)	0.99 (0.56 to 1.72)	0.96	1.61 (0.74 to 2.47)	4.98 (2.1 to 11.85)	0.001
	3	-0.015 (-0.57 to 0.54)	0.99 (0.56 to 1.72)	0.96	1.60 (0.74 to 2.47)	4.98 (2.1 to 11.83)	0.001
	4	-0.01 (-0.64 to 0.62)	0.99 (0.53 to 1.86)	0.97	1.50 (0.55 to 2.44)	4.46 (1.73 to 11.5)	0.002
	5	-0.02 (-0.66 to 0.61)	0.98 (0.52 to 1.85)	0.95	1.48 (0.54 to 2.42)	4.38 (1.71 to 11.2)	0.002

Table 38 Coefficients and Risk Ratio of the total of Diabetes Self-Care Behaviours score of Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8 Secondary Outcomes:

As explained in detail above in section (3.13.3), secondary outcomes were to examine the effectiveness of IMBDSME intervention on the main three elements of IMB model (Information-Motivation-Behavioural skills), glycaemic level (HbA1c) and diabetes dependent quality of life at three-month and six-month endpoints. Those outcomes were measured using several scales except the glycaemic level where glycated haemoglobin blood test (HbA1c) was used for this purpose. The differences in mean scores between each trial group at baseline, three-month and six-month visits as well as 95% confidence intervals and P values are presented in tables for each secondary outcome. In addition, GEE modelling is presented for each outcome separately before and after imputation and results were broadly comparable as was the case with primary outcomes in section (4.7). However, inferential statistics is presented for the imputed dataset in the following sections.

4.8.1 Knowledge of diabetes self-care behaviours:

Participants in the IMBDSME group had higher mean scores of 8.36± (0.81) and 8.37± (0.86) than baseline mean score of 6.51± (1.34) at three-month and six-month visits respectively. While participants in TAU group had mean scores of 6.86 ± (1.1) and 6.7 ± (1.03) than baseline mean score of 6.75± (1.0) at three-month and six-month visits respectively. Although the change in scores at three-month and six-month visits were higher from baseline score for participants in IMBDSME group than participants in TAU group, participants in TAU group had higher baseline score of 6.75 ± (1.0) than those in IMBDSME group 6.51 ± (1.34) and this difference was not statistically significant. The differences between trial groups were statistically significant and

were 1.48 (95% CI, 1.14 – 2.01) and 1.64 (95% CI, 6.45 – 6.98) at three-month and six-month visits respectively as all p-values were less than 0.001 as presented in Table 39 and Figure 15. However, effect size of the IMBDSME intervention on the level of knowledge is estimated in GEE modelling in the next section.

Knowledge about Diabetes Self-Care Behaviours (SKILLD)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	6.75 ± (1.0)	6.51 ± (1.34)	-0.24 (-0.63 – 0.15)	0.22
Three-month	6.86 ± (1.1)	8.36 ± (0.81)	1.48 (1.14 – 2.01)	0.001
Six-month	6.7 ± (1.03)	8.37 ± (0.86)	1.64 (6.45 – 6.98)	0.001

Table 39 Mean scores of SKILLD scale for both trial groups across trial visits after imputation with the differences and their 95% confidence interval differences

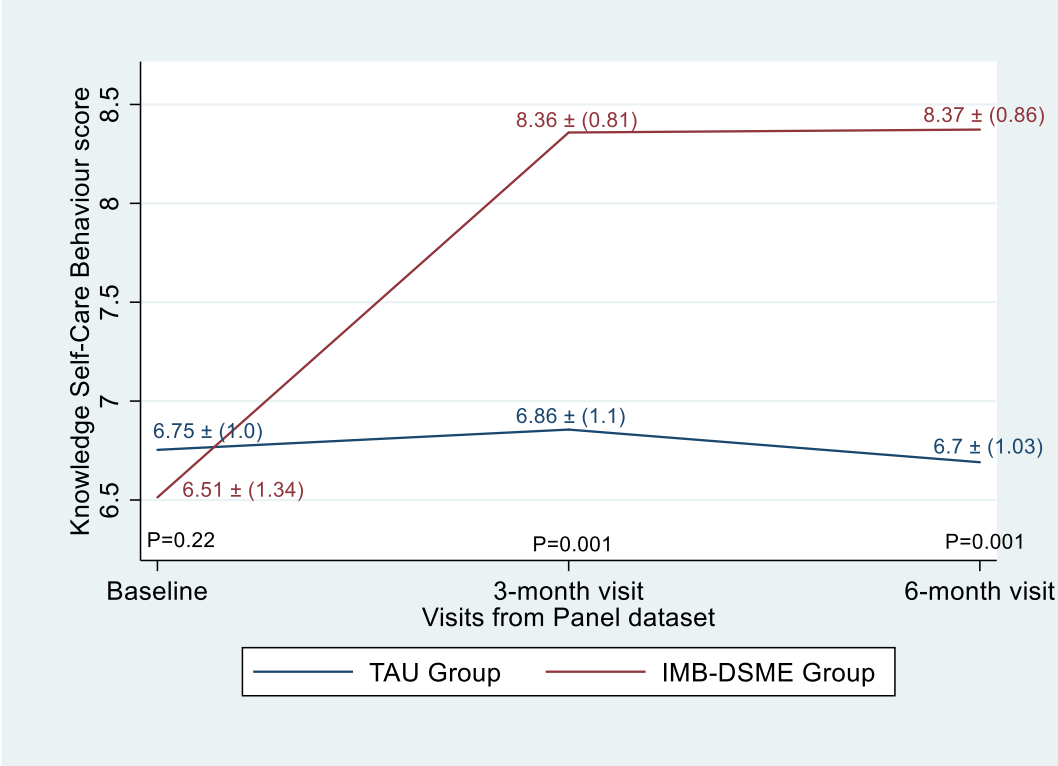


Figure 15 Mean Scores of SKILLD for both trial groups across trial visits and their P values

4.8.1.1 Modelling GEE:

Similar to primary outcomes, secondary outcomes were modelled using GEE approach in five models to estimate the effect size of IMBDSME intervention on the level of diabetes self-management knowledge. P values, estimated coefficients, risk ratios and their 95% CI of SKILLD score for both trial groups for all models are presented below at Table 40. Generally, estimated coefficients and risk ratios were statistically significant for participants in the IMBDSME group in all models where P value was less than 0.001 at three-month and six-month visits, while they were not statistically significant for participants in TAU group.

Details in the table below shows that estimated coefficient for participants in IMBDSME group decreased from 1.79 (95% CI, 1.53 to 2.05) to 1.72 (95% CI, 1.36 to 2.08) at three-month visit, and increased from 1.80 (95% CI, 1.52 to 2.07) to 1.85 (95% CI, 1.46 to 2.25) at six-month visit after baseline score adjustment. While after adjustment for other covariates in model five, estimated coefficient increased minimally to 1.74 (95% CI, 1.38 to 2.09) and 1.89 (95% CI, 1.48 to 2.29) at three-month visit and six-month respectively. On the other hand, estimates for participants in TAU group decreased from 0.07 (95% CI,-0.17 to 0.32) to 0.04 (95% CI, -0.22 to 0.31) and from -0.06 (95% CI,-0.34 to 0.23) to -0.11 (95% CI, -0.39 to 0.17) after adjusting for other covariates in model five at three-month and six-month respectively. Participants who received IMBDSME intervention were 5.57 (95% CI, 3.89 to 7.99) and 6.39 (95% CI, 4.30 to 9.49) times more likely to be knowledgeable on diet modification, physical activity and medications management at three-month and six-month visits respectively when the score is adjusted to the baseline (model

2). While participants in TAU group were 7% (95% CI, -16% to 37%) more likely to be knowledgeable on diet modification, physical activity and medications management at three-month, and less likely by 6% (95% CI, -29% to 26%) to have knowledge on the same self-management behaviours at six-month visit. After adjusting for other covariates in model five, the probabilities increased for participants who received IMBDSME intervention to be 5.67 (95% CI, 3.96 to 8.12) and 6.61 (95% CI, 4.41 to 9.92) at three-month and six-month visits respectively. However, it decreased further from model two for participants in TAU group to be 4% (95% CI, -20% to 36%) more likely to have knowledge on self-management behaviours at three-month visit, and less likely by 11% (95% CI, -32% to 18%) to have knowledge on those behaviours.

Knowledge about Diabetes (SKILLD)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.07 (-0.17 to 0.32)	1.07 (0.84 to 1.37)	0.57	1.79 (1.53 to 2.05)	5.99 (4.60 to 7.79)	0.001
	2	0.07 (-0.17 to 0.32)	1.07 (0.84 to 1.37)	0.57	1.72 (1.36 to 2.08)	5.57 (3.89 to 7.99)	0.001
	3	0.07 (-0.17 to 0.31)	1.07 (0.84 to 1.37)	0.57	1.72 (1.36 to 2.08)	5.57 (3.89 to 7.97)	0.001
	4	0.04 (-0.22 to 0.31)	1.04 (0.80 to 1.36)	0.75	1.74 (1.37 to 2.10)	5.68 (3.95 to 8.18)	0.001
	5	0.04 (-0.22 to 0.31)	1.04 (0.80 to 1.36)	0.76	1.74 (1.38 to 2.09)	5.67 (3.96 to 8.12)	0.001
6-month	1	-0.06 (-0.34 to 0.23)	0.94 (0.71 to 1.26)	0.69	1.80 (1.52 to 2.07)	6.03 (4.57 to 7.96)	0.001
	2	-0.06 (-0.35 to 0.23)	0.94 (0.71 to 1.26)	0.69	1.85 (1.46 to 2.25)	6.39 (4.30 to 9.49)	0.001
	3	-0.06 (-0.35 to 0.23)	0.94 (0.71 to 1.26)	0.69	1.85 (1.46 to 2.25)	6.39 (4.30 to 9.47)	0.001
	4	-0.07 (-0.36 to 0.21)	0.93 (0.70 to 1.23)	0.61	1.89 (1.48 to 2.30)	6.59 (4.38 to 9.90)	0.001
	5	-0.11 (-0.39 to 0.17)	0.89 (0.68 to 1.18)	0.44	1.89 (1.48 to 2.29)	6.61 (4.41 to 9.92)	0.001

Table 40 Coefficients and Risk Ratio of SKILLD score for both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8.2 Motivation toward Diabetes self-care behaviours:

As mentioned in detail in section (3.13.3.2), motivation level toward performing diabetes self-management behaviours was measured using two scales; Diabetes Empowerment Scale (DES) and Medical Outcomes Study (MOS). Total score of both scales was used to evaluate the motivation level for participants in this trial across visits.

As illustrated in Table 41 and Figure 16, participants in the IMBDSME group had higher mean scores in DES-MOS than baseline mean score 4.01 ± (0.43) and 4.04 ± (0.34) compared to participants in the TAU group 3.75 ± (0.43) and 3.74 ± (0.43) at three-month and six-month visits respectively. The difference was not statistically significant in baseline mean scores between trial groups and was 0.02 (95% CI, -0.17 to 0.12), where the baseline scores were 3.65 ± (0.45) and 3.62 ± (0.46) for TAU group and IMBDSME group respectively. While the differences in DES-MOS mean scores between trial groups were statistically significant at three-month visit 0.26 (95% CI, 0.10 – 0.41) and 0.31 (95% CI, 0.15 – 0.47) at six-month visit. P values were less than 0.001 at both visits.

Motivation for Diabetes Self-Care Behaviours (DES+MOS)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	3.65 ± (0.45)	3.62 ± (0.46)	-0.02 (-0.17 – 0.12)	0.74
Three-month	3.75 ± (0.43)	4.01 ± (0.43)	0.26 (0.10 – 0.41)	0.001
Six-month	3.74 ± (0.43)	4.04 ± (0.34)	0.31 (0.15 – 0.47)	0.001

Table 41 Mean scores of DES-MOS for both trial groups across trial visits after imputation with the differences and their 95% confidence interval differences

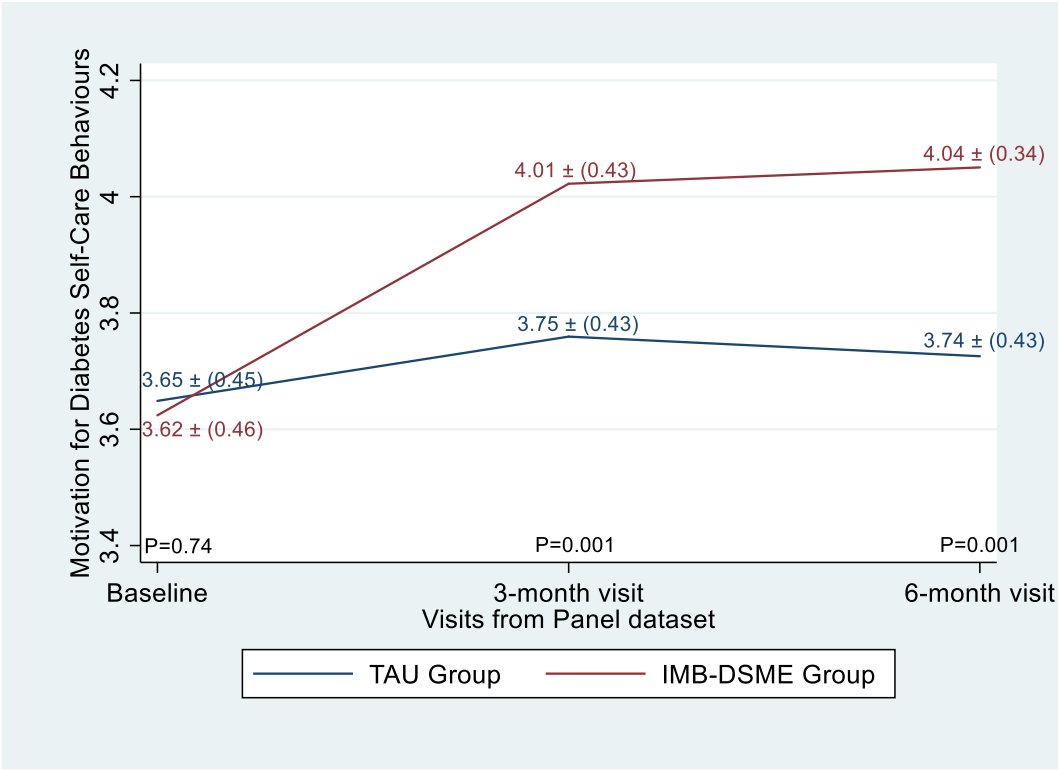


Figure 16 Mean Scores of DES-MOS for both trial groups across trial visits and their P values

4.8.2.1 Modelling GEE:

As presented in Table 42, estimates of the effect size of IMBDSME intervention on the level of motivation toward performing diabetes self-management behaviours were modelled using GEE. P values, estimated coefficients, risk ratios and their 95% CI of DES-MOS score for both trial groups for all models are presented below. In general, all estimated coefficients and risk ratios were statistically significant for participants in the IMBDSME group in all models where P value was less than 0.001 at three-month and six-month visits, while they were not statistically significant for participants in TAU group as P value was more than 0.06.

Participants who received IMBDSME intervention had an estimated coefficient of 0.38 (95% CI, 0.27 to 0.49) at three-month and increased to 0.40 (95% CI, 0.29 to 0.52) at six-month visit before any adjustment in model one, while after the adjustment to the baseline scores, estimated coefficient decreased to 0.28 (95% CI, 0.13 to 0.43) and 0.32 (95% CI, 0.15 to 0.48) at three-month and six-month visits respectively. Moreover, the estimates did not differ considerably after adjusting for other covariates at model five from estimates at model two where it was the same at three-month visit and increased 0.01 at six-month visit. In terms of probability, participants who received IMBDSME intervention were 33% (95% CI, 14% to 54%) and 37% (95% CI, 17% to 61%) more likely to be motivated toward performing diabetes self-management behaviours at three-month and six-month visits after baseline scores adjustment. Similar to the estimates, probabilities in model five remained the same as model two at three-month visit and increased 2% at six-month visit.

For participants in TAU group, estimates coefficients were the same before and after adjustments to the baseline scores and were 0.10 (95% CI, -0.004 to 0.20) and 0.08 (95% CI, -0.04 to 0.21) at three-month and six-month visits. These estimates decreased to 0.08 (95% CI, -0.03 to 0.19) at three-month visits and increased to 0.10 (95% CI, -0.02 to 0.21) at six-month visit after adjusting for other covariates in model five. All estimates and risk ratios for participants in TAU group were not statistically significant.

Motivation for Diabetes (DES-MOS)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.10 (-0.003 to 0.20)	1.10 (0.99 to 1.22)	0.06	0.38 (0.27 to 0.49)	1.46 (1.31 to 1.67)	0.001
	2	0.10 (-0.004 to 0.20)	1.10 (1.00 to 1.22)	0.06	0.28 (0.13 to 0.43)	1.33 (1.14 to 1.54)	0.001
	3	0.10 (-0.004 to 0.20)	1.10 (1.00 to 1.22)	0.06	0.28 (0.13 to 0.43)	1.33 (1.14 to 1.54)	0.001
	4	0.09 (-0.02 to 0.19)	1.09 (0.98 to 1.21)	0.11	0.27 (0.12 to 0.41)	1.31 (1.13 to 1.51)	0.001
	5	0.08 (-0.03 to 0.19)	1.09 (0.97 to 1.21)	0.14	0.28 (0.13 to 0.43)	1.33 (1.14 to 1.53)	0.001
6-month	1	0.08 (-0.04 to 0.21)	1.09 (0.96 to 1.23)	0.18	0.40 (0.29 to 0.52)	1.49 (1.33 to 1.67)	0.001
	2	0.08 (-0.04 to 0.21)	1.09 (0.96 to 1.23)	0.18	0.32 (0.15 to 0.48)	1.37 (1.17 to 1.61)	0.001
	3	0.08 (-0.04 to 0.21)	1.09 (0.96 to 1.23)	0.18	0.32 (0.15 to 0.48)	1.37 (1.17 to 1.61)	0.001
	4	0.08 (-0.03 to 0.19)	1.09 (0.97 to 1.21)	0.15	0.34 (0.20 to 0.49)	1.41 (1.22 to 1.63)	0.001
	5	0.10 (-0.02 to 0.21)	1.10 (0.99 to 1.23)	0.09	0.33 (0.19 to 0.47)	1.39 (1.21 to 1.61)	0.001

Table 42 Coefficients and Risk Ratio of DES-MOS score for both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8.3 Diabetes self-management self-efficacy:

As was explained in (3.13.3.3), perceived self-efficacy to perform diabetes self-management behaviours was measured to evaluate the element of behavioural skills, which is part of IMB model through using the Perceived Diabetes Self-Management Scale (PDSMS). As illustrated in Table 43 and Figure 17, participants in the IMBDSME group experienced higher mean scores 3.57 ± (0.57) and 3.61 ± (0.59) than baseline mean score compared to participants in TAU group 3.02 ± (0.44) and 3.03 ± (0.47) at three-month and six-month visits respectively. The difference in baseline mean scores for trial groups was 0.03 (95% CI, -0.22 – 0.15) and was not statistically significant. Baseline mean score for participants in IMBDSME group 2.85 ± (0.64) was lower than participants in TAU group 2.89 ± (0.48).

Diabetes self-management self-efficacy (PDSMS)	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	2.89 ± (0.48)	2.85 ± (0.64)	-0.03 (-0.22 – 0.15)	0.72
Three-month	3.02 ± (0.44)	3.57 ± (0.57)	0.54 (0.37 – 0.73)	0.001
Six-month	3.03 ± (0.47)	3.61 ± (0.59)	0.58 (0.37 – 0.79)	0.001

Table 43 Mean scores of PDSMS for both trial groups across trial visits after imputation with the differences and their 95% confidence interval differences

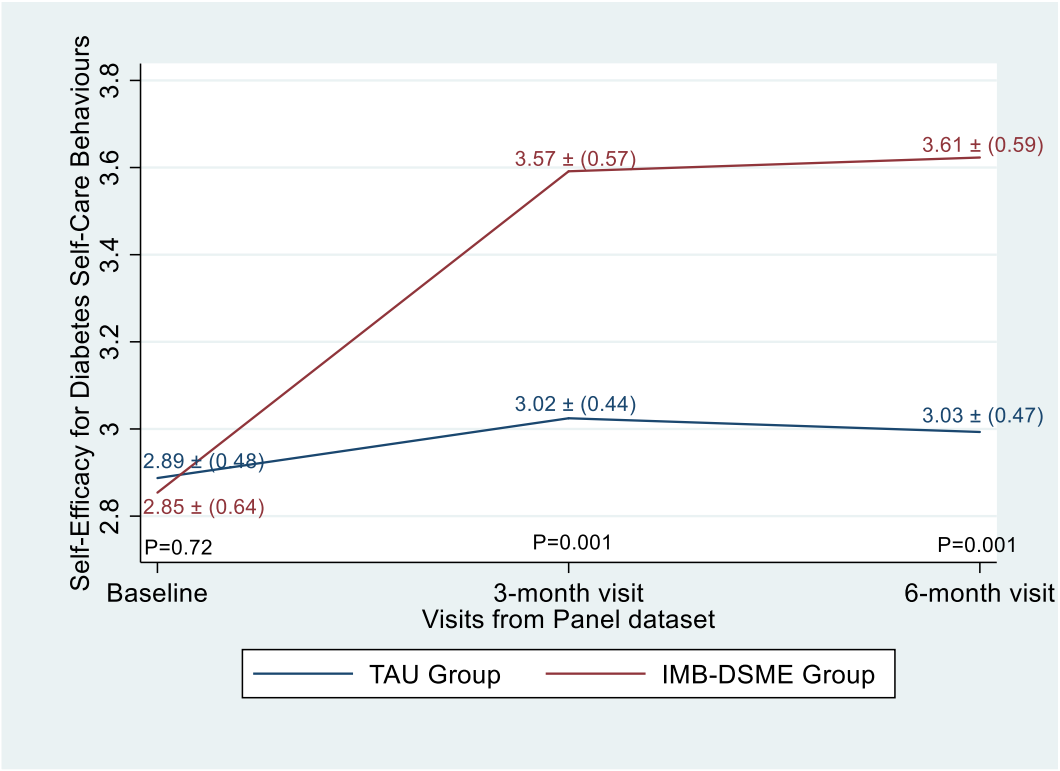


Figure 17 Mean Scores of PDSMS for both trial groups across trial visits and their P values

4.8.3.1 Modelling GEE:

As presented in Table 44, estimated coefficients of the effect size of IMBDSME intervention on the level of self-efficacy were modelled using GEE approach in five models. It consisted of P values, estimated coefficients, risk ratios and their 95% CI for both trial groups for all models. Generally speaking, estimated coefficients and their risk ratios for participants in the IMBDSME group were statistically significant in all models at three-month and six—month visits. What is more, they were statistically significant for participants in the TAU group in model two and three at three-month visit but not statistically significant at six-month visit.

Participants who received IMBDSME intervention had an estimated coefficients at three-month and six-month visits of 0.71 (95% CI, 0.55 to 0.87) and 0.75 (95% CI, 0.58 to 0.91) respectively before baseline score adjustment, while after adjustment in model two, they decreased to be decreased to 0.58 (95% CI, 0.38 to 0.78) and 0.61 (95% CI, 0.38 to 0.83) at same endpoints above. However, the estimate coefficients in model two increased in model five at three-month visit to be 0.61 (95% CI, 0.40 to 0.82) and decreased at six-month to be 0.55 (95% CI, 0.32 to 0.78). On the other hand, participants in TAU group had the same estimated coefficient before and after adjustment of the baseline score 0.13 (95% CI, 0.01 to 0.24) at three-month visit and decreased to 0.10 (95% CI, -0.03 to 0.23) in model five but was not statistically significant.

Regarding probability, participants who received IMBDSME intervention were statistically significant more likely by 79% (95% CI, 46% to 118%) and 83% (95% CI, 47% to 129%) to experience an increase in self-efficacy at three-month and six-month

visits after adjusting baseline mean score (model two). The probabilities in model two increased to 84% (95% CI, 50% to 127%) at three-month visit and decreased to 73% (95% CI, 38% to 117%) at six-month visit after adjusting for all covariates in model 5. However, the probability for participants in TAU group was 14% (95% CI, 1% to 28%) more likely to experience an increase in self-efficacy after baseline score adjustments and it was the only statistically significant figure.

Self-management self-efficacy (PDSMS)	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.13 (0.01 to 0.24)	1.14 (1.01 to 1.28)	0.03	0.71 (0.55 to 0.87)	2.03 (1.72 to 2.40)	0.001
	2	0.13 (0.01 to 0.24)	1.14 (1.01 to 1.28)	0.03	0.58 (0.38 to 0.78)	1.79 (1.46 to 2.18)	0.001
	3	0.13 (0.01 to 0.24)	1.14 (1.01 to 1.28)	0.03	0.58 (0.38 to 0.78)	1.79 (1.46 to 2.18)	0.001
	4	0.10 (-0.03 to 0.22)	1.10 (0.97 to 1.25)	0.12	0.59 (0.39 to 0.80)	1.81 (1.48 to 2.23)	0.001
	5	0.10 (-0.03 to 0.23)	1.10 (0.97 to 1.25)	0.15	0.61 (0.40 to 0.82)	1.84 (1.50 to 2.27)	0.001
6-month	1	0.14 (-0.01 to 0.30)	1.15 (0.99 to 1.34)	0.08	0.75 (0.58 to 0.91)	2.11 (1.79 to 2.49)	0.001
	2	0.14 (-0.01 to 0.30)	1.15 (0.99 to 1.34)	0.08	0.61 (0.38 to 0.83)	1.83 (1.47 to 2.29)	0.001
	3	0.14 (-0.01 to 0.30)	1.15 (0.99 to 1.34)	0.08	0.61 (0.38 to 0.83)	1.83 (1.47 to 2.29)	0.001
	4	0.12 (-0.04 to 0.30)	1.12 (0.96 to 1.31)	0.14	0.59 (0.36 to 0.82)	1.80 (1.43 to 2.26)	0.001
	5	0.15 (-0.01 to 0.30)	1.16 (0.99 to 1.35)	0.06	0.55 (0.32 to 0.78)	1.73 (1.38 to 2.17)	0.001

Table 44 Coefficients and Risk Ratios of PDSMS score for both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8.4 Glycaemic level (HbA1c):

As mentioned in section (3.13.3.4), glycated haemoglobin blood test (HbA1c) was used to evaluate the glycaemic level for all participants at baseline, three-month and six-month visits. As per the American Diabetes Association (ADA) guidelines, this blood test is usually arranged each three-month by the treating physician, and each six-month if their HbA1c level improved. As mentioned in (4.4.2.1), fundamentally, prescribing diabetes-related medications is informed greatly by the result of HbA1c. Those medications were determined and prescribed according to the utilised treatment regimens and the availability in each trial sites, in which each has different sponsor. Therefore, and in addition to estimate the effect size of IMBDSME intervention on Hba1c levels between trial groups, researcher investigated the effectiveness between trial groups for each trial site due to the fact that the difference in HbA1c between trial sites was statistically significant at baseline as was presented in (4.4.2.1). At baseline, participants who attended PHH had higher mean of HbA1c 10.2 ± (1.8) than participants who attended JUH who had a mean of HbA1c of 9.5 ± (1.5) and this difference was statistically significant ($P<0.015$).

4.8.4.1 Glycaemic level (HbA1c) in both sites:

Participants in the IMBDSME group had lower mean of HbA1c 8.73 ± (1.57) and 8.72 ± (1.55) at three-month and six-month, respectively, than baseline mean value 9.81 ± (1.67) as is presented below in Table 45 and Figure 18. Although participants in TAU group had lower mean of HbA1c 9.21 ± (2.40) and 8.97 ± (1.85) at three-month and six-month respectively than baseline value 9.73 ± (1.32), the improvement in HbA1c among participants who received IMBDSME intervention was higher than those who

did not receive in TAU group. Based on the mean values of HbA1c, the differences between trial groups across baseline, three-month and six-month visits were not statistically significant despite the variations in the level of improvement in HbA1c between TAU group and IMBDSME group. All P values were more than 0.05. Nevertheless, the true effect size of the IMBDSME intervention on HbA1c level is modelled using GEE approach in the next section.

Glycaemic level (HbA1c) for both sites	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	9.73 ± (1.32)	9.81 ± (1.67)	0.08 (-0.44 – 0.61)	0.75
Three-month	9.21 ± (2.40)	8.73 ± (1.57)	-0.48 (-1.26 – 0.30)	0.23
Six-month	8.97 ± (1.85)	8.72 ± (1.55)	-0.25 (-0.95 – 0.45)	0.76

Table 45 Mean of HbA1c for both trial groups across trial visits after imputation with the differences and their 95% confidence interval differences

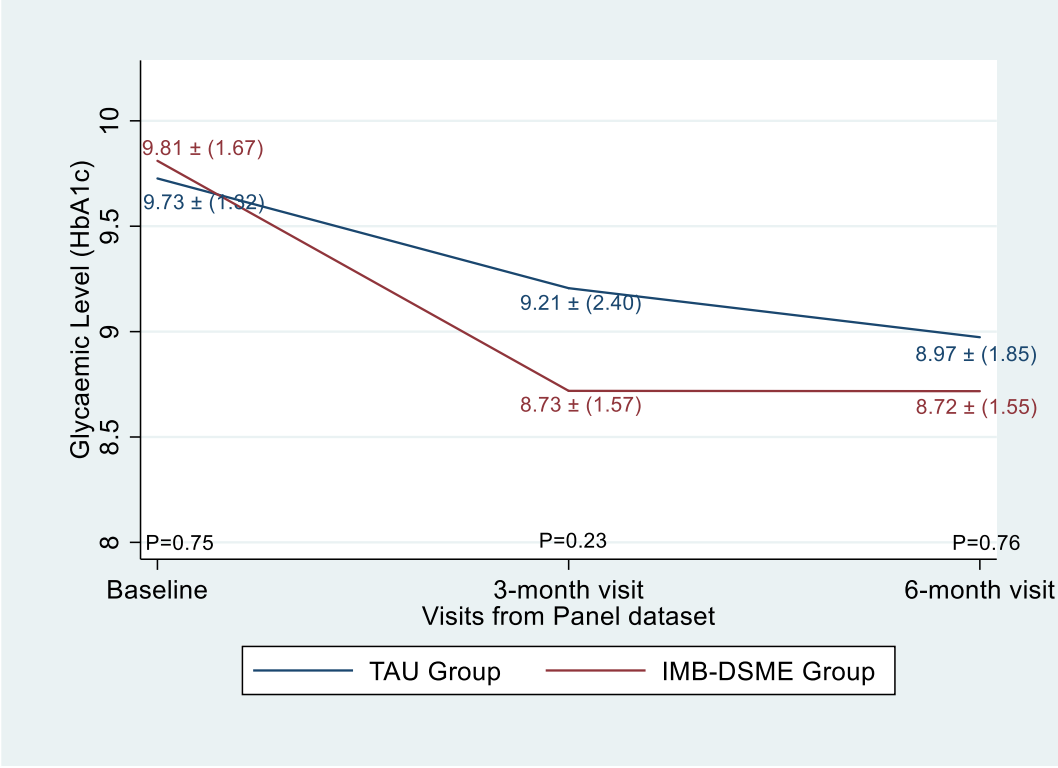


Figure 18 Mean of HbA1c for both trial groups across trial visits and their P values

4.8.4.2 Modelling GEE:

Using GEE approach, the estimates of the effect size of IMBDSME intervention on HbA1c level was statistically significant in model one before the adjustment of baseline score -1.09 (95% CI, -1.56 to -0.62) and -1.00 (95% CI, -1.50 to -0.49) at three-month and six-month respectively as shown in Table 46. However, estimates coefficients at the same model for participants in TAU group were -0.50 (95% Ci, -1.04 to 0.04) at three-month and -0.70 (95% CI, -1.20 to --0.18) at six-month. Estimate points for those in TAU group at three-month was not statistically significant (P = 0.07) but was statistically significant at six-month visit (P= 0.01). These estimates were overestimated due to the non-adjustment of the baseline score. While after the adjustment, all estimates were not statistically significant even after the adjustment for other covariates such as gender, age and medications for both trial groups at three-month and only for IMBDSME group at six-month visit. While for TAU group at six-month visit, they had statistically significant estimates of -0.70 (95% CI, -1.20 to --0.18) after adjustment of the baseline (model two) and -0.65 (95% CI, -1.17 to --0.14) after adjustment for gender, age and medications at model four. P values were less than 0.01 at both models. Consequently, participants in TAU group were more likely by 50% (95% CI, 16% to 70%) at model two and three, and 48% (95% CI, 13% to 69%) at model four to have a reduced level of HbA1c than participants in the IMBDSME group at six-month visit.

Patients' Glycaemic level (HbA1c) for all	Model	TAU			IMBDSME		
		Coef (95% CI)	Risk Ratio (95% CI)	P- value	Coef (95% CI)	Risk Ratio (95% CI)	P- value
3-month	1	-0.50 (-1.04 to 0.04)	0.61 (0.35 to 1.04)	0.07	-1.09 (-1.56 to -0.62)	0.34 (0.21 to 0.54)	0.001
	2	-0.50 (-1.04 to 0.04)	0.61 (0.35 to 1.04)	0.07	-0.59 (-1.31 to 0.13)	0.55 (0.27 to 1.14)	0.11
	3	-0.49 (-1.03 to 0.05)	0.61 (0.36 to 1.05)	0.08	-0.61 (-1.32 to 0.11)	0.54 (0.27 to 1.12)	0.10
	4	-0.46 (-1.02 to 0.10)	0.63 (0.36 to 1.10)	0.11	-0.62 (-1.34 to 0.10)	0.54 (0.26 to 1.10)	0.09
6-month	1	-0.70 (-1.20 to --0.18)	0.50 (0.30 to 0.84)	0.01	-1.00 (-1.50 to -0.49)	0.37 (0.22 to 0.61)	0.001
	2	-0.70 (-1.20 to --0.18)	0.50 (0.30 to 0.84)	0.01	-0.30 (-1.01 to 0.40)	0.74 (0.36 to 1.50)	0.40
	3	-0.70 (-1.21 to --0.19)	0.50 (0.30 to 0.83)	0.01	-0.29 (-1.00 to 0.42)	0.75 (0.37 to 1.52)	0.43
	4	-0.65 (-1.17 to --0.14)	0.52 (0.31 to 0.87)	0.01	-0.35 (-1.06 to 0.36)	0.70 (0.35 to 1.43)	0.33

Table 46 Coefficients and Risk Ratios of HbA1c value for both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for diabetes-related medications

4.8.4.3 Improvement in HbA1c levels:

The blood test (HbA1c) considers as an important indicator of glycaemic control for several reasons mentioned in section (3.13.3.4). American Diabetes Association (ADA) recommended a reasonable HbA1c goal for non-pregnant adults with T2DM is less than 7%. Thus, and in order to examine the effectiveness of IMBDSME intervention on HbA1c levels in three-month and six-month visits, participants in both trial groups were categorised by glycaemic level to either controlled (HbA1c<7) or uncontrolled (HbA1c >=7). And since all participants in this trial were screened and considered to be eligible by having an uncontrolled level of HbA1c of more than 8% at the point of recruitment, researcher can detect and compare the improvements in HbA1c between trial groups by examining the proportions of participants who had a controlled level of HbA1c at three-month and six-month visits.

Of those who received IMBDSME intervention at three-month visit, seven participants (9.9%) improved their HbA1c and their mean level was 6.00 ± (1.04), while 70 participants (90.1%) had an uncontrolled level of HbA1c and their mean was 9.15 ± (1.04). On the other hand, five participants (7.5%) of those who did not receive the IMBDSME intervention improved their HbA1c level and their HbA1c mean was 5.97 ± (1.06), while the rest 66 (92.5%) had an uncontrolled level of HbA1c and their HbA1c mean level was 9.57 ± (1.07). For six-month visit, eight participants (10.2%) of those who received IMBDSME intervention improved their HbA1c and their mean level was 6.16 ± (1.05), while 69 participants (89.8%) had an uncontrolled level of HbA1c and their mean was 9.19 ± (1.04). On the other hand, six participants (8.1%) of those who did not receive the IMBDSME intervention improved their HbA1c level

and their HbA1c mean was 6.01 ± (1.07), while the rest 65 (91.9%) had an uncontrolled level of HbA1c and their HbA1c mean level was 9.35 ± (1.06). The comparison between trial groups was tabulated using Chi-Square statistical test and the differences were statistically significant at both three-month and six-month visits due to P value less than 0.001 as shown in Table 47.

(HbA1c) for all attendees	TAU (n=71)				IMBDSME (n=77)				Chi Square test P Value
	Uncontrolled (HbA1c >=7)		Controlled (HbA1c<7)		Uncontrolled (HbA1c >=7)		Controlled (HbA1c<7)		
	Frequency (%)	Mean±(SD)	Frequency (%)	Mean±(SD)	Frequency (%)	Mean±(SD)	Frequency (%)	Mean±(SD)	
Three-month	66 (92.5%)	9.57 ± (1.07)	5 (7.5%)	5.97 ± (1.06)	70 (90.1%)	9.15 ± (1.04)	7 (9.9%)	6.00 ± (1.04)	0.001
Six-month	65 (91.9%)	9.35 ± (1.06)	6 (8.1%)	6.01 ± (1.07)	69 (89.8%)	9.19 ± (1.04)	8 (10.2%)	6.16 ± (1.05)	0.001

Table 47 Proportions of participants who had a controlled and uncontrolled level of HbA1c for both trial groups across trial visits.

4.8.4.4 Glycaemic level in PHH:

Means of HbA1c for participants who attended JUH for both trial groups across trial visits are demonstrated in Table 48 and Figure 19. Participants in TAU group had higher mean level of HbA1c 10.2 ± (2.40) than baseline at three-month and then reduced at six-month visit to 9.62 ± (1.85). On the other hand, participants who received the IMBDSME intervention had lower mean levels of HbA1c of 9.58 ± (1.57) and 9.40 ± (1.55) at three-month and six-month visit respectively. Although HbA1c at baseline was higher for IMBDSME group 10.45 ± (1.67) than of those in TAU group 9.99 ± (1.32), the difference was not statistically significant (P=0.40). Moreover, the differences between trial groups at three-month and six-month visits were not statistically significant (P=0.44) and (P=0.76) respectively.

Glycaemic level (HbA1c) for PHH attendees	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	9.99 ± (1.32)	10.45 ± (1.67)	0.46 (-0.63 – 1.56)	0.40
Three-month	10.2 ± (2.40)	9.58 ± (1.57)	-0.61 (-2.21 – 0.99)	0.44
Six-month	9.62 ± (1.85)	9.40 ± (1.55)	-0.22 (-1.73 – 1.29)	0.76

Table 48 Mean of HbA1c for both trial groups across trial visits for PHH attendees after imputation with the differences and their 95% confidence interval differences

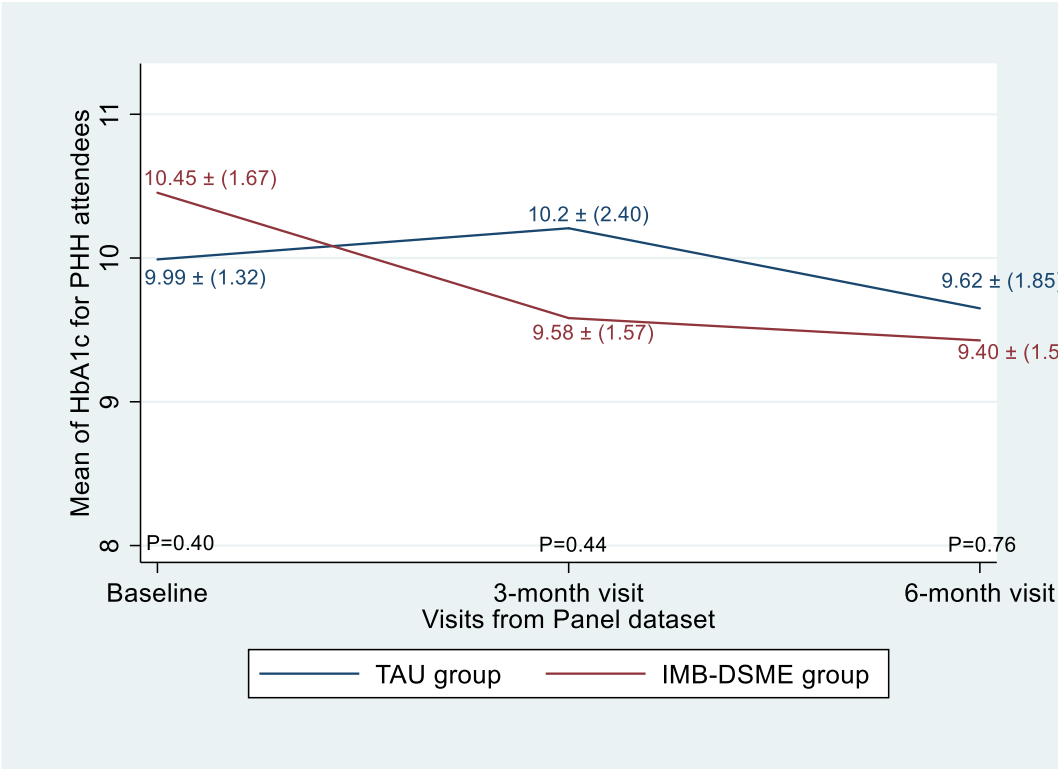


Figure 19 Mean of HbA1c of PHH attendees for both trial groups across trial visits and their P values

4.8.4.5 Modelling GEE:

In section (3.15.5.1), there is an explanation for the method of modelling trial primary and secondary outcomes across five models to accurately estimate coefficients to measure the effect size of IMBDSME intervention on those outcomes. However, in order to estimate coefficients and measure the effect size of the intervention on HbA1c levels in two different trial sites (PHH and JUH), the trial sites were included as an independent variable in each of these models for adjustment purposes. This aimed to calculate the estimate points according to trial sites after the adjustment to the baseline levels of HbA1c for each trial groups and trial sites.

From the Table 49, estimated coefficients were statistically significant among participants in the IMBDSME group before the adjustment to baseline score (model one). They were -1.09 (95% CI, -1.81 to -0.37) and -1.10 (95% CI, -1.87 to -0.33) at three-month and six-month visits respectively. While after the adjustment to the baseline values (model two), estimated points decreased to -1.16 (95% CI, -2.50 to 0.17) at three-month and increased to -0.77 (95% CI, -2.03 to 0.50) but were not statistically significant. Similar to other models, all estimated points were not statistically significant despite the further decrease at three-month visit to -1.31 (95% CI, -2.74 to 0.13) and the increase to -0.95 (95% CI, -2.21 to 0.31) in model four. On the other hand, estimated points for participants in the TAU group were 0.07 (95% CI, -1.07 to 1.21) at three-month and -0.33 (95% CI, -1.37 to 0.71) at six-month before the adjustment to the baseline value (model one). Those estimates continued to increase along with the models and were not statistically significant at both visits.

Patients' Glycaemic level (HbA1c) in PHH	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	0.07 (-1.07 to 1.21)	1.07 (0.34 to 3.36)	0.90	-1.09 (-1.81 to -0.37)	0.33 (0.16 to 0.69)	0.003
	2	0.07 (-1.07 to 1.21)	1.07 (0.34 to 3.36)	0.90	-1.16 (-2.50 to 0.17)	0.31 (0.08 to 1.19)	0.09
	3	0.11 (-1.04 to 1.26)	1.11 (0.35 to 3.51)	0.90	-1.19 (-2.54 to 0.16)	0.30 (0.08 to 1.17)	0.08
	4	0.16 (-1.06 to 1.38)	1.17 (0.35 to 3.97)	0.80	-1.31 (-2.74 to 0.13)	0.27 (0.06 to 1.14)	0.08
6-month	1	-0.33 (-1.37 to 0.71)	0.72 (0.25 to 2.03)	0.53	-1.10 (-1.87 to -0.33)	0.33 (0.15 to 0.72)	0.005
	2	-0.33 (-1.37 to 0.71)	0.72 (0.25 to 2.03)	0.53	-0.77 (-2.03 to 0.50)	0.74 (0.36 to 1.50)	0.24
	3	-0.37 (-1.40 to 0.66)	0.69 (0.25 to 1.93)	0.48	-0.72 (-2.00 to 0.55)	0.48 (0.14 to 1.71)	0.27
	4	-0.26 (-1.25 to 0.73)	0.77 (0.29 to 2.08)	0.61	-0.95 (-2.21 to 0.31)	0.39 (0.11 to 1.36)	0.14

Table 49 Coefficients and Risk Ratios of HbA1c for PHH attendees in both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for diabetes-related medication

4.8.4.6 Glycaemic level in JUH:

Means of HbA1c for participants who attended JUH for both trial groups across trial visits are demonstrated in Table 50 and Figure 20. Participants who received the IMBDSME intervention had lower levels of HbA1c 8.33 ± (1.57) and 8.50 ± (1.55) at three-month and six-month visits than baseline 9.52 ± (1.67). Although participants in the TAU group had lower levels of HbA1c 8.83 ± (2.40) at three-month and 8.77 ± (1.85) at six-month visit than baseline 9.62 ± (1.32), the reduction in HbA1c levels among IMBDSME group was greater than for those in the TAU group at three-month visit. However, at six-month visit, participants in TAU group had a further reduction in HbA1c levels, while those in IMBDSME group had an increase in HbA1c levels. All differences between trial groups were not statistically significant across trial visits.

Glycaemic level (HbA1c) for JUH attendee	**Mean±(SD)**		**Diff (95% CI)**	**P- value**
	TAU	**IMBDSME**		
Baseline	9.62 ± (1.32)	9.52 ± (1.67)	-0.10 (-0.68 – 0.48)	0.74
Three-month	8.83 ± (2.40)	8.33 ± (1.57)	-0.49 (-1.35 – 0.36)	0.25
Six-month	8.77 ± (1.85)	8.50 ± (1.55)	-0.27 (-1.07 – 0.52)	0.49

Table 50 Mean of HbA1c for both trial groups across trial visits for JUH attendees after imputation with the differences and their 95% confidence interval

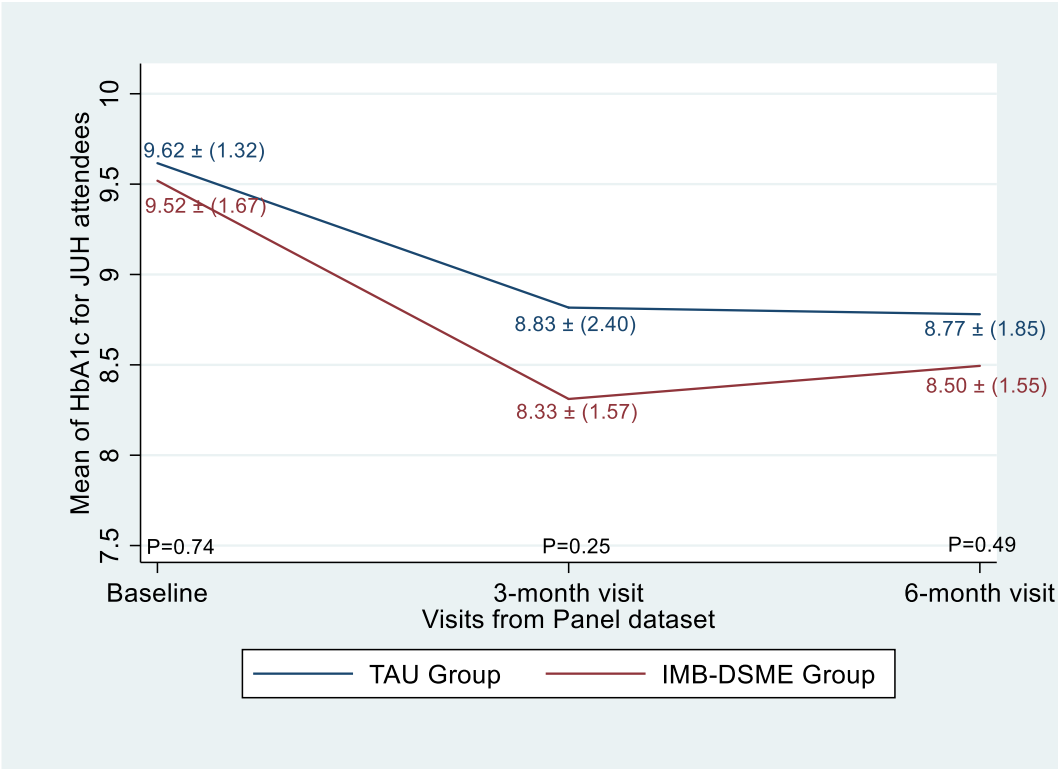


Figure 20 Mean of HbA1c of JUH attendees for both trial groups across trial visits and their P values

4.8.4.7 Modelling GEE:

Similar to the modelling approach of HbA1c among participants who attended PHH in section (4.8.4.5), estimate coefficients were calculated by including trial sites as an independent variable in each of these models for adjustment purposes.

From Table 51, estimated coefficients were statistically significant before the adjustment to the baseline values (model one) for participants in both groups at three-month and six-month visits. In details, participants who received IMBDSME intervention had coefficients of -1.65 (95% CI,-2.86 to -0.44) and -1.50 (95% CI, -2.72 to -0.27) at three-month and six-month respectively, while participants in TAU group had coefficients of -0.73 (95% CI, -1.33 to -0.13) and -0.82 (95% CI,-1.39 to --0.24) for the same time points. After the adjustment to the baseline values, those coefficients for participants in IMBDSME group decreased to -1.72 (956% CI, -3.39 to -0.06) and was statistically significant (P=0.04), and decreased for participants in TAU group to -0.80 (95% CI, -2.09 to 0.49) but was not statistically significant (P=0.22) at three-month visit. However, estimate coefficient was statistically significant at three-month visit only for participants in the IMBDSME group in model four and was -1.82 (95% CI, -3.44 to -0.20). Whereas at six-month visit, estimated coefficients increased for both trial groups, standing at -0.48 (-1.66 to --0.69) and -1.16 (-2.90 to 0.57) for TAU group and for IMBDSME group respectively and none of them were statistically significant after the adjustment in model two, three and four. Despite those results, estimates for participants in the IMBDSME group was higher -1.25 (95% CI, -2.87 to 0.38) in comparison to those participants in TAU group -0.60 (95% CI, -1.74 to --0.55).

In terms of probability, for three-month visit, participants in the IMBDSME group were 84% (95% CI, 18% to 97%) more likely to have lower HbA1c values than baseline in comparison to participants in the TAU group who were 58% (-89% to 66%). These results were statistically significant for participants in IMBDSME group but were not for participants in TAU group. For six-month visit, although all probabilities were not statistically significant after adjusting for all covariates, participants in the IMBDSME group were 71% (95% CI, 47% to 94%) more likely to have lower HbA1c values than baseline in comparison to participants in the TAU group who were 45% (73% to 82%).

Patients' Glycaemic level (HbA1c) for JUH attendees	Model	TAU			IMBDSME		
		Coef (95% CI)	Risk Ratio (95% CI)	P- value	Coef (95% CI)	Risk Ratio (95% CI)	P- value
3-month	1	-0.73 (-1.33 to -0.13)	0.48 (0.26 to 0.88)	0.02	-1.65 (-2.86 to -0.44)	0.19 (0.06 to 0.64)	0.01
	2	-0.80 (-2.09 to 0.49)	0.45 (0.12 to 1.63)	0.22	-1.72 (-3.39 to -0.06)	0.18 (0.03 to 0.94)	0.04
	3	-0.84 (-2.13 to 0.46)	0.43 (0.12 to 1.60)	0.21	-1.75 (-3.40 to -0.10)	0.17 (0.03 to 0.90)	0.04
	4	-0.86 (-2.23 to 0.51)	0.42 (0.11 to 1.66)	0.22	-1.82 (-3.44 to -0.20)	0.16 (0.03 to 0.82)	0.03
6-month	1	-0.82 (-1.39 to --0.24)	0.44 (0.25 to 0.79)	0.006	-1.50 (-2.72 to -0.27)	0.22 (0.07 to 0.76)	0.02
	2	-0.48 (-1.66 to --0.69)	0.62 (0.19 to 2.00)	0.42	-1.16 (-2.90 to 0.57)	0.31 (0.06 to 1.77)	0.19
	3	-0.44 (-1.61 to --0.73)	0.64 (0.20 to 2.07)	0.46	-1.08 (-2.78 to 0.62)	0.34 (0.06 to 1.86)	0.21
	4	-0.60 (-1.74 to --0.55)	0.55 (0.18 to 1.73)	0.31	-1.25 (-2.87 to 0.38)	0.29 (0.06 to 1.47)	0.13

Table 51 Coefficients and Risk Ratios of HbA1c for JUH attendees in both Trial Groups for all Models and their CI (Confidence Interval) across trial visits
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for diabetes-related medications

4.8.5 Audit of Diabetes Dependent Quality of Life (ADDQOL):

As detailed in section (3.13.3.5), diabetes patients' quality of life was measured using an Audit of Diabetes-Dependent Quality of Life (ADDQOL) scale. It consisted of two items regarding their quality of life in general at the beginning, and an additional 18 items asking about certain aspects related to their DM. Each of those is examined and modelled separately below.

4.8.5.1 Present Quality of Life:

Participants in both trial groups were asked to describe their present quality of life status by choosing an option out of seven. These options: "Excellent" received score of +3, "Very good" received score of +2, "Good" received score of +1, "Neither good nor bad" received score of 0, "Bad" received score of -1, "Very bad" received score of -2, "Extremely bad" received score of -3. As shown in Table 52 and Figure 21, participants in the IMBDSME group had higher mean score of 1.79 ± (0.81) and 1.90 ± (0.97) at three-month and six-month visits respectively than baseline mean score 0.82 ± (1.12). Although participants in the TAU group had higher baseline mean score by 0.06 (95% CI, -0.47 – 0.36), the difference was not statistically significant. They had mean scores of 1.28 ± (1.28) and 1.13 ± (1.08) at three-month and six-month visits respectively. As a result, the mean score of participants who received IMBDSME intervention was higher by 0.51 (95% CI, 0.17 – 0.86) and 0.77 (95% CI, 0.38 – 1.15) than of those who had TAU at three-month and six-month respectively, and those rises were statistically significant as P values were less than 0.05.

ADDQOL First Question	Mean±(SD)		Diff (95% CI)	P- value
	TAU	IMBDSME		
Baseline	0.87 ± (1.33)	0.82 ± (1.12)	-0.06 (-0.47 – 0.36)	0.79
Three-month	1.28 ± (1.28)	1.79 ± (0.81)	0.51 (0.17 – 0.86)	0.004
Six-month	1.13 ± (1.08)	1.90 ± (0.97)	0.77 (0.38 – 1.15)	0.001

Table 52 Mean of ADDQOL first question for both trial groups across trial visits after imputation with the differences and their 95% confidence interval

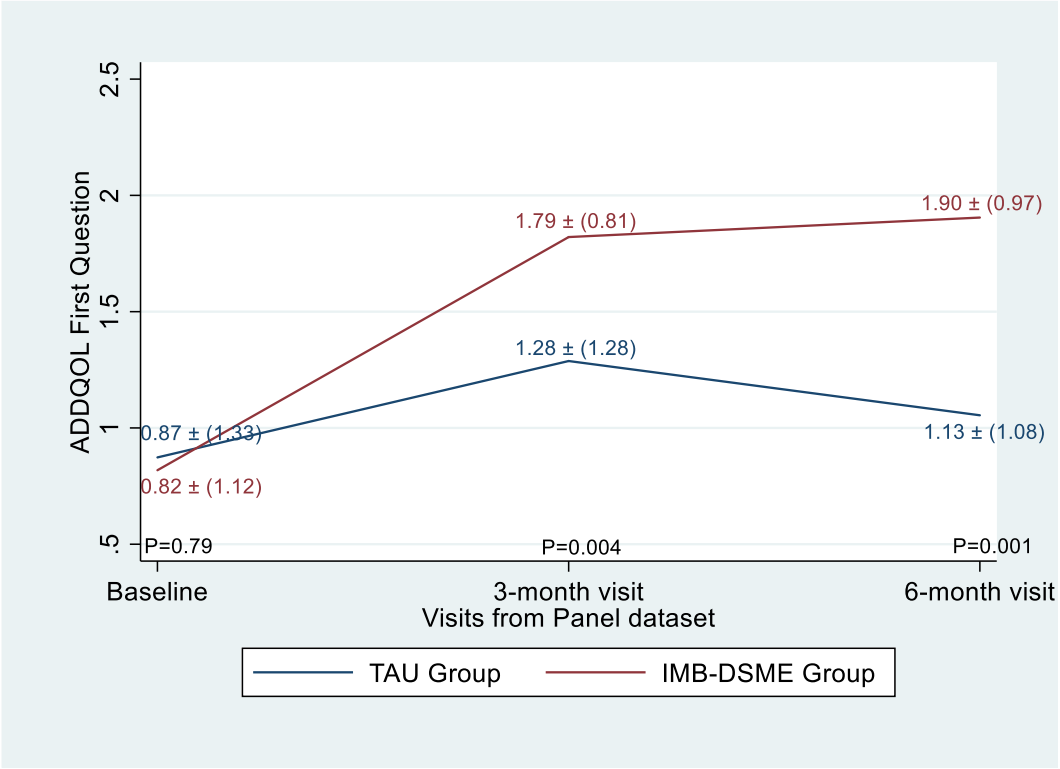


Figure 21 Mean of ADDQOL first question for both trial groups across trial visits and their P values

4.8.5.2 Modelling GEE:

As presented in Table 53, estimated coefficients for the effect size of IMBDSME intervention were calculated using GEE approach through five models. It shows P values, estimated coefficients, risk ratios and their 95% CI of ADDQOL first question score for both trial groups for all models. Overall, estimated coefficients were statistically significant for all participants except at six-month for those who did not receive IMBDSME intervention.

Estimates for participants in the IMBDSME group were 0.96 (95% CI, 0.68 to 1.25) and 1.07 (95% CI, 0.76 to 1.39) at three-month and six-month respectively before the adjustment of baseline score (model one). While after the adjustment at model two, estimates decreased to 0.57 (95% CI, 0.19 to 0.94) and 0.81 (95% CI, 0.37 to 1.26) at three-month and six-month visits respectively. With further adjustment at model five, it decreased to 0.53 (95% CI, 0.14 to 0.93) and 0.74 (95% CI, 0.32 to 1.16) for the same periods. On the other hand, estimates for participants who did not receive the IMBDSME intervention were the same before and after the adjustments and were 0.40 (95% CI, 0.15 to 0.65) and 0.26 (95% CI, -0.07 to 0.59) at three-month and six-month respectively. In model five, estimates decreased to 0.32 (95% CI, 0.02 to 0.62) and 0.14 (95% CI, -0.16 to 0.44) for the same periods and was not statistically significant at six-month. As regard the probability, participants in the IMBDSME group were more likely to have higher score of ADDQOL first question by 76% (95% CI, 21% to 156%) than participants in the TAU group who were likely to have a higher score by 49% (95% CI, 16% to 91%) after baseline score adjustment at three-month visit. In model five, the probability decreased to 70% (95% CI, 15% to 153%) and 38%

(95% CI, 2% to 86%) for participants in the IMBDSME group and TAU group respectively. both of which were statistically significant at three-month visit. At six-month visit, participants in the IMBDSME group were 1.26 (95% CI, 0.45 to 2.52) times more likely to have higher score of ADDQOL first question than participants in the TAU group who were 29% likely to have higher score than baseline after the adjustment for the baseline score. In model five, and similar to three-month visit, probabilities decreased to 1.1 (95% CI, 0.38 to 2.2) and 15% (95% CI, -15% to 56%) for participants in the IMBDSME group and TAU group respectively and was only statistically significant for participants who received the IMBDSME intervention where P value was less than 0.001.

ADDQOL First Question	Model	TAU			IMBDSME		
		Coef (95% CI)	Risk Ratio (95% CI)	P- value	Coef (95% CI)	Risk Ratio (95% CI)	P- value
3-month	1	0.40 (0.15 to 0.65)	1.49 (1.16 to 1.91)	0.002	0.96 (0.68 to 1.25)	2.62 (1.97 to 3.48)	0.001
	2	0.40 (0.15 to 0.65)	1.49 (1.16 to 1.91)	0.002	0.57 (0.19 to 0.94)	1.76 (1.21 to 2.56)	0.003
	3	0.40 (0.15 to 0.65)	1.49 (1.16 to 1.91)	0.002	0.57 (0.19 to 0.94)	1.76 (1.21 to 2.56)	0.003
	4	0.33 (0.04 to 0.62)	1.39 (1.04 to 1.86)	0.03	0.54 (0.15 to 0.94)	1.72 (1.16 to 2.56)	0.01
	5	0.32 (0.02 to 0.62)	1.38 (1.02 to 1.86)	0.04	0.53 (0.14 to 0.93)	1.70 (1.15 to 2.53)	0.01
6-month	1	0.26 (-0.07 to 0.59)	1.29 (0.93 to 1.80)	0.12	1.07 (0.76 to 1.39)	2.92 (2.13 to 4.01)	0.001
	2	0.26 (-0.07 to 0.59)	1.29 (0.93 to 1.80)	0.12	0.81 (0.37 to 1.26)	2.26 (1.45 to 3.52)	0.001
	3	0.26 (-0.07 to 0.59)	1.29 (0.93 to 1.80)	0.12	0.81 (0.37 to 1.26)	2.26 (1.45 to 3.52)	0.001
	4	0.11 (-0.19 to 0.41)	1.12 (0.82 to 1.51)	0.48	0.79 (0.36 to 1.21)	2.19 (1.44 to 3.34)	0.001
	5	0.14 (-0.16 to 0.44)	1.15 (0.85 to 1.56)	0.35	0.74 (0.32 to 1.16)	2.10 (1.38 to 3.20)	0.001

Table 53 Coefficients and Risk Ratios of ADDQOL first question for all participants in both Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8.5.3 Quality of life without diabetes:

The second item in ADDQOL scale was asking participants to describe how their quality of life would be without diabetes. The choices were from “very much better” received score of -3, “much better” received score of -2, “a little better” received a score of -1, “the same” received score of zero and “worse” received score of +1. As shown in Table 54 and Figure 22, participants in IMBDSME group had higher mean score -1.00 ± (1.36) and -0.91 ± (1.22) at three-month and six-month visits respectively than baseline score -1.56 ± (1.62). In contrast, participants in TAU group had lower score of -1.95 ± (1.14) and -1.79 ± (1.75) at three-month and six-month visits than baseline score of -1.7 ± (1.54). Although there was difference of 0.15 (95% CI, -0.16 – 0.45) in baseline score between trial groups, it was not statistically significant. However, there were statistically significant differences between trial groups at three-month visit and was 0.94 (95% CI, 0.62 – 1.27) and was 0.88 (95% CI, 0.56 – 1.21) at six-month visit where P values were less than 0.001.

ADDQOL Second Question	**Mean±(SD)**		**Diff (95% CI)**	**P- value**
	TAU	**IMBDSME**		
Baseline	-1.7 ± (1.54)	-1.56 ± (1.62)	0.15 (-0.16 – 0.45)	0.35
Three-month	-1.95 ± (1.14)	-1.00 ± (1.36)	0.94 (0.62 – 1.27)	0.001
Six-month	-1.79 ± (1.75)	-0.91 ± (1.22)	0.88 (0.56 – 1.21)	0.001

Table 54 Mean of ADDQOL second question for both trial groups across trial visits after imputation with the differences and their 95% confidence interval

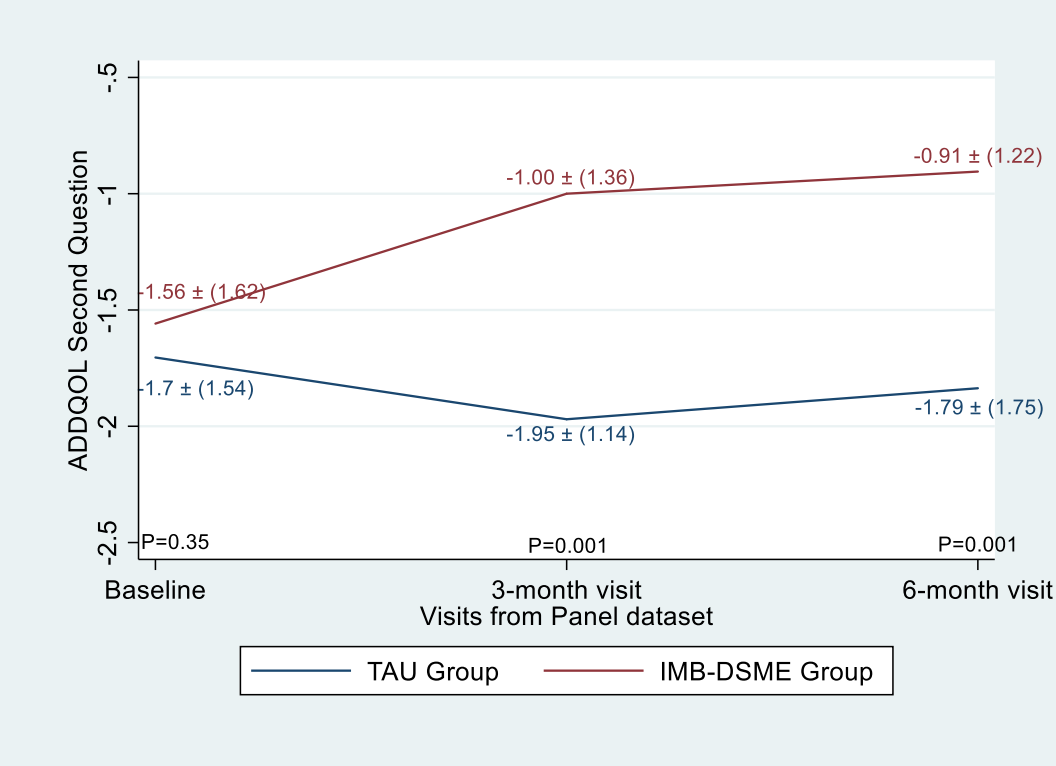


Figure 22 Mean of ADDQOL second question for both trial groups across trial visits and their P values

4.8.5.4 Modelling GEE:

As presented in Table 55, estimated coefficients for the effect size of IMBDSME intervention on second question in ADDQOL scale were calculated as well as P values, risk ratios and their 95% CI using GEE approach for both trial groups in five models. Overall, estimated coefficients were statistically significant for all participants before and after the adjustment to the baseline mean score except for those who did not receive IMBDSME intervention at three-month visit in model five and six-month visit. It is clear that participants who received the IMBDSME intervention had positive estimated coefficients while all estimates for participants in the TAU group were negative values in all models.

At three- month visit, participants in IMBDSME group had an estimate of 0.55 (95% CI, 0.35 to 0.75) before the adjustment in model one, whereas it increased to 0.80 (95% CI, 0.48 to 1.11) after the adjustment to the baseline score in model two, and increased further in model five to 0.83 (95% CI, 0.47 to 1.19). In contrast, participants in TAU group had the same estimates before and after the adjustment to the baseline score of -0.25 (95% CI, -0.50 to -0.01) and decreased further at model four -0.29 (95% CI, -0.57 to -0.01) and at model five -0.27 (95% CI, -0.56 to -0.02). At six-month, participants in IMBDSME group had an estimate of 0.65 (95% CI, 0.41 to 0.88) before the adjustment to baseline score, increased to 0.74 (95% CI, 0.42 to 1.05) after the adjustment in model two and 0.72 (95% CI, 0.40 to 1.05) in model five. Similar to three-month visit, participants in TAU group had the same estimate before and after the adjustment of -0.09 (95% CI, -0.31 to 0.12) and decreased further to -0.07 (95% CI, -0.29 to 0.09) in model five.

Participants who received IMBDSME group were 1.22 (95% CI, 0.62 to 2.04) and 1.3 (95% CI, 0.6 to 2.3) times more likely to had higher score of ADDQOL second question than baseline score in model two and model five respectively at three-month visit. At the same period, participants in TAU group were 22% (95% CI, 1% to 39%) and 24% (95% CI, 2% to 43%) likely to have lower scores than baseline in model two and model five respectively. At six-month visit, participants in IMBDSME group were 1.09 (95% CI, 0.53 to 1.86) and 1.06 (95% CI, 0.49 to 1.85) times more likely to have higher score than baseline in model two and model five respectively. While participants in TAU group were 9% (95% CI, -26% to 13%) and 6% (95% CI, -22% to 13%) likely to have lower scores than baseline in model two and five respectively and were not statistically significant.

ADDQOL Second Question	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	-0.25 (-0.50 to -0.01)	0.78 (0.61 to 0.99)	0.047	0.55 (0.35 to 0.75)	1.73 (1.41 to 2.11)	0.001
	2	-0.25 (-0.50 to -0.01)	0.78 (0.61 to 0.99)	0.047	0.80 (0.48 to 1.11)	2.22 (1.62 to 3.04)	0.001
	3	-0.25 (-0.50 to -0.01)	0.78 (0.61 to 0.99)	0.047	0.80 (0.48 to 1.11)	2.22 (1.62 to 3.04)	0.001
	4	-0.29 (-0.57 to -0.01)	0.75 (0.57 to 0.99)	0.048	0.83 (0.48 to 1.18)	2.30 (1.62 to 3.25)	0.001
	5	-0.27 (-0.56 to -0.02)	0.76 (0.57 to 1.02)	0.07	0.83 (0.47 to 1.19)	2.30 (1.60 to 3.30)	0.001
6-month	1	-0.09 (-0.31 to 0.12)	0.91 (0.74 to 1.13)	0.41	0.65 (0.41 to 0.88)	1.91 (1.51 to 2.42)	0.001
	2	-0.09 (-0.31 to 0.12)	0.91 (0.74 to 1.13)	0.41	0.74 (0.42 to 1.05)	2.09 (1.53 to 2.86)	0.001
	3	-0.09 (-0.31 to 0.12)	0.91 (0.74 to 1.13)	0.41	0.74 (0.42 to 1.05)	2.09 (1.53 to 2.86)	0.001
	4	-0.10 (-0.29 to 0.09)	0.90 (0.75 to 1.09)	0.29	0.75 (0.43 to 1.07)	2.11 (1.53 to 2.92)	0.001
	5	-0.07 (-0.29 to 0.09)	0.94 (0.78 to 1.13)	0.49	0.72 (0.40 to 1.05)	2.06 (1.49 to 2.85)	0.001

Table 55 Coefficients and Risk Ratios of ADDQOL second question for all participants in both Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.8.5.5 Diabetes-specific 18-items:

Diabetes-specific 18-items were designed to ask participants to express the impact of diabetes on certain aspects of life. In addition, participants were asked to respond on each item by stating how important that aspect was in their life. The calculation of each item's score and total score of ADDQOL was explained previously.

As presented in Table 56 and Figure 23, participants in IMBDSME group had higher mean score -1.97 ± (1.36) and -1.96 ± (1.22) at three-month and six-month visits respectively than baseline score -2.37 ± (1.62). In contrast, participants in TAU group had lower score of -2.9 ± (1.14) and -2.6 ± (1.75) at three-month and six-month visits than baseline score of -2.3 ± (1.54). Although there was difference of -0.11 (95% CI, -0.61 – 0.38) in baseline score between trial groups, it was not statistically significant. However, there were statistically significant differences between trial groups at three-month visit and was 0.91 (95% CI, 0.44 – 1.38) and was 0.65 (95% CI, 0.11 – 1.19) at six-month visit where P values were less than 0.02.

ADDQOL Total of 18 items	**Mean±(SD)**		**Diff (95% CI)**	**P- value**
	TAU	**IMBDSME**		
Baseline	-2.3 ± (1.54)	-2.37 ± (1.62)	-0.11 (-0.61 – 0.38)	0.66
Three-month	-2.9 ± (1.14)	-1.97 ± (1.36)	0.91 (0.44 – 1.38)	0.001
Six-month	-2.6 ± (1.75)	-1.96 ± (1.22)	0.65 (0.11 – 1.19)	0.019

Table 56 Mean score of ADDQOL 18-itmes for both trial groups across trial visits after imputation with the differences and their 95% confidence interval

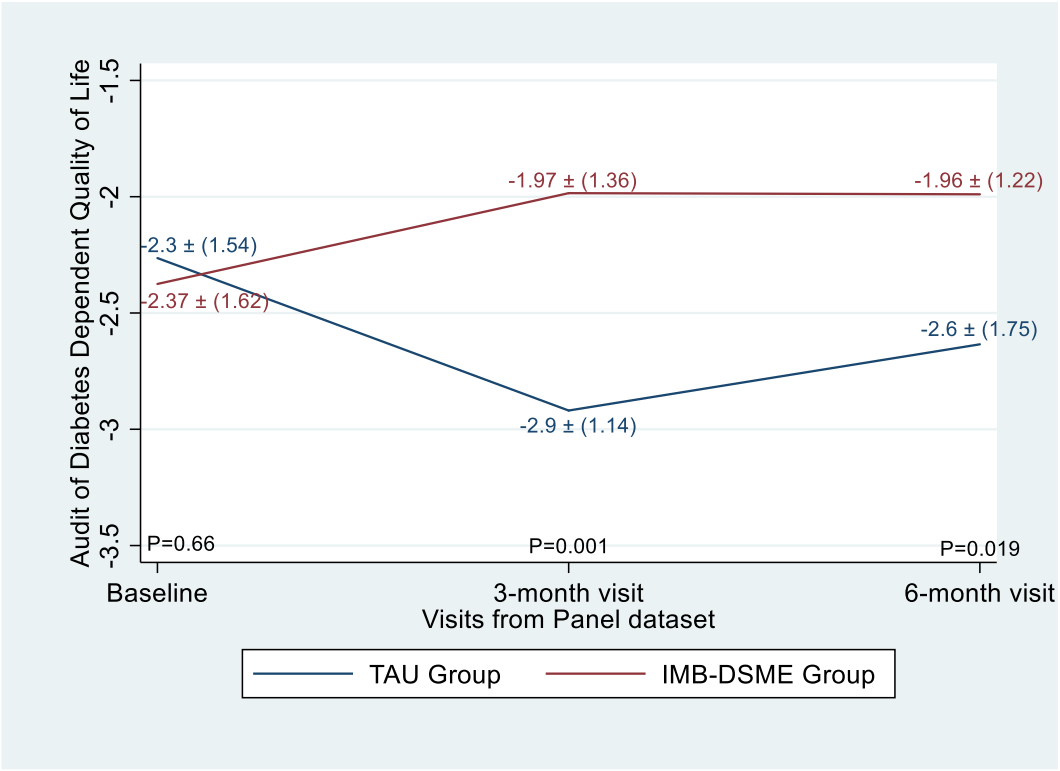


Figure 23 Mean score of ADDQOL 18-items for both trial groups across trial visits and their P values

4.8.5.6 Modelling GEE:

As presented in Table 57, estimated coefficients for the effect size of IMBDSME intervention on total score of ADDQOL 18-ietms scale were calculated as well as P values, risk ratios and their 95% CI using GEE approach for both trial groups in five models. Overall, and similar to the result of ADDQOL second question (4.8.5.3), estimated coefficients were statistically significant for all participants before and after the adjustment to the baseline mean score except for those who did not receive IMBDSME intervention at six-month visit. It is clear that participants who received the IMBDSME intervention had positive estimated coefficients while all estimates for participants in the TAU group were negative values in all models.

At three-month visit, participants in IMBDSME group had an estimate of 0.40 (95% CI, 0.01 to 0.81) before the adjustment in model one, whereas it increased to 1.02 (95% CI, 0.52 to 1.52) after the adjustment to the baseline score in model two, and increased further in model five to 1.15 (95% CI, 0.58 to 1.71). In contrast, participants in TAU group had the same estimates before and after the adjustment to the baseline score of -0.62 (95% CI, -0.91 to -0.32) and decreased further at model five to -0.63 (95% CI, -0.97 to -0.29). At six-month, participants in IMBDSME group had an estimate of 0.41 (95% CI, 0.05 to 0.87) before the adjustment to baseline score, increased to 0.77 (95% CI, 0.11 to 1.43) after the adjustment in model two and 0.90 (95% CI, 0.15 to 1.65) in model five. Similar to three-month visit, participants in TAU group had the same estimate before and after the adjustment of -0.36 (95% CI, -0.85 to 0.13) and decreased further to -0.40 (95% CI, -0.96 to 0.16) in model five.

Participants who received IMBDSME group were 1.78 (95% CI, 0.68 to 3.58) and 2.15 (95% CI, 0.79 to 4.55) times more likely to had higher mean total score of ADDQOL 18-items than baseline score in model two and model five respectively at three-month visit. At the same period, participants in TAU group were 46% (95% CI, 27% to 60%) and 47% (95% CI, 25% to 62%) likely to have lower scores than baseline in model two and model five respectively. At six-month visit, participants in IMBDSME group were 1.16 (95% CI, 0.11 to 3.21) and 1.46 (95% CI, 0.16 to 4.22) times more likely to have higher mean score than baseline in model two and model five respectively. While participants in TAU group were 30% (95% CI, 14% to 57%) and 33% (95% CI, 17% to 62%) likely to have lower scores than baseline in model two and five respectively and were not statistically significant.

ADDQOL Total of 18 items	Model	TAU		P- value	IMBDSME		P- value
		Coef (95% CI)	Risk Ratio (95% CI)		Coef (95% CI)	Risk Ratio (95% CI)	
3-month	1	-0.62 (-0.91 to -0.32)	0.54 (0.40 to 0.73)	0.001	0.40 (0.01 to 0.81)	1.50 (0.99 to 2.25)	0.041
	2	-0.62 (-0.91 to -0.32)	0.54 (0.40 to 0.73)	0.001	1.02 (0.52 to 1.52)	2.78 (1.68 to 4.58)	0.001
	3	-0.62 (-0.91 to -0.32)	0.54 (0.40 to 0.73)	0.001	1.02 (0.52 to 1.52)	2.78 (1.68 to 4.59)	0.001
	4	-0.66 (-1.00 to -0.32)	0.51 (0.36 to 0.73)	0.001	1.17 (0.60 to 1.73)	3.21 (1.83 to 5.63)	0.001
	5	-0.63 (-0.97 to -0.29)	0.53 (0.38 to 0.75)	0.001	1.15 (0.58 to 1.71)	3.15 (1.79 to 5.55)	0.001
6-month	1	-0.36 (-0.85 to 0.13)	0.70 (0.43 to 1.14)	0.15	0.41 (0.05 to 0.87)	1.51 (0.96 to 2.39)	0.048
	2	-0.36 (-0.85 to 0.13)	0.70 (0.43 to 1.14)	0.15	0.77 (0.11 to 1.43)	2.16 (1.11 to 4.21)	0.02
	3	-0.36 (-0.85 to 0.13)	0.70 (0.43 to 1.14)	0.15	0.77 (0.11 to 1.44)	2.17 (1.11 to 4.22)	0.02
	4	-0.40 (-0.96 to 0.16)	0.67 (0.38 to 1.17)	0.16	0.91 (0.17 to 1.66)	2.49 (1.18 to 5.24)	0.02
	5	-0.40 (-0.96 to 0.16)	0.67 (0.38 to 1.17)	0.16	0.90 (0.15 to 1.65)	2.46 (1.16 to 5.22)	0.02

Table 57 Coefficients and Risk Ratios of ADDQOL 18-items for all participants in both Trial Groups for all Models and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline.
Model 2 adjusted to the baseline.
Model 3 as in model 2 with adjustments for age and gender.
Model 4 as in model 3 with the adjustments for HbA1c.
Model 5 as in model 4 with the adjustments for diabetes-related medications.

4.9 Results conclusion:

As presented above, primary and secondary outcomes were analysed thoroughly and effect size for each was calculated and repeated in different models using GEE method. However, effect sizes do not explain how the IMBDSME intervention worked nor give an explanation on the underlying process of the intervention. Indeed, some researchers argued that RCTs of social complex interventions are simplifying the cause-and-effect relationship, due to the insignificant attention being payed to the influence of context, implementers and participants' acceptance (Clark et al., 2007). Others criticized and described RCTs which have poorly described interventions as the black box that need to be unpacked to allow expressive evaluation (Stephenson et al., 2003). Nonetheless, one of the main reasons behind RCTs is to ensure that differences between trial groups are seldom due to chance and not systematic. Therefore, and in addition to address these limitations, conducting process evaluation of complex interventions can inform future replication of either the trial interventions or the trial outcomes in a different context. Process evaluation of IMBDSME intervention is presented in the next section.

5 Process evaluation of IMBDSME intervention:

According to MRC guidance on process evaluation of complex intervention, process evaluation aims to provide more insight to improve the understandings of the causal assumption underpinning the intervention and raise further questions for exploration. It helps to identify which parts of the complex intervention are more effective than others and learn how and why they have a particular effect on the outcomes. Principally, it is vital to know how intervention works to build an evidence base that will inform policy and practice (Moore et al., 2015).

Researcher planned and designed process evaluation step of IMBDSME earlier before conducting the trial of examining the effectiveness of IMBDSME on the trial outcomes. However, at the time of designing process evaluation, the causal assumptions of IMBDSME intervention were already defined and described using a logic model by researcher in Figure 5. A logic model was used to clarify the development stages of IMBDSME intervention, the required materials and training, the structure in which the intervention should be delivered and both clinical and trial outcomes. Although Strange et al. (2006) recommended to report and analyse process evaluation data, qualitative data in particular, without being aware of the results of trial outcomes to allow for unbiased interpretations, it was not possible to postpone the analysis of the trial outcomes after process evaluation is completed because of several reasons; our main concern was the trial primary outcomes, done by one researcher and time constraints of the PhD program.

In this trial, process evaluation was designed for further understanding on how essential elements of IMB model (patients' Knowledge, Motivation, Behavioural

skills) worked together to affect the trial outcomes. To design process evaluation of IMBDSME, researcher looked-for appropriate theoretical framework to be utilised to inform the methods of data collection and the reporting of findings of process evaluation. According to MRC guidance, three main aspects of process evaluation need to be examined and they are; implementation, mechanism of impact and contextual factors. Firstly, implementation of IMBDSME and how the delivery was achieved and what was actually delivered in practice aimed largely to provide assurance on the internal validity by examining the quality (fidelity) and the quantity (dose) of the intervention. The Oxford Implementation Index framework was used to assess the implementation data in this trial (Montgomery et al., 2013). Secondly, mechanism of impact of the IMBDSME intervention and the understandings of how participants in the IMBDSME group responded and interacted with the received dose of the intervention through utilising theory-based evaluation approach. Thirdly, contextual factors that influenced the effectiveness of the IMBDSME that shaped what was implemented and shaped the conditions under which the mechanism of impact was processing.

Reporting findings of process evaluation is challenging due to the absence of a unified reporting guidelines that can fit all the used approaches in process evaluation. Moore et al. (2015) in MRC guidance mentioned that work was in progress to develop CONSORT- SPI 2018 (Social and Psychological Intervention) at that time by (Grant et al.). It is an extension to CONSORT 2010 statement developed to help researchers in behavioural medicine reporting trials that consist of complex interventions. Although they stressed that the new prospect extension have more expansion on reporting

process evaluation, CONSORT-SPI statement did not point or direct researchers to adopt or utilise evaluation frameworks or theories to report process evaluation data. Instead, they integrated process evaluation items within the main trial sections without relating each type of data to whether they are for implementation aspect, mechanism of impact or contextual factors. In other words, there was no elaboration on the process evaluation aspects as expected. However, they were considered during reporting the findings of process evaluation in this trial.

In this trial, researcher collected process evaluation data using quatitative methods. However, reporting full process evaluation is beyond the scope of this PhD. Therefore, researcher is presenting the quantitative data of the implementation aspect, acceptability of IMBDSME intervention and satisfaction with the treatment for both trial groups.

5.1 Implementation of IMBDSME:

The Oxford Implementation Index (OII) is a framework that was developed by a team of systematic reviewers to extract implementation data in order to be comparable with other interventions' implementation data across primary care trials. Researcher has adopted this index as it was suggested by the MRC and has the ground to make implementation data of IMBDSME trial comparable with other interventions for future systematic reviews. Domains of OII are as follow:

5.1.1 Intervention design:

Developers of OII endorsed that a clear description of the intervention need to be reported for all trial groups, IMBDSME and TAU groups. As a consequence, the description of the development of IMBDSME intervention and the theoretical model that underpinning the intervention are presented in chapter (2).

In fact, both groups received TAU, but participants in the control group in which researcher called TAU group did not receive any intervention from the researcher during the delivery period (three-month) apart from the educational booklet at the end of the trial. The description of usual treatment of patients with T2DM (TAU) is presented in section (3.9.4) for both trial sites and illustrated in a table to ease the comparability between both hospitals.

5.1.2 Intervention delivery:

The delivery of the intervention was done by the researcher who is a qualified registered diabetes nurse in Jordan. Neither of the independent outcome's assessors

nor any of the research team intervened in delivering any parts or components of the IMBDSME.

As per dosage of the IMBDSME intervention, knowledge, motivation and behavioural skills were three main determinants of the IMB model and formed the theoretical assumption of IMBDSME intervention. However, they were not equally delivered to all participants in this trial and participants in the IMBDSME group did not receive the same dose as it was an individualized DSME intervention.

As mentioned in section (3.11), the delivery of the IMBDSME intervention started by handing the intervention booklet to all participants who were allocated to IMBDSME group without any exclusion as a result of randomisation. The booklet consisted of an educational toolkit (PRIDE) to provide the required knowledge to perform DSCB. More details on the process of adapting and translating (PRIDE) is mentioned in section (2.2.2). Theoretically, knowledge on DSCB were sent to all participants through (PRIDE) toolkit, nevertheless, this does not mean that knowledge on all DSCB were delivered to those participants. In fact, the spotted difference was in the frequency and length of the delivered interventional phone calls in the IMBDSME group due to different participants' wishes and interests. During the interventional phone calls, Knowledge of PRIDE toolkit were discussed and delivered using MI and BAP to initiate a behavioural change. Therefore, as the proposed IMBDSME intervention was an individualized DSME, a deviation between the proposed dose of IMBDSME intervention and the actual implemented dose cannot be detected.

Efforts were exercised to monitor the adherence to the IMBDSME intervention through weekly logs. Six participants completed their weekly logs and returned them

on three-month visit while others did not bring the logs either because they failed to recall completing them or they underestimated the importance of completing the logs and thought that performing DSCB is the ultimate goal of the intervention. The presence of one researcher who conducted the trial and delivered the intervention limited the ability to collect data from other resources such as clinicians or independent observers to monitor participants' adherence to IMBDSME.

5.1.3 Participants' uptake of IMBDSME intervention:

Data on the frequency of the interventional phone calls and their length for all participants in the IMBDSME group were collected and are presented in Table 58. Mean of frequency of delivered phone calls was 6.21 ± (1.74) calls while the average length for all interventional phone calls per participant was 74.0 ± (1.55) minutes and the average length of each phone call was 12.2 ± (1.82) minutes.

Delivered dose of phone calls	Mean±(SD)	Minimum	Maximum
Frequency	6.21 ± (1.74)	2	10
Length of all calls (minutes)	74.0 ± (1.55)	29	108
Average length of each call	12.2 ± (1.82)	8.4	16.7

Table 58 Frequency and length of the delivered Interventional phone calls for IMBDSME group.

After data analysis, an inferential regression analysis conducted to investigate the correlation between the frequencies of interventional phone calls and mean score of performing DSCB. Receiving a frequency of five interventional phone calls was a statistically significant predictor to increase the mean score of DSCB by an estimated coefficient of 0.49 (95% CI, 0.04 to 0.94) where P value 0.032. Mean score of performing DSCB for those who received five interventional phone calls or more among IMBDSME group increased from 12.19 (95% CI, 11.6 to 12.8) at baseline to 14.1 (95% CI, 13.6 to 14.7) at three-month visit. Statistically, those who received five phone call, or more were more likely to have an increase in mean score of choosing heathier diet by an estimated coefficient of 0.21 (95% CI, 0.001 to 0.439) where P value 0.049. Mean score of diet for those who received five interventional phone calls or more among IMBDSME group increased from 2.81 (95% CI, 2.5 to 3.1) at baseline to 3.55 (95% CI, 3.3 to 3.8) at three-month visit. On the other hands, neither length of calls nor the average length of a single call as independent variables was statistically significant correlated with any of the trial outcomes.

5.2 Mechanism of impact:

IMBDSME intervention was an individualised tailored DSME and focused on patients' needs and concerns. Globally, there is a collective lack of agreement on the definition of patient-centred care and its intended outcomes; for example, patients' satisfaction (Mead and Bower, 2000). Generally, although patient-centred interventions such as IMBDSME were consistently correlated with enhanced patients' satisfaction, it did not clarify the mechanism of impact of an intervention and how it influenced behaviour change.(Shrivastava et al., 2013 , Al Shahrani and Baraja, 2014). Therefore, moving beyond measuring satisfaction, in particular, how participants in the IMBDSME group accepted and interacted with the received dose of IMBDSME intervention can elucidate the IMBDSME mechanism of impact (Moore et al., 2015). Acceptability measurement needs to cover all IMBDSME dimensions including the approach of delivery. Thus, researcher designed an acceptability questionnaire to examine participants' reactions toward IMBDSME intervention to all participants in the IMBDSME group.

5.2.1 Acceptability and Treatment Satisfaction Questionnaires:

Two questionnaires were administered to measure the acceptability and the degree of satisfaction on the delivered intervention among all participants in the intervention group; the self-developed acceptability questionnaire and the Diabetes Treatment Satisfaction Questionnaire (DTSQ). As mentioned in section (3.10), independent assessors collected the trial outcomes as well as participants' responses of acceptability and satisfaction measurements of IMBDSME after completing the delivery of intervention at three-month visit. DTSQ was used to measure satisfaction with treatment for participants in both IMBDSME and TAU groups at baseline and 3-month visit, while the self-developed acceptability questionnaire was used only in 3-month visit. Table 59 demonstrates when each questionnaire was used.

Table 59 Timeline of Acceptability and satisfaction questionnaires within the trial.

Variables	**Baseline**	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**	**Month 6**
DTSQS	X						
DTSQC				X			
Intervention Acceptability Questionnaires*¥[2]				X			
Process Evaluation Interviews				X			

5.2.1.1 The Diabetes Treatment Satisfaction Questionnaire (DTSQ):

The Diabetes Treatment Satisfaction Questionnaire (DTSQ) was firstly developed to measure the satisfaction of patients with DM with the treatment regimens in the clinics. The originally-developed questionnaire by Bradley (1994) is now referred as the status version DTSQs in order to differentiate it from the recently developed DTSQc "the change version". DTSQs is commonly used to measure satisfaction of patients with T2DM at baseline, while DTSQc was used to measure the change in the level of satisfaction at the follow-up visit from baseline. It has been developed to overcome the potential ceiling effects when respondents choose the maximum level of satisfaction at baseline, and is more relevant for trials that including an intervention (Bradley, 1994). Nowadays, it is widely used in clinical trials and has been recommended by WHO and IDF for the routine clinical monitoring and assessing diabetes care outcomes. It has been shown to be useful in trials that examined new treatments such as insulin pump and diabetes education programs (Lewis, 1994 , Bradley et al., 1992). Lastly, DTSQ is an assessment tool of eight items. Each item of DTSQs was scored on a scale from six to zero, while DTSQc items were scored from -3 to 3. The total score was calculated by summing six items (one, four, five, six, seven and eight) to produce the overall satisfaction on the treatment. For DTSQs, it ranged from a low score of zero to a high score of 36, while on DTSQc total score ranged from a minimum of -18 to a maximum of 18. Items two and three were asking about the perceived frequency of hyperglycaemia and hypoglycaemia respectively and were treated as separate units in data analysis in both DTSQs and DTSQc.

5.2.1.2 The acceptability questionnaire:

The acceptability questionnaire was a multidimensional and purposely-modified instrument of the one developed by Long et al. (2005). Their instrument used to measure the acceptability and explore patients' view on the telephone care centre support that has been delivered to patients with T2DM to improve their glucose level. Their intervention was delivered in the Pro-Active Call-Centre Treatment Support (PACCTS) randomized controlled trial where they recruited patients from 47 general practices in England (Young et al., 2005). Hence, researcher chose their instrument due to utilising a similar approach in this clinical trial where the IMBDSME was mainly delivered over interventional phone calls.

The developed questionnaire consisted of 26 items asking the IMBDSME group participants about different aspects of the delivered IMBDSME over phone calls. Each item scored on a five-points scale where five points indicated that participant strongly agreed, and one-point score indicated that they strongly disagreed with the provided statement. Participants have had the opportunity to choose neutral that scored three points if they neither agreed nor disagreed with the statement.

5.2.2 Analysis and Results of Acceptability and DTSQ Data:

The utilised data in this chapter are purely quantitative. The collected data were handled and analysed using the same approach that was used with the trial outcomes by STATA. However, the responses of the acceptability of IMBDSME intervention were not imputed and was handled per protocol. This was because they were collected only from the participants who received the intervention regardless of the received dose. Data handling and analysis are mentioned in sections 3.14 and 3.15.

5.2.2.1 The Diabetes Treatment Satisfaction Questionnaire (DTSQ):

As explained in section (5.2.1.1), patients' satisfaction of the received treatment was measured using the status version at baseline (DTSQs) and the change in the level of satisfaction was measured using the change version (DTSQc) at three-month visit. Nevertheless, researcher is presenting the level of satisfaction with treatment at three-month by summing the change score and the baseline status score for all participants. During analysis, DTSQs and DTSQc were each treated and presented as three sections; total of items (one, four, five, six, seven, and eight) and this measured the overall level of satisfaction with treatment, 2nd item measured the frequency of hyperglycaemia and 3rd item measured the frequency of hypoglycaemic episodes.

All participants who were randomised (148) completed the DTSQ at baseline visit and response rate was 89.9% at three-month visit. Of all participants from both trial groups, 15 participants did not complete DTSQc; five participants in the TAU group and ten in the IMBDSME group.

As for the overall score of DTSQ, participants in the IMBDSME group reported higher mean score 36.2 ± (7.06) than baseline scores 24.7 ± (6.08) compared to participants in the TAU group who had a mean score of 33.4 ± (7.01) at three-month visit and 25.0 ± (6.3) at baseline. Although participants in IMBDSME group had lower mean score than TAU group by -0.38 (95% CI, -2.33 – 1.57) at baseline, the difference between both groups at baseline was non-statistically significant (P=0.7), while it changed to become statistically significant (P=0.02) after delivering the IMBDSME intervention at three-month visit and was 2.85 (95% CI, 0.41 – 5.28). All details are presented in Table 60 and Figure 24.

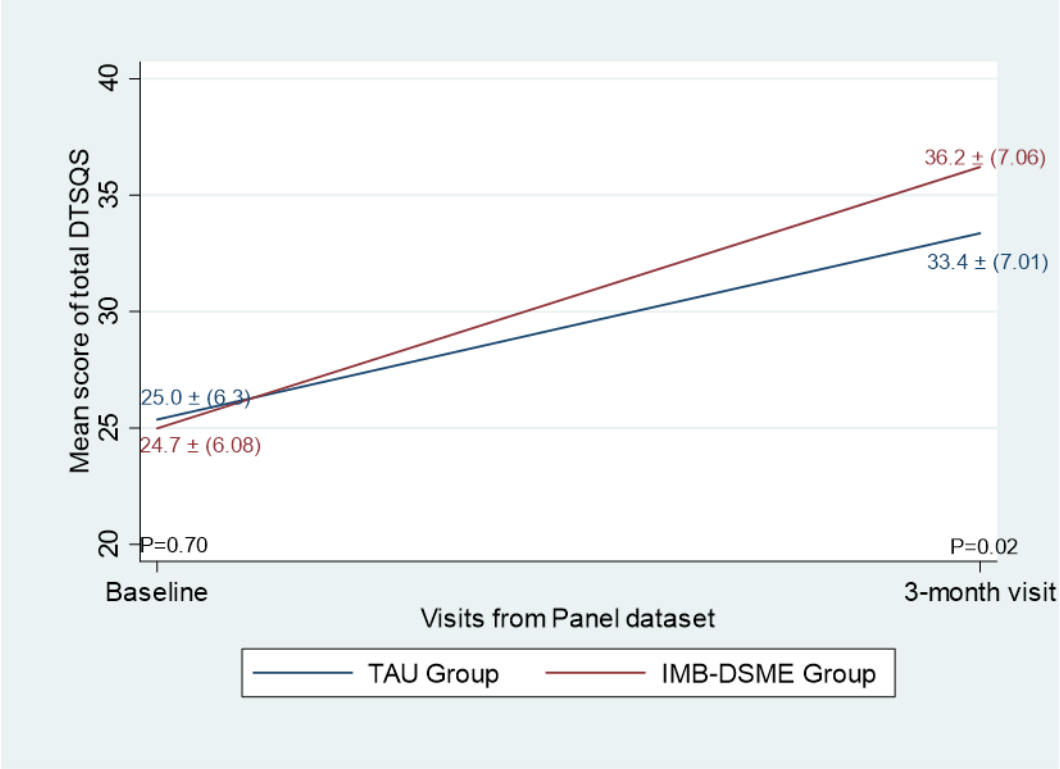


Figure 24 Mean score of DTSQ status for both trial groups at baseline and three-month.

For the 2nd item, participants had nearly same mean score in both trial groups where there was non-statistically significant difference at baseline and three-month visits because P value was more than 0.05. Participants in TAU group and IMBDSME group

had mean score of 4.23 ± (1.59) and 4.24 ± (1.49) respectively at baseline and the difference was minor and was -0.02 (95% CI, -0.50 – 0.47). Similarly, at three-month visit, participants in TAU group and IMBDSME group had mean score of 5.56 ± (1.73) and 5.55 ± (1.98) respectively and the difference was parallel to the baseline and was -0.02 (95% CI, -0.63 – 0.59). It can be seen there was an increase in the mean score at three-month from the baseline for both trial groups, however, it cannot be rationalized as an effect of the IMBDSME intervention.

For the 3rd item, although participants in the IMBDSME group had higher mean score of 1.87 ± (1.64) than participants in the TAU group who had mean score of 1.57 ± (1.37) at baseline, the difference was non-statistically significant and was 0.20 (95% CI, -0.29 – 0.70). However, it is clear that participants in both groups had higher mean score at three-month. Of those who received the IMBDSME group, their mean score was 3.18 ± (1.86) and was higher than participants who did not receive the IMBDSME intervention (TAU) group who had 3.10 ± (1.86) at three-month visit. The difference was -0.08 (95% CI, -0.69 – 0.53) between trial groups but was non-statistically significant due to be P=0.80.

Mean score of all sections of DTSQ	DTSQ overall score Mean±(SD)		DTSQ score 2nd item Mean±(SD)		DTSQ score 3rd item Mean±(SD)	
	TAU	IMBDSME	TAU	IMBDSME	TAU	IMBDSME
Baseline	25.0 ± (6.3)	24.7 ± (6.08)	4.23 ± (1.59)	4.24 ± (1.49)	1.57 ± (1.37)	1.87 ± (1.64)
Difference (95% CI) and P value	-0.38 (95% CI, -2.33 – 1.57), P=0.70		-0.02 (95% CI, -0.50 – 0.47), P=0.94		0.20 (95% CI, -0.29 – 0.70), P=0.42	
Three-month	33.4 ± (7.01)	36.2 ± (7.06)	5.56 ± (1.73)	5.55 ± (1.98)	3.18 ± (1.86)	3.10 ± (1.86)
Difference (95% CI) and P value	2.85 (95% CI, 0.41 – 5.28), P=0.02		-0.02 (95% CI, -0.63 – 0.59), P=0.95		-0.08 (95% CI, -0.69 – 0.53), P=0.80	

Table 60 Mean score of all sections of DTSQ for both Trial groups at baseline and three-month visit

5.2.2.1.1 Modelling GEE for DTSQ:

In order to calculate the effect size of IMBDSME intervention on the level of treatment satisfaction, Generalised Estimating Equation (GEE) was applied to analyse the DTSQ data. Researcher conducted GEE approach only to the DTSQ overall score due to the presence of statistically significant difference between trial groups at three-month visit. As explained above about the utilisation of GEE approach, researcher applied model one and two within GEE to calculate the estimated coefficients for DTSQ score before and after adjusting the baseline score.

As presented below, participants in the IMBDSME group had a higher mean score of 11.35 (95% CI, 10.54 to 12.15) than mean score of 7.6 (95% CI, 6.55 to 8.63) for participants in the TAU group at three-month visit in model one before adjustment for the baseline score, whereas after the adjustment, the net increase in the mean score of DTSQ for participants in the IMBDSME group was 3.76 (95% CI, 2.44 to 5.07) than participants who did not receive the intervention (TAU) group.

DTSQ overall score	Model	TAU	P-value	IMBDSME	P- value
		Coef (95% CI)		Coef (95% CI)	
3-month	1	7.6 (6.55 to 8.63)	0.001	11.35 (10.54 to 12.15)	0.001
	2			3.76 (2.44 to 5.07)	0.001

Table 61 Coefficients of DTSQ overall score for all participants in both Trial Groups and their CI (Confidence Interval)
Model 1 is unadjusted to the baseline
Model 2 Adjusted to the baseline.

5.2.2.2 The acceptability questionnaire:

Sixty-nine participants responded to the acceptability questionnaire and response rate was 89.6%. Those who did not complete the acceptability questionnaire were eight participants and they did not attend their three-month visit and could not be reached by phone by the independent assessors.

At three-month visit, “Appropriate call timing for me” and “It was useful to complete weekly logs” items were either agreed or strongly agreed by around 76% of participants who responded to the acceptability questionnaire. In detail, 16% were neutral and 8% disagree or strongly disagree that interventional phone calls timing was appropriate for them. However, 17% disagree or strongly disagree that weekly logs were useful for them and 6% were neutral.

Items where participants chose neutral by 12% and 7% were “Staff knowledgeable about diabetes” and “I recommend it to my colleagues” respectively. Moreover, 6% disagreed to recommend IMBDSME intervention to their colleagues. However, other items of acceptability questionnaire (22 items) were rated by choosing strongly agreed or agreed by all participants. Cronbach Alpha was calculated using STATA and was 0.49 for the 26 items combined. All proportions of participants who chose the rating are presented in below.

Aspect (n=69)	Strongly Agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly disagree (%)
Friendly and helpful	65	35			
Appropriate call timing for me	44	32	16	7	1
Staff knowledgeable about diabetes	49	39	12		
Staff provide me with useful advice	52	48			
Happy to speak with the same staff regularly	54	46			
Like telephone contact for specialist advice	55	45			
Amount of time on phone acceptable	61	39			
It was useful to complete weekly logs	36	41	6	13	4
Happy with the care received	54	46			
Easy to understand advice	55	45			
The advice given was relevant to me	48	52			
Sufficient time to ask questions and seek advice	46	54			
Talk about relevant things to me	55	45			
Acceptable to receive phone advice	54	46			
Staff on phone enhanced my confidence	56	44			
Feel much better after receiving the advice by call	58	42			
I recommend it to my colleagues	46	41	7	6	
Feel more knowledgeable about my diabetes now	55	45			
Have taken the advice on board	55	45			
Feel more in control of my diabetes	64	35		1	
Prefer to see health professional	49	51			
Increased my awareness	56	44			
3 months long enough to make a behaviour change	58	42			
It should be applied in the hospital	61	39			
Number of phone calls was acceptable	56	44			
Having choice over the phone calls frequency was important	56	44			

Table 62 Proportions of participants who rated the acceptability items at three-month visit.

5.3 Conclusion:

To conduct process evaluation in this trial, researcher collected quantitative to provide an insight on how participants interacted with IMBDSME intervention and made an impact. However, only quantitative data were presented that were related to the process of implementation and mechanism of impact of IMBDSME intervention.

The Oxford Implementation Index (OII) was used to report the aspect of implementation of process evaluation. It included reporting the IMBDSME design, delivery and participants' uptake. Results revealed that participants who received five interventional phone calls or more had a statistically significant rise in their DSCB mean score and their healthier diet score at three-month visit from the baseline.

Satisfaction with treatment and acceptability questionnaires were used to examine participants' reactions toward IMBDSME intervention in order to get more vision on the mechanism of impact aspect of process evaluation. From the results after the adjustment of baseline scores for both trial groups, mean score of the overall level of satisfaction with the treatment (DTSQ) was statistically significant higher by a clear of 3.76 (95% CI, 2.44 to 5.07) for participants who were allocated to the IMBDSME group than participants in the TAU group. By the same token, almost 90% of participants in the IMBDSME group responded to the acceptability self-developed questionnaire where they agreed or strongly agreed that IMBDSME intervention was acceptable on 22 items that were related to either the intervention design or the delivery.

6 Discussion:

In this chapter, the reader is given an insight to a critical discussion based on the trial results. Across scientific studies, different approaches are followed in writing the discussion section where writer is meant to delve into the meaning, explain the findings and how it relates to the wide literature. To enhance the quality and transparency of reporting, CONSORT statement were followed as was reported earlier in (3.2.3). In their guidelines, Moher et al. (2012) supported Horton (1995) who criticised authors for their use of rhetorkkkic more often to support their trials results to be "saleable" in the discussion section. Instead, they recommended to create a gracious argument of pros and cons of the trial and its results. They suggested to follow a structured discussion to draw a justified conclusion. Their proposed structure to discuss trial results was an appropriated example from the *Annals of Internal Medicine* journal and is briefed in Table 63. Their proposed structure did not include a section on the strengths side of the trial. However, similar structure is followed here with the addition of the trial strengths along with the limitations in regard to the trial design. Then trial results are interpreted within the IMB model context and were compared with other results in literature before explaining the trial implication on research and clinical settings in the conclusion.

Suggested structure for discussion from CONSORT statement
• A brief summary of the key results. • Suggesting potential mechanisms and justifications. • Weaknesses of the current study and what methods used to decrease them. • Differences with relevant findings from other studies in literature • A summary on the clinical and research implications of the trial in the conclusion.

Table 63 Structure for Discussion section adopted from the Annals of Internal Medicine journal

6.1 Principal results of the trial:

To our knowledge, this is the first randomised clinical trial that aimed to examine the effectiveness of delivering an IMB model-based educational intervention (IMBDSME) and assess outcomes at three-month and six-month time points. Briefly, principal results of the effectiveness of IMBDSME on primary and secondary outcomes are presented in the following sections.

6.1.1 Effectiveness on Primary outcomes:

Primary outcomes were the changes in diet, physical activity, and medications management self-care behaviours. In comparison to participants in TAU group, analysis revealed that participants in IMBDSME group had statistically significant higher scores in diet and medications management self-care behaviours at three-month and six-month visits than baseline scores after adjusting for all covariates. In addition, they had higher scores for physical activities self-care behaviour at both visits than baseline score, but the changes were not statistically significant. The three self-care behaviours were summed after weighting adjustments to create a total score for performing Diabetes Self-Care Behaviours (DSCBs) as mentioned in (3.13.2). Those who were in IMBDSME group had statistically significant higher scores at three-month and six-month visits than baseline score in comparison to participants in TAU group for all DSCBs.

6.1.2 Effectiveness on secondary outcomes:

Secondary outcomes were the changes in levels of knowledge, motivation, self-efficacy of diabetes self-care behaviours, glycaemic levels (HbA1c) and quality of life.

Overall, participants who received IMBDSME intervention had statistically significant higher scores in knowledge, motivation and self-efficacy determinants than baseline scores in comparison to participants in TAU group at three-month and six-month visits after adjusting for all covariates. In addition, the reductions in HbA1c for participants in IMBDSME group were greater in comparison to participants in TAU group than baseline values at three-month visit but was not statistically significant. Whilst at six-month visit, participants in TAU group had greater reduction in HbA1c than baseline values in comparison to participants in IMBDSME group and the reduction was statistically significant. Further analysis to investigate the effect of different treatment regimens in trial sites on HbA1c reductions for all participants in both trial groups revealed that the reduction in HbA1c values for those who attended JUH was greater than of that for those who attended PHH at three-month and six-month visits after adjusting for all covariates. The reduction in HbA1c values was only statistically significant at three-month visit for participants in IMBDSME group who were attending JUH site.

For diabetes-related quality of life, participants in both trial groups responded to ADDQOL questionnaire, which consisted of three parts as it was explained in (3.13.3.5). Participants in IMBDSME group had higher scores than baseline scores in comparison to participants in TAU group at all parts of ADDQOL questionnaire at three-month and six-month visits after adjusting for all covariates.

6.2 Strength and weakness of the trial:

Strengths and weaknesses characteristics of the trial are discussed in the following sections in relation to multiple aspects such as trial design, recruitment and randomisation. Sections are provided with arguments over the advantages and disadvantages of the trial design, challenges during the recruitment process and how they could have been addressed, and safeguarding randomisation procedure as well as comparing the figures here with international published figures.

6.2.1 Trial design:

As was well-explained why RCT experiment design was chosen in section (3.2.2). It was reported that it was used to examine the effectiveness of IMBDSME intervention on performing DSCB as It is considered the gold standard of evidence in clinical research. It was hypothesised that participants who received IMBDSME intervention should have performed DSCB more frequent than participants who only received the usual treatment. However, Polit (2008) and Privitera (2017) agreed that on the fact that high valued RCT must include three essential and fundamental characteristics to conclude whether to accept or reject the research hypothesis; random sampling, manipulation and control. These three characteristics were utilized in this trial as was described in detail in chapter 3. Briefly, in this trial, high level of control was exerted to control who were eligible to be recruited and to be allocated randomly within trial groups to reduce systematic bias. This resulted in two comparable groups as all measured confounders did not statistically significant vary at baseline. Subsequently, a group received the IMBDSME intervention as an addition to the usual treatment

(Intervention group), and the other received the usual treatment only (control group).

During planning stage, several measures were considered to increase the internal validity of the trial. These measures were important elements to the success of this trial and were highly effective as evidenced by the improvements in primary outcomes for those who received the IMBDSME intervention and had positive consequences on their quality of life and HbA1c. One of these measures is the adoption of wide inclusion criteria and minimise the exclusion criteria. It was suggested that 68.4% of patients with T2DM could be eligible when applying the criteria. Thus, it was broad to cover around two third of all patients who were diagnosed with T2DM. The criteria were carefully developed to reflect the real clinical practice. It aimed to recruit a representative sample of the population to minimize the threats to external validity of the trial. More about eligibility and exclusion criteria are described in (3.2.4). While the trial design met the three essential characteristics for high-quality RCT additionally with the discussed measures above, this trial can be seen as high valued RCT. However, some threats that might have affected the quality of this trial can be spotted and are presented in the following discussion.

To begin, as it was shown above in trial design, two groups were used to examine the effectiveness of IMBDSME intervention where all participants in both groups received the Treatment As Usual (TAU), and it can be seen that participants in one of the groups received the IMBDSME intervention as an addition while participants in the other group received nothing extra. This description is not far from the Freedland

et al. (2011) description for behavioural intervention trials. They claimed that most trials that examined the superiority of an intervention by comparing them to standard or usual care group deserve careful scrutiny because they do not eliminate differential attention as threats to internal validity. They elaborated on this point by stating that those in TAU group were contacted and followed up by the trialist, thus, received more attention that could expose them to some sort of clinical experience and was in reality TAU additionally with more attention. Or from another angle, it can be claimed that participants in IMBDSME group who received more care should simply have better outcomes because they received an extra attention and not because it was an IMB model based DSME. This claim can be raised for any RCT that use two arms where one of which is control group. They suggested that three-arm trials can help to eliminate the effect of the attention. However, a multiple arms RCT was proposed to address this claim in the early stage of this trial because It has the power to provide more specific information about the effectiveness of a new intervention and compare it with other current intervention as well as the TAU group and can refute the latter claim (Baron et al., 2013). However, design and data analysis of multiple arms RCT are more complicated due to the numbers of potential comparisons between groups and sample size calculations. Therefore, the idea of conducting multiple groups RCT was inconceivable within the timeline.

Another point for discussion regarding the trial design is the fact that this trial was an individualised RCT while MRC framework state that individualised RCTs are not appropriate if the intervention is directed to be applied in a practice or organizational level. Therefore, they recommended that the clustered designs are particularly

suitable to evaluate those interventions. They added that cluster design increases the feasibility of conducting a true experiment and reduces the chance of exchanging information between participants from both trial groups due to the nature of the clustered design where the trial sites are randomly allocated to any of the trial arms. However, a cluster randomised design was not appropriate because of two reasons. First, the nature of the intervention required an individualised design because IMBDSME intervention was an individualised DSME. Second, each trial site has different treatment regimen and different sponsor. Consequently, this may serve different populations who may differ in their personal characteristics that may end up with a group imbalance and bias leading to an incomparable trials' groups. Even though matching strategy may help to deal with group imbalance, it has its own limitation because we cannot identify all confounding factors before conducting the trial; thus, a remaining imbalance continues to be existed. Moreover, sharing and exchanging information between participants is inevitable in clinical research but it is more likely to occur in individualised designs. Clustered randomised trials require higher level of power, larger sample size, higher costs and complexity during analysis stage and these requirements cannot be afforded within PhD degree. Nevertheless, the individualised design is similar to other trials that examined the effectiveness of DSME in the literature and this is vital because it allows others to combine results from other trials for systematic reviews and meta-analyses purposes. Moreover, Torgerson (2001) recommended that clustered design should not be used unless there is a significant reason to adopt it. All in all, and by referring back to the research question of interest and the scope of this research in section (1.7.8), and following a

critically thinking process during the planning stage about several methods of randomization and control measures of trials, it was concluded that this trial had to be an individualized randomized controlled trial with parallel random allocation of participants to Treatment-As-Usual (TAU) and intervention group IMBDSME on 1:1 basis.

Another point to be mentioned that following MRC framework expansively in developing and evaluating IMBDSME intervention requires several studies, research team and adequate fund which is not feasible within PhD program. Nevertheless, all relevant MRC framework phases were conducted to answer the research question.

6.2.2 Randomisation:

Another measure is the randomisation procedure where an online randomisation software was used to allocate the recruited participants. At the point of recruitment, nobody was aware of the allocation until the participants' sequence number was entered on the software to reveal that participants' allocation. The software followed the order of a sequentially numbered list that was developed by an independent researcher and consisted of simple randomised blocks that were stratified according to the trial site. As was explained in (4.2.2), participants' allocation was compared with the uploaded randomisation list after the trial and were identical. What is more, significance statistical tests were utilised to compare baseline characteristics and comorbidities between trial groups, and the results showed that there were no significant relationships between IMBDSME group and TAU group at baseline. Although Altman (1985) stressed that using significance tests to compare baseline characteristics to assess that the probability of the variation in baseline between trial

groups is illogic. His claim was based on the actual fact behind conducting randomisation where it guarantees a variation to a highly extent in baseline since it necessarily occurred due to chance rather than bias. Despite this fact about randomisation, baseline data were compared using significance statistical tests due to the presence of a threat that may weaken this RCT. This threat is the non-concealment of participants' allocation in trial groups from people who operated the trial, which is known as blinding. As a result of the statistically non-significant findings at baseline, researcher concluded that trial groups were homogenous and comparable at the point of recruitment. Therefore, it can also be concluded that randomisation procedure was safeguarded.

The threat of non-concealment of participants' allocation could not be avoided in this trial because this was conducted solely by the student who randomised, delivered the IMBDSME intervention and analysed the collected data. Participants' allocation was known for him and could not be concealed. Although participants were randomised to trial groups, randomisation procedure does not guarantee to neutralize any differential assessment of trial outcomes. Therefore, two independent assessors were asked to collect trial outcomes who agreed and participated voluntarily. Although their involvement increased the likelihood of eliminating any biased estimates of treatment effects between trial groups, data analysis of the trial outcomes was done by the same student. Theoretically, it means that the estimated treatment effects could be biased due to fact of having access to trial outcomes during analysis.

6.2.3 Sample size:

Adding to the previous measures is the values that were involved in calculating the trial sample size. Alpha level of 0.05 and a power of 80% consider as ideal for most trials (Suresh and Chandrashekara, 2012). Those were used to calculate a sample size to detect a small difference of effect size between trial groups on the primary outcomes to avoid falling into Type II or β error. The calculated sample size was 200 and was not accomplished during the period of recruitment. One of the major reasons was for the fact of being tied in a recruitment interview. The engagement in a recruitment interview with a consented participant prevented from accessing other eligible potential participants who left the trial site without invitation. As can be seen, recruiting the required sample size was more difficult than expected and reaching the planned sample size failed within the envisaged timescale of the trial. Therefore, the trial was underpowered.

More than the required sample size could have been achieved (317 participants) in this trial based on simple calculation. Referring back to the recruitments' statistics in Table 7, if we assume that another independent researcher invited those who were unapproachable (215) at that time and assume that same proportion of whom consented in this trial (80.8%) applies, we would have recruuited (215*80.8%= 173) more participants. Thus, the total number of recruited participants could have changed to be 324 (173+151) at baseline. Likewise, if we assume that 2% of those 173 chose to withdraw at baseline (173*2%= 4) the number of those who could have been randomised to trial groups is (173-4=169) added to those who were randomised 148, the total would be 317 participants. Their baseline data could have been

collected over phone calls prior randomisation if it was not possible to be collected in trial site.

6.2.4 Recruitment:

According to patients' screening statistics, results showed that 85.6% of the screened patients were not eligible to be invited to participate in this trial. In fact, this high percentage appears to contradict the suggested proportion of (68.4%) of patients with T2DM whom were predicted to be eligible for invitation in section (3.2.4). This incongruity between proportions occurred because the suggested proportion was estimated from a dataset that was collected in 2012 in the National Centre for Diabetes where all attendees were diagnosed with T2DM. The initial plan for this trial was to be conducted at the national centre for diabetes but due to the high number of clinical studies there, research team had to choose outpatient's clinics at other two hospitals as mentioned in (3.9.2). In both trial sites, a considerable proportion of attendees have had a broad range of disorders and chronic conditions, for example, heart failure, renal diseases or haematological disorders. Endocrinology outpatients' clinics in JUH focus on endocrinology-related disorders where diabetes is the core of their competency, while outpatients' clinics in PHH are not specialised clinics and they receive patients with different chronic conditions without focusing on a particular disorder such as diabetes. If any of those patients in PHH required further consultation on their diabetes condition, they normally would be referred to an endocrinologist which is lengthy process and can take months. This might explain the lower rate of attendance within PHH outpatients' clinics (29%) of those who were screened as it seems not preferable because it is not speciality-focused in contrast to JUH outpatients' clinics which were attended by large proportion (71%) of those who were screened. On the other side, lower rate of attendance facilitated approaching

and inviting more eligible patients with T2DM in PHH in comparison to JUH relatively. This can be seen by the percentage of those who were approached out of those who were eligible in PHH (60 participants invited /114 eligible participants =53%) compared to the percentage in JUH (127 participants invited /288 eligible participants = 44.1%) in Table 7. Being tied up with a participant during recruitment interview where they completed baseline data had a detrimental effect in both trial sites on recruitment rate because it prevented from accessing other eligible patients who used to leave the clinic once they finish their consultation to queue up in pharmacy. Subsequently, higher number of eligible participants were not invited in JUH compared to PHH. All the aforementioned factors were critical in the recruitment process and limited the ability to recruit the required sample size of 200 participants within three months.

As mentioned previously, recruitment rate was (80.8%) where (151) participants consented and were recruited out of those who were approached and eligible 187 from both trial sites. However, 200 participants were required according to the sample size calculation and 76% of the original sample size was achieved (151) participants. Failing to meet the original sample size is a frequent problem in many trials as was described by Walters et al. (2017) following the results of their review. They conducted a comprehensive review of the consent and recruitment of 151 publicly funded RCTs in UK and published by the UK NIHR from 2004 to the end of 2016. The majority of the reviewed trials were two-armed, parallel groups and multicentre trials and reported that 79% of the reviewed studies recruited around 80% of their original sample size and 56% achieved their final target sample size. They

added that a median of 70% (IQR 51%–87%) of eligible patients consented and were randomised. Apart from the achieved proportion of 76% of the required sample size in this trial, recruitment's statistics were slightly better than the published figures above where 80.8% of those who were invited consented and recruited and 79.7% were randomised.

6.2.4.1 Discussing risk:

A potential problem with recruitment is that participants who were allocated to intervention group have been invited for the fact they had an uncontrolled glycaemic level (HbA1c >8%) where some of them have not approached that level before. It was crucial to relief their potential anxiety and not to endanger any fears from the high glucose level and its related complications by simplifying the language of communication. It has been stressed on the PIS about the medications side effects such as hypoglycaemia and the importance of managing glucose level to avoid them. During the recruitment interview, researcher has handled the risk of having an uncontrolled glycaemic level by stressing on the high possibility of reversing the surge of glucose level and its complications such as neuropathic pain, rather than conveying a message of threat of having an uncontrolled diabetes. In fact, many patients were aware of the risk of uncontrolled diabetes and its complications from other relatives or friends' earlier experiences. Researcher has found that using a positive approach is very helpful to facilitate the enrolment into DSME programmes, for example, emphasizing on the benefits of being physically active on general well-being, rather than focusing on diabetes complications such as blinding or haemodialysis that may

alienate them from enrolment during recruitment interviews (Gillies and Entwistle, 2012).

Some of the eligible patients who did not meet the inclusion criteria or have been allocated to control group were asking for an advice on managing glycaemic level and obesity during the recruitment interview. They were given a simple superficial guidance related to maintaining activity and healthy food choices and were referred to their physician if they were concerned about their medications or health status.

6.2.5 Retention rate:

As is the case with most trials, sample size decreases during follow up due to dropouts. Those who were lost to follow up were ten participants and the reasons for dropouts were mentioned in (4.1) and the sample size calculation to determine how many participants needed to be recruited is explained in (3.2.3.1.2). Those ten participants represented for an attrition rate of 6.6% from those who had valid primary outcomes data for analysis. This proportion was less by almost one third of the proportion that was used during sample size calculation which was 15%. In other words, retention rate was 93.4% and valid primary outcomes data were available from 141 participants at six-month endpoint. This rate was higher than the reported median retention rate of 89% (IQR 79–97%) by Walters et al. (2017) in literature. Their results were published after reviewing the retention rate of 151 publicly funded RCTs in UK and published by the UK NIHR from 2004 to the end of 2016. They noted that recruitment success is improving slightly within RCTs compared with previous figures on recruitment covering the period 1994-2002 that were published by McDonald et al. (2006). Although this trial was not funded, it proves once again that

the considered measures during planning stage including the recruitment criteria had successful consequences on the trial results.

Another arrangement that enhanced the retention rate in this trial is the timepoints of data collection. Primary and secondary outcomes were measured at baseline, three-month visit and six-month visit to detect the changes in questionnaires' scores overtime. Three months interval between visits was the most common interval for attending follow ups and to renew their medications' prescription for patients with T2DM. This arrangement facilitated meeting them to collect their responses on the trial outcomes in both trial sites to increase participants retention. Their biomedical results were collected whenever possible during data collection stage from electronic records.

One more procedure that took place to enhance attendance and showing up for collecting outcomes was the appointments reminders. Participants were reminded in both groups about their prospective treatment appointments on phone calls to confirm there was no change on the second and third appointments. Whenever any change had occurred, it was updated on the participants' CRF and the research diary with their new appointment to follow them up. In addition, participants had the flexibility to schedule their interventional phone calls based on their preferences. All efforts were made to ensure that participants were engaged with the IMBDSME intervention by stressing the importance of performing DSCA to improve their glycaemic level. It was proposed to tackle any reason that could undermine participants' adherence to the IMBDSME intervention unless it contradicts with the

trial design. This was to ensure the voluntary continuity and the highest level of compliance.

6.2.6 Trial measures:

In order to produce valid results, it is essential to use reliable and valid measurements tools in RCTs when assessing baseline and trial outcomes. Although the used measures were validated and known to be reliable in previous studies as mentioned in (3.13.2) and (3.13.3), response bias exists wherever self-reported measures are used especially when double blinded practice cannot be exercised as is the case in this trial and all human behaviours RCTs. It can be seen from the preceding section (3.13) that the used measurements were all self-reported measures except for the HbA1c blood test, the results were supplied by the hospitals laboratories. It introduces further threat to the internal validity of any RCT due to the effect they can prompt on participants' responses such as Hawthorne effect or measurement reactivity. Hawthorne effect can be described as the possibility of affecting trial results or participants' behaviour as a consequence of being observed (Capellan et al., 2017). Another special case of Hawthorne effect is the measurement reactivity that focuses on the processes by which administering measurements repeatedly is leading to the improvements in the participants' behaviour being measured (French and Sutton, 2010). To illustrate, the measurements or trial instruments may enlighten the trial participants of the targeted self-care behaviours, which in turn have an impact on the trial outcomes. Both, Hawthorne effect and measurement reactivity, might have been introduced in this trial as a result of using self-reported measurements. Holden (2001) claimed that this can create doubts as to whether or not the improvements in trial outcomes were solely due to delivering the intervention for those in the IMBDSME group. On the other hand, it may explain any

improvements in practising self-care behaviours among those in the TAU group, consequently, improvements in their HbA1c as we can notice in the results section (4.8.4.2). Elaboration on this point and additional discussion on trial results interpretation for IMBDSME and TAU groups are presented in the next section.

6.3 Interpretation of trial results: Strengths and weaknesses in relation to other studies, discussing particularly any differences in results

In this trial, the behavioural change model (IMB) was used to design IMBDSME intervention and the delivery was designed based on its fundamental assumption. As mentioned in 2.1.2), authors of IMB model proposed that there are causal relationships between the primary determinants of any self-care behaviour; knowledge, motivation and behavioural skills, that can produce change in the level of practice of that behaviour. Here in this section, trial results are interpreted in light with the current literature to unfold how the utilisation of IMB model in designing the trial intervention (IMBDSME) affected the practice of the targeted DSCBs positively. Also, to attempt to explain the change in their practices among both IMBDSME group and TAU group with other trials that delivered behavioural change DSCB interventions in the literature.

6.3.1 The utilisation of IMB model determinants:

It was hypothesized that IMBDSME intervention can produce positive changes for those who received it in the performance of DSCBs (primary outcomes) at three-month and six-month. The hypothesis was established because the delivered IMBDSME intervention aimed to improve the level of main determinants; diabetes knowledge, motivations, and behavioural skills' self-efficacy, and sequentially, affect the performance of DSCBs, which would improve HbA1c level and quality of life. With respect to the trial's results in (4.7) and (4.8), the statistically significant increase in the level of the three main determinants collectively for those in IMBDSME group has improved the primary outcomes, and as a result, improved quality of life and HbA1c

levels (secondary outcomes) at three-month and six-month from baseline. All outcomes for those in IMBDSME group were improved statistically significant except for HbA1c where it was only statistically significant at three-month for those who attended JUH. On the other hand, the change in the level of those determinants for those who did not receive the intervention in TAU group were not statistically significant at three-month and six-month from baseline and they changed slightly in the positive direction apart from the knowledge determinant that changed negatively at six-month. Consequently, the changes in primary and secondary outcomes for those participants were not statistically significant and were in various irrelevant orders either positive or negative changes at three-month and six-month from baseline. The surprising statistically significant improvement for those in TAU group was in medications management self-care behaviour at three-month. While as it looked as a spontaneous result of not receiving any intervention, both diet self-care behaviour and quality of life level changed statistically significant adversely at six-month and three-month respectively for those at TAU group.

From the perspective of linking the changes in DSCBs with the main determinants of IMB model, we can perceive that the magnitude and pattern of change at three-month and six-month between trial groups could not be due to chance since the changes in the outcomes for IMBDSME group were statistically significant but were not the case in TAU group at both time points. The direct correlations between IMB determinants and trial outcomes were not measured cross-sectionally in this trial at any time points including baseline because it was irrelevant to the trial outcomes. However, although the differences at baseline between both groups were not

statistically significant in all variables, it was noticeable that those in TAU group had a slightly higher scores than those who were in IMBDSME group in the level of IMB determinants, primary outcomes except physical activity behaviour, quality of life, and HbA1c for those who attended JUH as presented in (4.4). Based on the account that all the recruited participants had different characteristics at baseline and were recruited from two settings each had a different treatment regimen, the only clear difference between both groups after three-month and six-month was that one received IMBDSME intervention and the other did not. All in all, this supports the claim that there is positive relationship between any self-care behaviours' determinants and its level of performance, which was assumed by the developers of IMB model and was mentioned in (2.1.2) (Fisher and Fisher, 1993). Accordingly, it can be concluded that IMBDSME intervention made an improvement in the level of practicing DSCBs for those in IMBDSME group more than those in TAU group.

Although participants in TAU group did not receive extra knowledge, motivation, or skills on DSCBs, the changes in those determinants were positive, however, were not statistically significant. This trend might be related to other reasons such as Hawthorne effect or measurement reactivity that might act as a hint to seek for further knowledge and learn behavioural skills that are related to DSCBs.

6.3.1.1 Improvement in knowledge:

As mentioned earlier, knowledge level improved statistically significant for those in IMBDSME group at three-month and six-month from baseline. The improvement was believed due to being exposed to the Arabic-version of the educational booklet (PRIDE) that was handed to all those in IMBDSME group and discussed over interventional phone calls. These improvements were on a par with those reported in several systematic reviews and meta-analyses in literature about the effectiveness of DSME (Ricci-Cabello et al., 2014 , Mohamed et al., 2019 , Norris et al., 2001 , Norris et al., 2002). Norris et al. (2001) reported in their systematic review that several DSME trials showed statistically significant improvements in knowledge on DSCBs for both intervention and TAU groups on the short term less than six months but not on long term six months or higher. They added, those who received regular reinforcement on DSCBs showed a sustainable high level of knowledge on DSCBs on long term parallel with the performance of those in IMBDSME group in this trial. Similarly, Osborn et al. (2010) delivered an IMB-model based DSME in a brief one session and those in the intervention group had a statistically significant improvement in knowledge level at three-month. No data were reported on six-month time point because their trial stopped due to funding matters.

It is evident from the results reported by Phillips et al. (2018) that DSME interventions increase knowledge level about managing diabetes. They studied the relationship between diabetes knowledge and glycaemic control using qualitative study design where they administered multiple-choice test during interviews to assess diabetes knowledge. Although the reported relationship was not statistically significant

because their study was exceptionally underpowered as it was part of qualitative study, participants who have never received any diabetes education scored lower than those who have had any education about diabetes on the diabetes knowledge test.

Most studies justified the improvement in knowledge level among TAU group due to contamination factor that was explained in (6.2.1). Contamination was possible in this trial because participants of both trial groups were recruited from each trial site, as a matter of fact, blinding participants is deemed infeasible in behavioural and education trials (Page and Persch, 2013). On the other hand, participants in TAU groups were incapable to recall the correct answer or knowledge as it can be concluded from the statistically significant decrease in knowledge level at six-month. What is more, the decrease might be attributed to the diminished influence of the measurement reactivity factor, which was mentioned in (6.2.6), for those in TAU group during follow-up because knowledge about DSCBs in this trial were self-reported on SKILLD measurement tool that was consisted of ten open-ended questions as presented in (3.13.3.1). This type of measurement tool that use open-ended questions assesses participants' comprehensive on specific subject differently than multiple-choice questions that are common in DSME and behavioural research especially when it comes to measure the level of knowledge of diabetes (Campbell, 2000). Open ended questions provide limited information as retrieval prompts. The retrieval of the knowledge or information on DSCBs from memory in a prompts-recall task mainly relies on recollection processes (Graesser et al., 2010). In contrast with process of answering open-ended questions, the process of answering multiple-

choice questions is endorsed to some extent by automatic retrieval or familiarity because the correct answer is presented within the choices that frequently lead to successful identification of the correct answer (Yonelinas, 2002). Accordingly, participants' performance on diabetes knowledge measurement tools in other trials, in particular TAU group, might have been aided by the concept of perceived familiarity that apply to multiple-choice questions, thus, high influence of measurement reactivity factor. While in this trial, the utilisation of SKILLD required participants to actively use and search their memory, and if they did not know the correct answer they often were unsuccessful due to the lack of cues or prompts in those questions, thus, low influence of measurement reactivity factor (Ozuru et al., 2013).

6.3.1.2 Improvement in motivations:

Similar to knowledge level in this trial, motivation level improved statistically significant for those in IMBDSME group at three-month and six-month visits after receiving IMBDSME intervention. The improvement was believed due to using Motivational Interviewing (MI) approach that include Brief Action Planning (BAP) and was described in (2.2.2.2). Most studies in literature did not measure the change in the level of motivation before and after DSME, and instead focused on comparing the performance of DSCBs or the level of HbA1c between those who received DSME that included MI and those who received the routine care or what is called control group. However, in this trial the changes in motivations level were measured using self-reported instruments that measured both the participants' personal and social motivations at baseline, three-month and six-month as was introduced at (3.13.3.2). In literature, Siminerio et al. (2005) and Atak et al. (2008) compared the motivation level before and after receiving DSME intervention for both control and intervention group using Diabetes Empowerment Scale (DES) that was used in this trial. In both studies, DES score increased after receiving the DSME intervention from baseline in comparison to those who were in control group, but the differences between both groups were not statistically significant in both studies. Siminerio et al. (2005) justified the nonsignificant improvement due to the limited power to detect a difference from baseline to the end-of-study results, while Atak et al. (2008) justified the limited improvement in DES due to the inadequate and short DSME intervention. In addition, both studies neither utilised MI approach nor focused to improve the psychological outcomes in their DSME interventions. While in this trial, the IMBDSME

intervention was delivered using MI approach and focused on psychological factors, which might justify the statistically significantly improvement in DES score for those in IMBDSME group at three-month and six-month from baseline. Moreover, as is the case with most self-reported measures, DES score improved slightly among those in TAU group at both time-points due to probably the same reasons that affected the other measurements such as Hawthorne effect or measurement reactivity.

6.3.1.3 Improvement in self-efficacy:

As was mentioned earlier, behavioural skills' self-efficacy scores improved statistically significant for those in IMBDSME group in comparison to those in TAU group at three-month and six-month from baseline. The improve among those in IMBDSME was strongly believed as a spontaneous consequence due to receive IMBDSME intervention; mainly, as an extent from the statistically significant improvement in knowledge and motivation levels. As was described through intervention mapping steps in (2.2.2), those who received IMBDSME intervention had the chance to choose to practice a specific self-care behaviour to start learning and discussing the related knowledge of that behaviour through MI approach prior establishing goals. Once they sat up individualised short-term goals, they directed their attention and focus to take on board new tactics they gained from the education to succeed in exercising this behaviour in real life, in which motivation level moved upward. Their motivation strived themselves to change a DSCB positively and enhanced their self-efficacy toward that DSCB (Lenz and Shortridge-Baggett, 2002). Several studies in literature similar to our trial reported higher level of self-efficacy for those who receive DSME intervention. Peña-Purcell et al. (2015) delivered an empowerment based DSME through educational sessions to 103 participants who were allocated in the intervention group. They reported that those who received the intervention had statistically significant higher scores at three-month from baseline in both self-efficacy and the performance of DSCBs than those who were in the control group. Another study that was conducted by Dogru et al. (2019) delivered DSME that included MI approach and assessed self-efficacy level for participants in

both control group and intervention group before and after the intervention but did not follow them up. They used the same instrument that was used in this trial to measure self-efficacy level; the Perceived Diabetes Self-Efficacy Scale (PDSMS), which was described in (3.13.3.3). Those who received the intervention had statistically significant higher scores in PDSMS from baseline than those who were in the control group. Similar results were reported in other studies where self-efficacy improved statistically significant among those who received psychological DSME interventions (Guo et al., Liu et al., 2012 , Moriyama et al., 2009 , Shi et al., 2010). All in all, we can understand that other DSME interventions that included psychological factor such as empowerment or motivation style alongside providing information on DSCBs can improve participants' self-efficacy parallel to this trials' results.

The perceived diabetes self-efficacy is strongly correlated with practicing DSCBs as was reported above. Al-Khawaldeh et al. (2012) conducted a cross sectional study in Jordan among 223 participants to investigate the association between the perceived diabetes self-efficacy and DSCBs as well as the glycaemic control. Their results shown a statistically significant association between participants' self-efficacy and their performance in DSCBs such as diet, physical activity, and medications management. Those who reported higher self-efficacy level, reported better self-care behaviours. In addition, those who performed better self-care behaviours had better glycaemic control. This is consistent with the results in this trial and with the assumption of IMB model that was described in (2.1.2).

6.3.2 The effect of IMBDSME intervention:

IMBDSME intervention was developed and mapped onto IMB model main determinants as was explained in (2.2.2). It is less likely that a separate determinant whether knowledge, motivation or behavioural skills was solely responsible in changing participants' level of practicing DSCBs. All those determinants interacted to change the primary DSCBs. Information about DSCBs were given in an educational booklet and those information were discussed during the delivery process throughout MI and BAP approach alongside with individualised goal setting in a collaborative way as was explained in chapter (2). Comparably, didactic DSME intervention produced less favourable results in literature than collaborative DSME interventions as stated by Norris et al. (2001) because the effect on the outcomes were short-lived. Empowering participants through DSME intervention by using motivational approach such as MI, supports the opportunity for interpreting their newly received knowledge into changing DSCBs practice as a result of improving self-efficacy state (Siminerio et al., 2005). It would have been useful to statistically estimate and evaluate the extent to which of the three main determinants of IMB model explained the variability in each DSMB such as diet. These estimations were not computed as they were out of the scope of the trial's research question as mentioned earlier. Therefore, exploring those associations statistically in the literature is pointless in this section. However, the fact that each determinant of IMBDSME intervention contributed differently in changing each DSCB cannot be denied because they certainly did not equally contribute in changing the level of each DSCBs for those in IMBDSME group. This claim can be supported from the results

reported by Osborn and Egede (2010) who conducted an RCT to validate the utilisation of IMB model in DSME to improve diet and exercise self-care behaviours among a sample of T2DM. They examined the fundamental assumed relationships between IMB model constructs to help inform any potential modifications to the IMB model based DSME intervention using structural equation modelling. They showed how each determinant of IMB model impacted their trial outcomes and this will be cited in the next sections below additionally with the effect of IMB determinants on each of this trial outcomes. It is explained narratively and supported with evidence from the literature whenever is applicable.

6.3.2.1 Effect on diet self-care behaviour:

According to trial results, those who were in IMBDSME intervention reported a statistically significant positive change in diet self-care behaviour at three-month and six-month points. In fact, after receiving the IMBDSME intervention, they reported that they have improved in planning for healthful eating diets, consuming five or more servings of fruits and vegetables and eating less high fat foods such as red meat and full-fat dairy products over the last seven days from reporting. These outcomes could not be met unless they were informed about how to control portion sizes using "Dividing the plate approach" to balance all types of food across daily meals and how food types affect their diabetes condition. For example, how eating food with carbohydrate increases the blood glucose level and how different food with carbohydrates increases the glucose level differently where glycaemic index varies. With regard to eating out and snacks, a detailed guidance was included on what type of snack to eat between meals (three main meals) and what to choose when eating out and how many calories are in many of the well-known fast-food items. All this knowledge was vital and fundamental for participants in IMBDSME group to be able to make an informed decision on their healthy dietary plans, that is, if they were motivated enough to exercise diet self-care behaviour. However, if they had the required motivation to change their dietary habits without any evidence-based knowledge on healthy diet, they could have exercised diet self-care behaviour based on their previous eating behaviours. Generally, eating behaviour includes food selection and eating pattern and is usually influenced by behavioural, cultural and social elements (Oltersdorf et al., 1999 , Nestle et al., 1998). Participants' previous

eating behaviours contributed to the development of T2DM and is a lifelong history that cannot be altered rapidly as a result of the diagnosis (Savoca and Miller, 2001). Their past eating pattern and knowledge on diet could be a mixture of facts and myths that were developed and collected from different resources and were interpreted incorrectly or derived from the culture. An example on food selection, vegetables are recommended for those with T2DM as healthy type of food, but potatoes cannot be treated same as carrots due to high level of carbs, which is in fact need to be controlled. Another example on eating pattern where some participants thought that by replacing all-day meals with one big meal is an efficient way to limit food intake regardless of the types of food consumed. One of the IMBDSME participants was aware of the fact that fruits or vegetables are healthy choices for patients with T2DM and was motivated to start practicing this healthy habit. When it was discussed to create a SMART goal as part of BAP it was revealed that she was inadvertently planning to consume five portions of fruits such as banana in a form of juice as it facilitates consuming larger quantity of vitamins and was perceived as better practice while ignoring the benefits of the wasted fibers. Another factor is the food preparation process where there is huge difference between fried, boiled or grilled. The majority of participants were not aware on the fact that the quantity of fat is also important alongside the type of fat in managing their dietary fat intake that ultimately affects their weight status. To give an example, olive oil is seen as a healthy and recommended type of fat for Jordanians as the majority of population farm olives, thus, the availability. It is considered as a prestigious type of oil due to its cultural and religious root in Jordan. Therefore, significant number of participants in

IMBDSME group were underestimating the amount of olive oil used in food preparation. Due to its known benefits, they were ignoring the fact that olive oil produces high level of energy similar to other types of oil. That energy is stored as fat when it is not consumed in energy cycles, which in turn, increases insulin resistance and worsen glucose level control (Pérez-Jiménez et al., 2007).

Away from IMB model, De Vriendt et al. (2009) investigated the role of nutrition knowledge and their dietary behaviour among 803 Belgian women. They concluded that higher level of nutrition knowledge was significantly associated with higher consumption of fruit and vegetables and those who had higher level of nutrition knowledge perform better dietary behaviours in general.

From the discussion above, it can be concluded that knowledge determinant within IMB model was predominant to change diet self-care behaviour for participants in IMBDSME group at six month. This conclusion can be supported by Osborn and Egede (2010) study who examined the effectiveness of a brief IMB model-based DSME and reported that knowledge determinant had a significant direct impact on the diet self-care behaviour. While for motivation determinant, they reported that motivation determinant had no significant direct impact on diet self-care behaviour, nonetheless, it had a significant impact on diet-related behavioural skills, which in turn, had direct significant impact on diet self-care behaviour for those who received the intervention. They concluded that IMB model was accounted for almost 40% of the change in diet self-care behaviour.

Although it appears that knowledge determinant deemed predominant, underestimating the impact of motivation determinant is not true and knowledge

determinant as standalone intervention has down sides. Ekong and Kavookjian (2016) explored the evidence in literature for MI interventions and outcomes in adults with T2DM by conducting a systematic review. Seven out of 14 studies that were included in their review assessed eating behaviour changes such as increase fruit and vegetables or reduce saturated fat intake. Five studies reported statistically significant improvement in eating behaviours for those who received MI intervention than of those in TAU group. To elaborate how knowledge and motivation work together, Miller and Cassady (2012) conducted a study to understand how younger and older adults make decision regarding food choices by examining the association between diet-related knowledge and motivation. They concluded that diet-related knowledge mediates the relationship between self-motivation and how well they can decide upon healthful food. Their study results indicated that although motivation provides the required impetus to apply what people know about food choices, motivation with higher level of knowledge together increased the accuracy in making healthier food decisions when making comparisons between different food choices and improved decision quality.

6.3.2.2 Effect on physical activity self-care behaviour:

Trial results showed that participants in the IMBDSME group reported higher change from baseline score in physical activity than those in TAU group at three-month and six-month visits. Although there were positive changes for IMBDSME group in physical activity, the change appeared to be not statistically significant after baseline adjustment. After receiving IMBDSME intervention, participants who were in IMBDSME group reported that they were practicing at least 30 minutes' walking a day and participated in physical exercises more frequently over the last seven days from reporting. These achievements were highly likely related to the IMBDSME intervention as it is clear that those who were in TAU group did not achieve any noticeable progress in physical activity at three-month and six-month points as mentioned in section (4.7.2). Similar to the diet self-care behaviour, knowledge determinant provided the required knowledge to practice an adequate level of physical activity that could affect their diabetes condition positively. IMBDSME intervention included a chapter called "Be Active" that described variety of ways to exercise and practice physical activities during the day. It stressed out the importance of walking briskly for at least 30 minutes on a daily basis and how this can lower blood glucose level and increase their insulin resistance. Information on the appropriate pace of walking and how to manage glucose level after an exercise were also provided. However, for those who had trouble in practicing walking exercise, other activities were encouraged such as chair exercise, stretches while sitting in a chair, and to wheel themselves if they use wheelchair using their arms and hands. Other ideas for physical exercise were delivered such as using stairs instead of lifts and park

further away from their destination to allow for longer walk. All these instructions were discussed with participants in IMBDSME group at one or more interventional phone call using MI and BAP where large number utilized goal setting approach to improve their physical activity behaviour. However, two scenarios can explain the trial results regarding physical activity self-care behaviour. **First scenario**, the improvement among participants in IMBDSME group could be due to chance because the baseline score for IMBDSME group was higher than of those in TAU group, which means that IMBDSME participants might have been already practicing physical exercise more often than participants in TAU group before delivering any intervention. Therefore, it can be seen in the trial results that there was a statistically significant difference between the trial groups at three-month and six-month points before adding any adjustments in the analysis model as it shown in (4.7.2.1), while after the adjustments the differences between trial groups were statistically nonsignificant despite the fact that those in IMBDSME group had higher mean scores than those in TAU group at three-month and six-month points.

On the other side, a **second scenario** can be considered as reasonable interpretation and claim that IMBDSME intervention was effective to improve the physical activity behaviour for those who received it, and a statistically significant relationship is really existed, but the analysis model could not detect any between trial groups due to several internal threats. Threats such as small sample size and the reliability of the subscale that measured physical activity behaviour. Both have led to be fallen in type II or β error in terms of measuring physical activity behaviour. First, as mentioned in section (6.2.3), the calculated sample size was not achieved, thus the trial was

underpowered, and this can be supported by two claims. First, the increment from baseline at three-month in physical activity behaviour was far higher for those in IMBDSME group than the increment for those in TAU group and that level of physical activity was maintained at six-month point for IMBDSME group as shown in (4.7.2). Second, after modelling GEE in (4.7.2.1), those in IMBDSME group had P values of 0.21 and 0.19 at three-month and six-month visits respectively and were near the marginal statistically significant point. An average of P value of 0.2 defines as there was 80% chance to accept the fact that improvements for those in IMBDSME group at three-month and six-month were due to the IMBDSME intervention, a probability of type II or β error is 80% and a probability of type I error by 20% (Tanha et al., 2017). Second, only two questions were used in measuring the performance of physical activity self-care behaviour and were administered as a subscale within SDSCA instrument. More details about SDSCA are presented in section (3.13.2.1). The first question asked about the frequency of walking for at least 30 minutes and the second question asked if they generally have exercised any other activities apart from walking or other Homework. Both asked to self-report their activities over the last seven days from the point of reporting. However, the instrument did not include measuring other physical activities such as the frequency of using stairs, chair exercises or the walking pace. Those activities could have been measured and reflected in the analysis model leading to greater differences between trial groups, thus, increasing the chance to interpret the improvement in the IMBDSME group compared to TAU group as a statistically significant difference. Having into consideration the scenarios above, second scenario was highly likely the most

reasonable interpretation for not detecting statistically significant differences between trial groups at three-month and six-month points due to the justifications mentioned above.

Physical activity behaviour is complex due to everyday barriers that need ongoing problem-solving skills and new ideas to add more physical activity into routine. As previously mentioned, knowledge, motivation and behavioural skills determinants were delivered within IMBDSME intervention and defining which determinant was mostly predominant in changing in physical activity behaviour statistically is not possible. However, from a descriptive point of view, the provided knowledge to improve physical activity behaviour within IMBDSME intervention was summarized in one chapter and was in contrast to that for diet self-care behaviour where several chapters were about diet and eating behaviour. This is similar to what Osborn et al. (2010) reported when they examined the relationship between IMB model constructs in terms of physical activity behaviour. They stated that knowledge determinant had no significant direct impact on physical activity behaviour and the most critical determinant was the personal motivation that represented ones' attitudes toward physical activity and had significant impact on physical activity behaviour when mediated through behavioural skills determinant. Similarly, they reported statistically nonsignificant difference in physical activity behaviour between those who received IMB model-based intervention and those who received TAU group and concluded that their intervention accounted for 23% of the variability in physical activity behaviour and was considered as small effect size.

Away from IMB model, Ekong and Kavookjian (2016) stated that across all the 14 studies that used MI interventions, no statistically significant differences were detected between those who received MI intervention and TAU group in the studies that examined physical activity behaviour.

6.3.2.3 Effect on medications management self-care behaviours:

After delivering IMBDSME intervention, participants in both trial groups reported higher scores in medication management self-care behaviour at three-month and six-month than baselines score. Although both groups had relatively high scores of around eight out of ten at baseline and improved at three-month and six-month, the improvement was higher for IMBDSME group. For both groups, the improvements were statistically significantly at three-month and only statistically significant higher for IMBDSME group than those in TAU group at six-month. The significant improvements in IMBDSME group at both visits were due to trial intervention as clearly they maintained higher level of medications adherence in contrast to those in TAU group according to the trial results in (4.7.3).

Before delivering IMBDSME intervention, medications' side effects were reported as the main reason to avoid taking medications during baseline assessment. Likewise, for those who use insulin, how and when to take the insulin dose and how to handle missed dose were the mostly discussed issues during the interventional phone calls. These barriers were also reported in Rubin (2005), Rezaei et al. (2019) and Mayberry and Osborn (2014) studies in literature. Rezaei et al. (2019) in their qualitative study found out that medications' side effects had negative impact on their lived experience with T2DM and led to avoid or skip medications because they were lacking the required knowledge on how to deal with those side effects. Furthermore, Mayberry and Osborn (2014) study reported the same barrier regarding insulin administration during their empirical study among patients with T2DM. While after receiving IMBDSME intervention, medications adherence practice improved for

those in IMBDSME group as those barriers were discussed and tackled within knowledge and skills determinants using MI and BAP as explained in chapter 2. However, the slight improvement in medications adherence mean score for those in TAU group at both visits might have been caused mainly by two factors; their poorly controlled diabetes condition, and Hawthorne effect by the influence of measurement reactivity factor. Those factors might have interacted together because they were introduced at baseline, and thus, amplified their motivation toward medications adherence over the following three-month. To explain, all those who participated in the trial had an uncontrolled HbA1c as per the eligibility criteria, and their poor HbA1c level was announced and discussed during their consultation visit with the physicians at trial settings, where at the same visit, most of them were asked to respond to the Medications Adherence Rating Scale (MARS) as part of the baseline collection once they finished the visit. It is believed that those factors interacted and increased their passion to control their diabetes condition over the following three-month for those in TAU group, and yet, had no options apart from focusing on the practice of adhering with diabetes medications since they have not received any further guidance on other self-care behaviours that could improve glucose level such as diet and physical activity self-care behaviours. Another reason that could have influenced the improvement in medications management in TAU group is the delivered guidance during critical situation such as dealing with emergent hypoglycaemic episodes. During out of hours, health advice service is not available through phone call in Jordan, and the last resort was to call the trialist to receive an advice which was ethically inevitable. Participants in TAU group received

guidance on how to handle an ongoing hypoglycaemic episode and were encouraged to visit or call their medical practice next day on several occasions.

In terms of the MARS instrument, it is highly likely that it masked a great level of improvement for participants in IMBDSME group due to different reasons. First, participants were asked to respond to ten questions by choosing either “yes” or “no” for each question. In other words, these questions asked whether participants agreed or disagreed with their statement where there was a great tendency to agree with the statement regardless of their content generating another type of bias called acquiescence bias (Hinz et al., 2007). According to Callegaro et al. (2015), this type of questions is called forced choice question and can generate an overestimated response when it is administered as self-report instrument by a factor of 1.42 compared to choose-that-all-apply format, in this case, the medications adherence level for those in TAU group might have been overestimated. Second, MARS instrument did not include questions about insulin administration or dealing with insulin complications, which was discussed significantly during the interventional phone calls with those in IMBDSME group and use insulin. This means that the overall response for those in IMBDSME group might have not been completely reflected, and thus, underestimated. This is consistent with the trial results when it is interpreted ahead. To reflect on the trial results for argument purposes, mean scores of medications adherence behaviour above in (4.7.3) at both visits showed that IMBDSME group answered approximately one more question correctly from baseline, while those in TAU group answered approximately half a question more correctly from baseline. The difference between groups in mean scores at three-

month and six-month can be considered as inaccurate representation of the true improvement that was caused by IMBDSME intervention.

Although a considerable amount of information on medications management was provided, only case-relevant information was discussed with IMBDSME participants using MI and BAP during interventional phone calls to facilitate simplicity in using the educational toolkit. Similar to diet and physical activity self-care behaviours, knowledge determinants within IMBDSME intervention provided information on diabetes medications, in particular, antihyperglycemic tablets, while those who were on regular insulin doses received a separate appendix as an addition for insulin administration. The IMBDSME intervention explained the importance of diabetes medication, how they help to adverse the long-term complications, how they affect blood glucose level once administered and what may happen otherwise. In addition, expected side effects of diabetes medications were addressed such as metformin that can cause diarrhoea and how to manage hypoglycaemia once occurred by tablets or insulin. Other situations were addressed such as the importance of not skipping meals by maintaining food or snack nearby, check their glucose level, use their own needles before administering any insulin, the best place to store insulin and the best places to inject insulin with the importance to rotate the injection site each time to avoid Lipohypertrophy (insulin lumps). For behavioural skill determinant, all insulin-related administration instructions were demonstrated graphically whether using insulin pen or using insulin vials and when to administer insulin whether short acting, long acting and mixed insulin. All the above knowledge and skills aimed to increase the level of skills and understanding for those in

IMBDSME to properly adhere with their medications. It can be established that knowledge determinant highly contributed and was leading the improvement in medications adherence level. This can be supported by Mayberry and Osborn (2014) who conducted a study to validate IMB model of diabetes medications adherence among patient with T2DM. Although they showed that knowledge determinant and motivation determinants had an indirect impact on the medication's adherence behaviour, they explained that knowledge showed a trend of direct impact on the adherence behaviour because it was near the marginal statistically significant point ($p<0.08$). They rationalised the statistically nonsignificant result to the fact that their knowledge assessment was not complex enough to cover further details about medications adherence. They added that the effect for both determinants was highly statistically significant on medications' adherence behaviour when mediated by the adherence behavioural skills as per the original assumption of IMB model. IMB model explained 41% of the variability in medications' adherence behaviour in their validation study, and the adherence explained 9% of the variance in glycaemic control.

6.3.2.4 Effect on HbA1c level:

According to trial results, although the improvement in HbA1c for those in IMBDSME group at three-month and six-month were higher compared to those in TAU group, it was not statistically significant. On the other hand, the improvement for those at TAU group was statistically significant at six-month but not at three-month visit. It was noticeable that the improvements after the adjustments for **both groups** had a trend toward statistical significance as P values were below 0.10 at three-month visit. The statistically nonsignificant results might be due to being underpowered trial and had fallen in Type II or β error as was explained in (6.2.3), similar to physical activity behaviour. Another explanation that is more likely possible is that the improvement could be due to multiple factors and not necessarily due to IMBDSME intervention because TAU group had the same trend in P values. These inconsistent results were also found in literature. A systematic review that was done by Chrvala et al. (2016) found that when reviewing trials that examined the effectiveness of DSME on glycaemic control, multiple factors contributed with the outcomes due to interventions heterogeneity. Factors such as clinical and demographic characteristics, mode of DSME delivery, DSME provider qualification, duration and contact hours. Per se, they showed that 73 trials (61.9%) demonstrated statistically significant difference between intervention and control groups compared with 45 trials (38.1%) that resulted in no statistically significant difference between groups. Parallel to our trial results in regard to HbA1c, their review reported that almost 47% of those individually delivered DSME interventions had no statistically significant difference between trial groups while 53% had statistically significant difference.

Moreover, 43.7% of those DSME interventions that were delivered by single provider were associated with no statistically significant difference between trial groups. From the above, it can be concluded that this is not the only trial that found no statistically significant difference between trials groups, but there was a trend toward statistical significance point in both groups. It is clinically known that Hba1c greatly explain the change in HbA1c and that trend might be caused by other confounders, and highly likely in this case, different treatment regimens in each trial site. It was explained in (3.9.2) how each trial site manage diabetes conditions, what are the facilities and services available for those patients and the qualifications for those Health Care Professionals (HCPs) in each trial site. Those differences are believed due to have different sponsor for each. As such, it was noticeable that each trial site used different treatment regimens with respect to prescribing diabetes medications especially insulin as presented in (4.4.2.1) in Table 11. Therefore, it was worth investigating Hba1c levels across trial sites at three-month and six-month since there was a statistically significant difference in HbA1c at baseline between participants who attended PHH who had higher mean of HbA1c 10.2 ± (1.8) than participants who attended JUH who had mean of HbA1c of 9.5 ± (1.5). By observing the prescribed insulin in each site in Table 11, the trend in PHH was prescribing pre-mixed insulin (Mixtard) additionally with Anti Hyperglycaemic Tablets (AHTs) for the majority, while in JUH they used to prescribe basal insulin (Lantus) additionally with other AHTs, and often, escalated to prescribe two types of insulins basal-bolus if it was not controlled by the basal insulin alone. In numbers, none of those who attended PHH were using the basal and bolus insulin regimen and only one participant was

prescribed basal insulin compared to the rest who were using pre-mixed insulin in addition to the AHTs. While in JUH, almost half of participants were using either basal insulin or basal-bolus insulin in addition to the AHTs compared to twenty participants (19.1%) who were using pre-mixed insulin.

Regardless of the group allocation, it can be claimed that Hba1c was managed greater by those who used basal and bolus insulins and attended JUH compared to those who used pre-mixed insulin and attended PHH according to the results from each trial sites at three-month and six-month visits. In PHH, although the differences between trial groups were not statistically significant after the adjustments at both visits, the improvements in HbA1c for those in IMBDSME group were far greater than those in TAU group at both visit and P values were near the significant margin (0.08) and (0.14) at three-month and six-month respectively as shown in (4.8.4.4) and Figure 19. Similarly in JUH, the improvements in HbA1c were greater for those in IMBDSME group than those in TAU group at both visits and was only statistically significant at three-month visit as shown in (4.8.4.6) and Figure 20. The latter claim above can also be supported by recognising the greater improvement in HbA1c for those in TAU group and attended JUH than those who attended PHH in the same group despite the fact that they did not receive any external educational intervention. Therefore, IMBDSME intervention as well as the treatment regimens in each trial sites have already contributed to the improvement in HbA1c results in IMBDSME group at three-month and six-month visits.

Bellido et al. (2015) and Shanmugasundar et al. (2012) both compared the basal-bolus and premixed insulin regimens in separate studies and concluded that both can

improve HbA1c and found no statistically significant difference between the regimens. None of them was found to be superior on the other. However, both reported that those who used the pre-mixed insulin reported statistically significant higher incidences of hypoglycaemic episodes that could have affected their adherence to the insulin regimen. Garcia-Perez et al. (2013) reported in their article about the adherence to therapies in patients with T2DM that hypoglycaemic episodes hugely impact the adherence to insulin treatment and lead to low adherence to the treatment regimen and uncontrolled HbA1c as it is highly likely the case among those who attended PHH and used pre-mixed insulin in this trial. This was also backed by Skyler et al. (2009) who reviewed the relationship between the intensive glycaemic control treatment and cardiovascular events. This low adherence to insulin might have not been detected in this trial because the Medications Adherence Rating Scale (MARS) that was used in this trial did not include questions about the adherence to insulin as mentioned before in (6.3.2.3). Nevertheless, those who attended JUH and were using pre-mixed insulin were in better position compared to those who attended PHH because they usually were referred to a diabetes educator to be educated on administering insulin and may know how to deal with hypoglycaemic episodes. While in PHH, this service was not available. Another factor was the demographic characteristics for those who attended trial sites. As mentioned before, JUH in a university hospital and serves mainly academic staff and their families that could have added more privilege regarding the educational level, and thus, better diabetes management, while PHH serves ordinary

people. The differences between trial sites in managing diabetes were mentioned in section (3.9.2).

6.3.2.5 Effects on quality of life:

According to trial results in (4.8.5), participants in IMBDSME group reported higher quality of life scores compared to TAU group and these improvements were statistically significant at three-month and six-month visits. Before delivering IMBDSME intervention, it was assumed that IMBDSME intervention improves the levels of knowledge, motivation and behavioural skills, and subsequently, improves the level of practicing self-care behaviours which will reflect on their quality of life. According to the ADDQOL instrument, the improvements were reported among IMBDSME group in the first two general questions and in the additional 18 items that asked how their T2DM impacted certain aspects in their life such as the enjoyment of food, holidays or leisure activities. While for TAU group, although participants reported a statistically significant higher level of general quality of life in the first question only when they were asked at three-month visit, the improvement was relatively smaller than of those in IMBDSME group. What is more, their mean scores decreased significantly when they were asked how their life would be without diabetes in the second question and when they responded to the 18 additional items. The improvement was expected in IMBDSME group after delivering the intervention as a result of practicing self-care behaviours more frequent than before the intervention. They reported that the impact of T2DM on their general quality of life was shrinking and was changing positively almost similar to the life they used to live before the onset of T2DM, or interestingly, better than before in some cases. For example, some participants reported they were more confident, knowledgeable and motivated after IMBDSME intervention with regards changing their physical

appearance, enjoyment of chosen food, freedom to eat and drink in the ADDQOL instrument and became more in control on their lifestyle. Similar finding was found by Chong et al. (2017) study that compared behavioural changes between those who changed their lifestyle after being diagnosed with T2DM and those who were without T2DM. During follow up period, they found that those who changed their lifestyle had statistically significantly lost more weight, increased their vegetables' consumption and decreased the number of smoked cigarettes compared to those who were not diagnosed with T2DM. They concluded that being diagnosed with T2DM may act as a wakeup call and led to minimally change unhealthy lifestyle habits by practicing healthy self-care behaviours.

Deakin et al. (2006) conducted a trial where they used ADDQOL to measure the effectiveness of a group-based self-management educational program (X-PERT) on quality of life as one of the secondary outcomes. Apart from being delivered in a group setting, their intervention was parallel to IMBDSME intervention as they developed their program on theories of empowerment. They reported that those who received X-PERT intervention experienced more freedom to eat and drink and reported higher level of quality of life on the 18-items of ADDQOL compared to those who did not receive the intervention, but the differences between trial groups were not statistically significant and was near the statistically significant margin ($P < 0.1$) during follow up period. It can be justified that X-PERT intervention could not change quality of life as an outcome significantly because it was not a tailored and individualized message as IMBDSME intervention that produced statistically significant change as mentioned earlier. To add on this point, individually tailored

DSME programs, such as IMBDSME intervention, proved to be more effective than those delivered at a group level and developed as “one size fits all” as mentioned before in literature review in (1.7.1) Kreuter and Skinner (2000).

6.4 Conclusion

In this chapter, principal results of this trial were described at the beginning and were interpreted along the entire chapter. These results were explained around the axis of IMB model by exploring how the IMBDSME intervention changed the level of main determinants of IMB model at three-month and six-month, and subsequently, how this affected the trial outcomes whether primary or secondary. In terms of the strengths and limitations in this trial, a considerable section shed the light on the conducted stages of trial design such as the recruitment process, randomization, sample size and retention rate across the trial visits.

As was explained earlier in this chapter, high level of control was exerted to minimize all forms of bias whether response bias or selection bias. However, the explanation of cause-and-effect relationship under the controlled conditions might not be the same explanation occurs in real situations (Privitera, 2017). Although internal and external threats existed here and could have affected the quality of the trial, this can be considered as high valued RCT and those improvements at three-month and six-month visits in primary and secondary outcomes for those in IMBDSME group were due to the trial intervention and not due to chance except for physical activity behaviour.

Trial results were interpreted and compared with other studies in literature, in particular, those that used IMB model among patients with T2DM. In consistent with Mayberry and Osborn (2014) and Osborn et al. (2010) studies, this trial revealed that knowledge and behavioural skills determinants contributed greatly in the improvements of practicing diet and medications management self-care behaviours.

In contrast, motivation determinant was found to hugely affecting the level of practicing physical activity more than knowledge and behavioural skills determinants. Moreover, in comparison to those two aforementioned studies that used IMB model, this trial examined the change in the level of determinants before and after delivering the IMBDSME, while other studies did not and focused on the changes in the outcomes. However, the comparison with other studies that did not use behavioural change model and appeared to measure the same outcomes were often confronted by the heterogeneity factor whether methodological or clinical and the fact that each trial used different outcomes measures (Coster, 2013 , Fletcher, 2007).

From the above, this trial can lead to multiple implications on clinical practice and research. In terms of clinical setting, IMBDSME intervention was found to be effective within DSME interventions and was delivered in busy clinics and over phone calls. The impact on those behaviours were mediated by motivation determinant. Motivation determinant was directly linked to the improvement in physical activity behaviour, nonetheless, many barriers were not addressed within the IMBDSME intervention that need ongoing support. These barriers need to be investigated and addressed in the future. These features within IMBDSME intervention are important nowadays during these unprecedented circumstances due to COVID-19 virus where many health care services are turning to provide remote advice because many patients with chronic diseases are not followed up properly due to missing and cancelling appointment as a result of self-isolation. Therefore, IMBDSME

intervention is substantial and necessary to be implemented at the organisational level and training on how to use MI and BAP style are crucial than ever.

According to the implication on research, this trial showed the importance of investigating the cultural and physical barriers that preventing patients from practicing physical activity self-care behaviour among Jordanian patient with T2DM. Practicing physical activity behaviour is vital to avoid macrovascular complications such as MI and strokes. What is more, in order to detect any improvement or down sides of any future intervention, well-fitted instruments should be implemented to detect any facilitators or barriers toward any targeted self-care behaviour. Another factor that may help to achieve robust and valid conclusion is planning carefully for recruitment process to be able to approach the required sample size. Involving independent recruiters in randomised controlled trials was found to be worthy because considerable proportion of those who were eligible could not be approachable. Future trials need to consider the differences in the existed practice within trial sites especially if they are sponsored from different governmental bodies. This was shown to generate a valid difference in clinical and treatment regimens between participants who attend different sites at baseline that may interfere with how new intervention act. This trial results can be included in future systematic reviews or meta-analysis to influence any future clinical guidelines.

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8 Appendices:

Appendix 1 PRIDE modules and their related groups

	If Your Patient needs help with:	Consider these handouts:
1	General Information About Diabetes:	• What is Diabetes • Low Blood Sugar
2	Glucose Monitoring	• Blood Sugar Checks • Blood Sugar Log Sheet - Simple • Blood Sugar Log Sheet – Advanced • Paired Testing
3	Nutrition Information	• Nutrition for Diabetes • Using your Plate to Control your Carbs • Counting your Carb grams • What Can I Eat for a Snack? • What Should I Eat When I Eat Out?
4	Oral Diabetes Medication	• Diabetes Pills • Taking Your Medicines
5	Insulin and Byetta	• Drawing and Self-Injecting Insulin (BD) • Mixing Insulin for Self-Injecting (BD) • How To use an Insulin Pen • Set Dose Insulin • Insulin for Set Dose Plus Correction • Long Lasting Insulin Dose Chart • How To Take Byetta • Taking Your Medicines • Where to Give Your Insulin Shots
6	Lifestyle Management and Behavior Change	• Be Active • How Can Losing Weight Help Me? • Smoking and Diabetes • Why Should I be Careful About Drinking Alcohol?
7	Foot Care	• Foot Care Do's and Don'ts (BD)
8	Cardiovascular Risk Factors	• Blood Pressure Control • Cholesterol • Taking Your Medicines
9	Coping with Stress and Depression	• Stress and Depression
10	Oral Health	• Problems With Your Teeth and Mouth
11	Women's Health	• How Diabetes Can Affect Women
12	Men's Health	• How Diabetes Can Affect Men

Appendix 2 Trial Advertisement

The University of Nottingham

UNITED KINGDOM · CHINA · MALAYSIA

D. Researcher Zaki Albelbisi

We would like to invite you to take part in a research study

Study purpose:

This research is to study the effects of Diabetes education program on your diabetes self-care activities performance (diet, physical activity and medications management) after six months from starting this trial. In addition, we will examine the usefulness of this program on your blood-glucose level, weight, blood pressure, quality of life, your information and motivation level about diabetes self-care activities and your ability to enact them.

Why me?

You are being invited to take part because you have diabetes type 2 for more than 6 months, taking at least one type of diabetes medication and attending the outpatient diabetes clinic. We will invite 230 patients like you to take part.

Will my data kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the institution will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Will my doctor be involved?

Your diabetes treating physician at the clinci will be notified about your participation in this study.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Faculty of Medicine and School of Health Sciences Research Ethics Committee (REC) at the University of Nottingham. In addition, this study has been reviewed by the Institutional Review Board at the hospital.

If you have any concern about this study, you should speak to the researcher **Zaki** who will try to answer your questions.

If you wish to complain formally, you should then contact **Louise Sabir**.

Her email: **louise.sabir@nottingham.ac.uk**

Inconvenience allowance

Participants will not receive an inconvenience allowance for participation in the study. Travel expenses will be reimbursed for any clinic visits in excess of usual care.

Is there any risks of taking part?

Participants in the intervention group might feel mild hypoglycemia (low blood sugar) as a result of changing their daily routine. The diabetes education program will teach you how to deal and treat those symptoms. However, if you report frequent experience of low blood glucose symptoms that might be life threatening or demonstrate an inability to deal with these attacks by feeling more and severe symptoms, you will be asked to withdraw from the study.

Benefits from taking part?

The information we will get from your participation in this study may help in developing a structured diabetes educational program that might improve diabetes patient glucose level and their quality of life in the future.

This study has been registered on clinicaltrial.gov website. Identifier: **NCT02699541**

What I have to do next?

In the next table, there is an overview of the procedures you are required to follow each visit, whether you have been allocated to intervention group or control group. Please don't hesitate to ask researcher about each procedure.

Clinic visit	Procedure
First visit	1. All participants will fill the questionnaires (20-25 minutes). 2. Computer software will assign you to one of study groups (2 minutes). 3. Participants in the intervention group will receive first face to face session with the study booklet (20-30 minutes). 4. Participant in the control group will receive usual care. 5. All participants will get two questionnaires copies to be completed afterwards.
(3 months / 90 days)	1. Participants in the intervention group will receive the educational phone calls (approx. 15-20 minutes per call). 2. Participants in the control group will not receive any intervention from the researcher. 3. All participants will receive up to 2 reminders text message or phone call to complete questionnaires. 4. Before your next appointment of the second visit by 3 days, you will receive a confirmation phone call about your next appointment details.
Second visit (post intervention)	1. All participants will bring the completed questionnaires to the independent assessor. 2. All participant will fill some questionnaires at the education room with trained independent assessor (20-25 minutes). 3. You will get two questionnaires copies to be completed afterwards. 4. Participants in the intervention group will receive a face-to-face session to summaries the delivered phone calls (20-30 minutes). Researcher might invite you for an interview (approximately 30 minutes) to evaluate the operation of the educational program.
(3 months / 91 days)	You will receive up to 2 reminders text message or phone call to complete the questionnaires. Before your next appointment of the third visit by 3 days, you will receive a confirmation phone call about your next appointment time and date.
Third visit (Post follow up)	1. You will bring the completed questionnaires to the independent assessor. 2. You will fill some questionnaires at the education room with trained independent assessor (20-25 minutes).

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving reason. You can decide now or if you need to think about participation, you will be given a chance of 2 days to decide. After 2 days, you can call the researches to confirm or I will call and ask you for your final decision on phone. If you agreed to participate, you will have to come to the clinic during the next 48 hours during working hours. researcher will pay the travel costs at the centre.

What will happen if I agreed?

You will sign the consent form of participation for the next 6 months and then you will be asked to fill the questionnaires related to your disease condition at first visit. This task will take around 20-25 minutes. Those questionnaires will ask you about your information, motivation and your ability to enact diabetes self-care activities, your quality of life while living with diabetes and how many times you are practicing those activities.

Following this, a computer program will randomly choose to be either at the group who will receive the educational program (intervention group) or to be at the group who will only receive the usual treatment care (control group).

Participants' Personal Information Sheet

Treating Dr	study	Given code	File number	Phone number	Name
	1 / 2				.1
	1 / 2				.2
	1 / 2				.3
	1 / 2				.4
	1 / 2				.5
	1 / 2				.6
	1 / 2				.7
	1 / 2				.8
	1 / 2				.9
	1 / 2				.10
	1 / 2				.11

Date / / 2016 **Abbreviation key:** 1: Prince Hamaza hospital / 2: University hospital

Follow up Information Sheet

study	Treating Dr	Third visit		Second visit		First visit		Name
		Questions	Labs	Questions	Labs	Questions	Labs	
1 / 2								.1
1 / 2								.2
1 / 2								.3
1 / 2								.4
1 / 2								.5
1 / 2								.6
1 / 2								.7
1 / 2								.8
1 / 2								.9
1 / 2								.10
1 / 2								.11

Date / / 2016 **Abbreviation key:** 1: Prince Hamaza hospital / 2: University hospital

Appendix 6 Interventional phone calls contents

Interventional·phone·calls·contents¶

Patient·code:·¶

Phone·number:¶

¤	[·····/·····/2016¤ ¤
¤	[·····/·····/2016¤ ¤
¤	[·····/·····/2016¤ ¤
¤	[·····/·····/2016¤ ¤
¤	[·····/·····/2016¤ ¤
¤	[·····/·····/2016¤ ¤

Appendix 7 Recruitment follow up sheet

Recruitment follow up sheet

Date of visit	Assessed	Eligible	Recruited	Excluded	Unapproachable	Declined	Site
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2
							1 / 2

Abbreviation key: 1: Prince Hamzeh hospital / 2: Jordan University Hospital

The University of Nottingham

Faculty of Medicine and Health Sciences

Research Ethics Committee
School of Medicine Education Centre
B Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham
NG7 2UH

Direct line/e-mail
+44 (0) 115 8232561
Louise.Sabir@nottingham.ac.uk

27th January 2016

Mr Zaki Albelbisi
PhD Student
c/o Dr Holly Blake
Associate Professor of Behavioural Sciences
A Floor, Medical School Block
School of Health Sciences
QMC Campus
Nottingham University Hospitals
NG7 2UH

Dear Mr Albelbisi

Ethics Reference No: OVS18012016 SoHS – please always quote
Study Title: The effectiveness of Information-Motivation-Behavioural Skills Model-based Diabetes Self-Management Education among patients with type 2 diabetes in Jordan.
Short Title: IMB-DSME
Chief Investigator/Supervisors: Dr Holly Blake, Associate Professor of Behavioural Sciences, Dr Richard Windle, Associate Professor in E-learning, School of Health Sciences.
Lead Investigators/Student: Zaki Albelbisi, PhD Student, School of Health Sciences, Faculty of Medicine and Health Sciences.
Duration of Study: 01/02/2016-31/10/2016 9 months
No of Subjects: 230 (18-65 yrs)

Thank you for submitting the above application which was considered by the Committee at its meeting on 18th January 2016 and the following documents were received:

IMB-DSME:

- FMHS Research Ethics Application form final version 1.0, 10/12/2015
- Risk Assessment Form dated 12/2015
- Protocol final version 1.0 3 December 2015
- Recruitment Poster, Final Version 1.0, 10/120/2015
- Participant Information Sheet Final Version 1.0, 19/11/2015
- Consent Form Final version 1.0: 1/11/2015
- 5 x validated Questionnaires to be used for measuring parameters.
- Information-Motivation-Behavioural Skills Model-based Diabetes Self-Management Educational programme materials to be used.
- Weekly log Sheet

These have been reviewed and are satisfactory and the study has been given a favourable opinion.

A favourable opinion is given on the understanding that the Conditions set out below are followed.

1. Please submit copies of the approval/ permission letters from: The National Centre For Diabetes, Endocrinology and Genetic President and the Institutional Review Board (IRB) when these are available.

2. A Favourable opinion is given on the understanding that all appropriate ethical 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.
3.
4. You must follow the protocol agreed and inform the Committee of any changes using a notification of amendment form (please request a form).

5. You must notify the Chair of any serious or unexpected event.

6. This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.

7. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

pp

Professor Ravi Mahajan
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

Appendix 9 Ethical Approval from NCDEG

المعهد الوطني للسكري والغدد الصم والوراثة

NATIONAL INSTITUTE FOR DIABETES ENDOCRINOLOGY & GENETICS

Ref. .....

Date .....

الرقم ٢٧٩١/٩/

التاريخ 25/2/2016

Mr Zaki S Albelbisi
PhD Student
c/o Dr Holly Blake
Associate Professor of Behavioural Sciences
A Floor, Medical School Block
School of Health Sciences
QMC Campus
Nottingham University Hospitals
NG7 2UH

Dear Mr Albelbisi

Thank you for submitting your application related to the research titled with **"The effectiveness of Information-Motivation-Behavioural skills model-based Diabetes Self-Management Education among patients with type 2 diabetes in Jordan".**

The Institutional Review Board (IRB) discussed the detailed protocol of the research above at 24th November 2015 and pleased to inform you that your application was reviewed and approved by the Board with the following recommendation:

- Researcher has to be committed with the research policy adopted in the National Centre.
- Data collected should be used only for research purposes with confidentiality.
- The IRB has the right to request all study approvals from researcher anytime and to possess all study-related documents in the National Centre archive.

Prof. Mohammed El- Khateeb
Vice President
National Center for Diabetes
Endocrinology & Genetics

عمان – الأردن – شارع الملكة رانيا – هاتف: ٥٣٠١١١١ فاكس: ٥٣٥٦٦٧٠ ص.ب: ١٣١٦٥ عمان ١١٩٤٢ الأردن

The University of Nottingham

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Louise.Sabir@nottingham.ac.uk

Faculty of Medicine and Health Sciences

Research Ethics Committee
School of Medicine Education Centre
B Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham
NG7 2UH

10th August 2016

Mr Zaki Albelbisi
PhD Student
c/o Dr Holly Blake
Associate Professor of Behavioural Sciences
A Floor, Medical School Block
School of Health Sciences
QMC Campus
Nottingham University Hospitals
NG7 2UH

Dear Mr Albelbisi

Ethics Reference No: OVS18012016 SoHS – please always quote
Study Title: The effectiveness of Information-Motivation-Behavioural Skills Model-based Diabetes Self-Management Education among patients with type 2 diabetes in Jordan.
Short Title: IMB-DSME
Chief Investigator/Supervisors: Dr Holly Blake, Associate Professor of Behavioural Sciences, Dr Richard Windle, Associate Professor in E-learning, School of Health Sciences.
Lead Investigators/Student: Zaki Albelbisi, PhD Student, School of Health Sciences, Faculty of Medicine and Health Sciences.
Duration of Study: 01/02/2016-31/10/2016 9 months
No of Subjects: 230 (18-65 yrs)

Thank you for your letter dated 6th August 2016 notifying the Committee of amendment no 1: 06 August 2016 the following documents were received:

IMB-DSME:

- Notice of Amendment no 1: 06 August 2016
- Approval letter from the National Centre for Diabetes (NCDEG) dated 25/2/2016
- Approval letter from Prince Hamzeh Hopsital (PHH) dated 5/4/2016
- Approval Letter from Jordan University Hospital (JUH) ref 10/2016/1828 dated 25/4/2016
- Ethical process flowchart version 1.0 dated 15/7/2016
- Local Participant Information Sheet for Jordanians with card version 1.0 dated 14/3/2016

These have been reviewed and are satisfactory and the study amendment no 1: 06 August 2016 has been given a favourable opinion.

A favourable opinion is given on the understanding that the Conditions set out below are followed.

1. A Favourable opinion is given on the understanding that all appropriate ethical 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. You must follow the protocol agreed and inform the Committee of any changes using a notification of amendment form (please request a form).

3. You must notify the Chair of any serious or unexpected event.

The University of Nottingham

4. This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.

5. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

Professor Ravi Mahajan
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

Appendix 11 Ethical Approval from JUH

Jordan University Hospital

Ref. 10/2016/1828
Date: 25/4/2016

مستشفى الجامعة الأردنية

الرقم :
التاريخ :

Mr. Zaki Albelbisi

The Institution Review board committee discussed and approved in its meeting No. (6/2016) , Date : 29/3/2016 ,the research project entitled :

"The effectiveness of Information- Motivation - Behavioural Skills Model-based Diabetes Self- Management Education among patients with type 2 diabetes in Jordan " . Author shall:

1. A bide by the hospital pharmaceutical policy studies at the hospital (Adm po21/3. Adm po32/1).
2. Data is confidential must not be used except for research project aims.
3. The committee has the right to question the ca-authors about their participation in the study project.
4. Abide by the regulations of safety measures of dealing with human products tissues .
5. Human products (blood....etc) and tissues and argon shall not be used for after then the research project aims.

Chairman of the IRB

Professor Abdelkarim Al-Qudah

تلفون ٥٣٥٣٤٤٤ - فاكس ٥٣٥٣٣٨٨ - صندوق بريد ١٣٠٤٦ - عمان - الأردن
Tel. 5353444 Fax 5353388 - P.O.Box 13046 - Amman - Jordan

Appendix 12 Ethical Approval from PHH

وزارة الصحة
مستشفى الامير حمزه بن الحسين

الرقم ٨٤٦/١٣٢/٢٥
التاريخ
الموافق 5/4/2016

Dear Researcher,

Reference to the request you have submitted to Prince Hamzah Hospital to conduct a study titled:

The effectiveness of Information - Motivation – Behavioural Skills Model -based Diabetes Self-Managent Education among patients with type 2 diabetes in Jordon

We would like to inform you that the Institutioanl Reviw Board (IRB) has discussed your request in the meeting held on March 29th 2016

After the discussion and the meeting with you, the IRB has approved and accepted your application to start data collection at Prince Hamzeh hospital with a condition to supply the IRB with study results before publication process.

General Manager of Prince Hamzeh hospital

Dr. Mazen Naghawi

نسخة:
- الملف العام.
ع ح
2016/4/4

المملكة الاردنية الهاشمية
هاتف: ٠٦٥٣٨٢٦٠٠ فاكس: ٠٦٥٣٧٩٠٠ الموقع الالكتروني www.phh.gov.jo

Weekly log sheet

Patient name: .....

Patient file number/ code: .....

Day Date of Sunday .../.../....	Breakfast			Lunch			Dinner			Bedtime		Minutes of exercise	Other comments
	Blood Sugar		Meds	Blood Sugar		Meds	Blood Sugar		Meds	Blood Sugar	Meds		
	Before	After		Before	After		Before	After					
Sunday													
Monday													
Tuesday													
Wednesday													
Thursday													
Friday													
Saturday													

*Note: Write down if you are sick, have a large meal, feel stressed, a low sugar, or other things that can change your blood sugar

ورقة التسجيل الأسبوعي

الاسم: ..... تاريخ يوم الأحد من كل أسبوع: ...../...../2016

رقم الملف /رمز المريض: ..... ضع علامة √ في المربع المقابل للتصرف الذي قمت به في ذلك الوقت.

اليوم	الفطور			الغداء			العشاء			وقت النوم		دقيقة رياضة	ملاحظات
	فحص السكر قبل الأكل	الحمية	الدواء	فحص السكر قبل الأكل	الحمية	الدواء	فحص السكر قبل الأكل	الحمية	الدواء	فحص السكر	الدواء		
الأحد													
الأثنين													
الثلاثاء													
الأربعاء													
الخميس													
الجمعة													
السبت													

ملاحظة: اكتب ما اذا كنت مريضا ,متوتر, تشعر بهبوط في السكر أو أية حدث ممكن أن يرفع السكر عندك.

استبيان

رمز المريض: ..... **المستشفى**: الأمير حمزة / الجامعة الأردنية

العمر: ..... **الجنس**: ذكر / أنثى **الحالة الاجتماعية**: متزوج / أعزب / أرملة / مطلقة.

المستوى التعليمي: غير متعلم / أقل من 12 سنة / 12 سنة / أكثر 12 سنة.

التدخين: مدخن سابق / غير مدخن / مدخن .....سيجارة في اليوم.

الوظيفة: عامل مياومة/ عامل محترف / مدير أو مسؤول / ربة منزل / أخرى .....

التأمين الصحي: مؤمن / غير مؤمن.

الدخل المادي: .....شهري. **شرب**

الكحول: نعم / لا.

عمر مرض السكري: .....

الأمراض المزمنة:

ضغط الدم: نعم / لا. **الدهنيات:** نعم/ لا. **أمراض**

القلب: نعم / لا.

اعتلال الكلى: نعم / لا. **اعتلال الشبكية**: نعم /لا. **اعتلال**

الأعصاب: نعم /لا.

Anthropometric and Laboratory measurements:

المؤشر	الزيارة الأولى التاريخ ..... 16/...../	الزيارة الثانية التاريخ ..... 16/...../	الزيارة الثالثة التاريخ ..... 16/...../
الوزن			
الطول			
محيط الخصر			
ضغط الدم			
HbA1c			
F.S/ R.S			
HDL			
LDL			
Triglyce			
Cholest			

أدوية السكري	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Diabetes self-management knowledge questionnaire (SKILLD):

1. ماهي علامات وأعراض ارتفاع السكر في الدم؟ بماذا تشعر عندما يكون السكر في دمك مرتفعا أو لحظة تشخيصك بالسكري؟ ماهي علامات وأعراض انخفاض السكر في الدم؟ بماذا تشعر عندما انخفاض السكر في دمك؟

2. كيف تتعامل مع انخفاض السكر في دمك؟ ماذا عليك أن تفعل في حالات انخفاض السكر؟ كيف من الممكن أن ترفع السكر في دمك في حالة الانخفاض؟ كيف تتعامل مع ارتفاع السكر في الدم؟ ماذا عليك أن تفعل في حالات الارتفاع؟

3. كيف تتعامل مع وجباتك الغذائية في اليوم؟ كم وجبة رئيسية يجب أن تأكل في اليوم؟ وكم وجبة فرعية؟ كيف هي الطريقة الصحيحة في تعاملك مع صحنك وقت الأكل؟ ماهي طريقة توزيع الغذاء في صحنك؟

4. ماهي أنواع الغذاء الرئيسية؟ هل يجب أن أتوقف عن أيا منهم؟ أية نوع منهم يجب أن أكل أكثر؟ وأية نوع منهم يجب أن أقلل؟

5. هل يجب أن أخذ دواء السكري كل يوم أم عندما يكون السكر مرتفع؟ ماذا تفعل عندما لا تأكل وجبتك الرئيسية، هل تؤجل أخذ الدواء أم عليك أن تأخذه؟

6. كيف هي الطريقة الصحيحة لتأخذ دوائك سواء الحبوب أو الإبر كل يوم؟ هل يجب أن أمتنع عن أخذ دواء السكري في حالات الانخفاض؟ ماذا يجب علي أن أفعل في حالات الارتفاع؟ هل يجب أن أزيد جرعة الدواء؟

7. ما هو المعدل الطبيعي للسكر في الدم وأنت صائم؟ عندما تستيقظ من النوم وتفحص السكر قبل الأكل أو قبل أخذك للدواء، كم يجب أن يكون؟ ما هما الرقمين؟

8. ما هو المعدل الطبيعي للسكر التراكمي في الدم؟ عندما يسحب دم من يديك، ما هو المعدل الطبيعي لقراءات السكر التراكمي؟ ماذا يجب أن يكون؟

9. كم مرة بالأسبوع يجب على مريض السكري أن يمارس الرياضة؟ وكم تحتاج من الوقت في اليوم لتمارس الرياضة؟

10.ماهي المضاعفات للسكري الغير منتظم على المدى البعيد؟ هل تعرف أحد يعاني من هذه المضاعفات؟ أذكر بعض هذه المضاعفات؟

Diabetes Self-Management Motivation (Diabetes Empowerment Scale (DES) + Medical Outcomes Study Social Support Survey (MOS-SSS)):

Diabetes Empowerment Scale (DES):

لا أوافق بشدة (1)	لا أوافق (2)	عادي (3)	أوافق (4)	أوافق بشدة (5)	**Managing the psychosocial aspects of diabetes (9 items)**
1	2	3	4	5	**بشكل علم أعتقد أني أعرف طرقا إيجابية تساعدني لأتكيف مع القلق المصاحب للسكري**
1	2	3	4	5	**بشكل عام, أعتقد أني أستطيع التكيف جيدا مع القلق المصاحب للسكري**
1	2	3	4	5	**بشكل عام, أعتقد أني أعرف أين من الممكن الحصول على مساعدة للاعتناء بالسكري**
1	2	3	4	5	**بشكل عام, أعتقد أني أستطيع الحصول على المساعدة للاعتناء بالسكري عند الحاجة**
1	2	3	4	5	**بشكل عام, أعتقد أني أستطيع مساعدة نفسي في التعامل مع السكري**
1	2	3	4	5	**بشكل عام, أعتقد أني أعرف ما يساعدني لأبقى مندفعا للاعتناء بالسكري**

بشكل عام أعتقد أني مندفعا للاعتناء بالسكري	5	4	3	2	1
بشكل عام, أعتقد أني على دراية كافية بالسكري لأختار الطريقة الصحيحة لأعتني بنفسي.	5	4	3	2	1
بشكل عام, أعتقد أني على دراية كافية عن قدرتي لوضع خيارات مناسبة لي تتعلق بالعناية بالسكري	5	4	3	2	1
Assessing dissatisfaction and readiness to change (9 items)	أوافق بشدة (5)	أوافق (4)	عادي (3)	لا أوافق (2)	لا أوافق بشدة (1)
بشكل عام, أعتقد أني أعرف أية جزء من العناية الشخصية بالسكري أنا راضي عنه	5	4	3	2	1
بشكل عام, أعتقد أني أعرف أية جزء من العناية الشخصية بالسكري أنا غير راضي عنه	5	4	3	2	1
بشكل عام, أعتقد أني أعرف أية جزء من العناية بالسكري أنا مستعد لتغييره.	5	4	3	2	1
بشكل عام, أعتقد أني أعرف أية جزء من العناية بالسكري أنا غير مستعد لتغييره.	5	4	3	2	1
بشكل عام, أعتقد أني أستطيع التحدث عن شعوري كمريض سكري.	5	4	3	2	1

بشكل عام, أستطيع التحدث عن شعوري حول العناية بمرض السكري	5	4	3	2	1
بشكل عام, أعتقد أني أعرف كيف ممكن أن يقلقني السكري في حياتي	5	4	3	2	1
بشكل عام, أعتقد أني أعرف طرقا سلبية للتكيف مع القلق المصاحب للسكري	5	4	3	2	1
بشكل عام, أعتقد أني قادر على تمييز ما اذا كان يستحق العناء بأن أغير الطريقة التي أعتني بها بالسكري	5	4	3	2	1
بشكل عام, أعتقد أني أستطيع اختيار أهداف معقولة لتنظيم السكري	5	4	3	2	1
بشكل عام أعتقد أني أعرف أية أهداف تنظيم السكري هي الأهم لي	5	4	3	2	1
بشكل عام, أعتقد أني أعرف أشياء عن نفسي اما تساعدني أو تمنعني من الوصول للأهداف التي أضعها لتنظيم السكري	5	4	3	2	1
بشكل عام أنا قادر على تبني أفكار جيدة تساعدني على الوصول لأهدافي	5	4	3	2	1
بشكل عام, أعتقد أني قادر على تحويل أهداف تنظيم السكري الى خطة فعالة على أرض الواقع	5	4	3	2	1
بشكل عام, أعتقد أني قادر على الوصول الى أهداف تنظيم السكري عند وضع الخطط وتحديد الأفكار	5	4	3	2	1

بشكل عام, أعتقد أني أعرف أية عرائق تجعل من تحقيق أهداف تنظيم السكري شيء أصعب من ذي قبل	5	4	3	2	1
بشكل عام, أعتقد أني أستطيع التفكير بطرق أخرى لتجاوز العوائق خلال تحقيق أهداف تنظيم السكري	5	4	3	2	1
بشكل عام, أعتقد أني أستطيع تجربة طرق مختلفة لتجاوز العوائق خلال تحقيق أهداف تنظيم السكري.	5	4	3	2	1
بشكل عام, أعتقد أني قادر على اختيار أية طريقة أفضل معي لتجاوز العوائق خلال تحقيق أهداف تنظيم السكري.	5	4	3	2	1

Modified Medical Outcomes Study Social Support Survey (mMOS-SSS):

Aspects	كل الوقت (5)	أغلب الوقت (4)	بعض الوقت (3)	قليل من الوقت (2)	غير متاح (1)
Emotional/informational support					
شخص تلجأ اليه لأخذ اقتراحات حول التعامل مع مشكلتك الشخصية	5	4	3	2	1
شخص يستطيع تفهم مشاكلك	5	4	3	2	1
Tangible support					
شخص موجود لمساعدتك إذا كنت طريح الفراش	5	4	3	2	1
شخص موجود لأخذك إلى الطبيب إذا احتجت	5	4	3	2	1

1	2	3	4	5	شخص موجود يحضر لك وجباتك إذا كنت غير قادر على عملها بنفسك
1	2	3	4	5	شخص موجود لمساعدتك في حياتك الروتينية إذا كنت مريض
					Affectionate support
1	2	3	4	5	شخص تحبه ويجعل منك شخص مرغوب به دائما
					Positive social interaction
1	2	3	4	5	شخص تستمتع بوجودك معه وتقضي معه وقتا جيدا

Diabetes self-management self-efficacy questionnaire (Perceived Diabetes Self-Management Scale (PDSMS)):

Item	أوافق بشدة (5)	أوافق (4)	عادي (3)	لا أوافق (2)	لا أوافق بشدة (1)
أعتني بنفسي جيدا باعتبار أني مريض سكري	5	4	3	2	1
أنا قادر على تنظيم وترتيب كل الأمور المتعلقة بالسكري كما هو الحال مع معظم الناس	5	4	3	2	1
أنا دائما أنجح في خططي التي أتبعها لتنظيم السكري	5	4	3	2	1
أنا قادر على تحقيق أهدافي التي أضعها لتنظيم السكري عادة.	5	4	3	2	1
Item	**أوافق بشدة (5)**	**أوافق (4)**	**عادي (3)**	**لا أوافق (2)**	**لا أوافق بشدة (1)**
من الصعب أن أجد حلول فعالة للمشاكل التي تواجهني خلال تنظيم السكري	1	2	3	4	5
أحتاج إلى جهد كبير لتغيير عادات سيئة خلال تنظيم السكري	1	2	3	4	5
حرفيا، كل خططي لتنظيم السكري لا تنجح كما أريد	1	2	3	4	5
مهما حاولت بجد واجتهاد، تنظيم السكري لا ينجح معي كما كنت متوقعا	1	2	3	4	5

The Summary of Diabetes Self-Care Activities Scale (SDSCA) and Medications Adherence Rating Scale (MARS):

Summary of Diabetes Self-Care Activities (SDSCA):

الأسئلة التالية سوف تسألك عن أنشطة العناية الذاتية بالسكري التي مارستها خلال السبعة أيام الماضية. اذا كنت مريضا خلالها، فكر في الأيام السبعة التي سبقت أيام مرضك:

(0)	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**الحمية الغذائية:**
								كم مرة خلال السبعة أيام الماضية اتبعت حمية غذائية صحية؟
								بالمعدل خلال الشهر الماضي، كم يوم بالأسبوع اتبعت خطتك الغذائية؟
								كم مرة خلال السبعة أيام الماضية أكلت خمس حصص أو أكثر من الخضروات والفواكه؟
								كم مرة خلال السبعة أيام الماضية أكلت غذاء ملي بالدهنيات مثل اللحم أو منتجات الألبان كاملة الدسم Reversing item
(0)	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**التمارين الرياضية**
								كم مرة خلال السبعة أيام الماضية اشتركت

على الأقل لمدة نصف ساعة في نشاط بدني مثل المشي؟								
كم مرة خلال السبعة أيام الماضية اشتركت على الأقل في نشاط رياضي معين مثل السباحة أو ركوب الدراجة (عدا عن المشي أو الأفعال المنزلية)؟								
فحص السكر في الدم	**(7)**	**(6)**	**(5)**	**(4)**	**(3)**	**(2)**	**(1)**	**(0)**
كم مرة خلال السبعة أيام الماضية فحصت السكر في دمك؟								
كم مرة خلال السبعة أيام الماضية فحصت السكر في دمك؟								

Medication Adherence Rating Scale:

الرجاء منك وضع دائرة حول الإجابة التي تمثل تصرفاتك وطريقتك في التعامل مع أدوية السكري خلال السبعة أيام الماضية:

نعم	لا	Questions:
نعم (0)	لا (1)	هل نسيت أن تأخذ أدوية السكري الخاصة فيك؟
نعم (0)	لا (1)	هل أنت غير مهتم بالمواعيد المطلوبة منك لأخذ أدوية السكري؟

عندما تشعر بتحسن، هل تتوقف عن أخذ أدوية السكري؟	لا (1)	نعم (0)
أحيانا عندما تشعر بأعراض الدواء الجانبية، هل تتوقف عن أخذ الدواء؟	لا (1)	نعم (0)
أنا أخذ أدويتي فقط عندما أشعر بسوء أو في حالة سيئة؟	لا (1)	نعم (0)
من غير الطبيعي لجمسي وعقلي أن يتحكم به عن طريق الأدوية؟	لا (1)	نعم (0)
أفكاري تكون أوضح عندما أخذ الدواء	لا (0)	نعم (1)
طالما أنا أخذ الدواء باستمرار، إذا أنا أستطيع أن أمنع مضاعفات السكري	لا (0)	نعم (1)
أشعر بأني غريب عندما أخذ دواء السكري	لا (1)	نعم (0)
الدواء يجعلني أشعر بأني مرهق ومنطوي على نفسي	لا (1)	نعم (0)

Acceptability questionnaire:

الأسئلة التالية سوف تسألك عن رأيك في البرنامج التثقيف الصحي للسكري الذي تلقيته عن طريق الهاتف خلال الثلاثة أشهر الماضية:

المحور	أوافق بشدة (5)	أوافق (4)	لا أوافق (2)	لا أوافق بشدة (1)
لطيف ويساعد كثيرا	5	4	2	1
أوقات اتصال مناسبة لي	5	4	2	1
المتصل يعرف جيدا بالسكري	5	4	2	1
المتصل يزودني دائما بنصائح عملية	5	4	2	1
سعيد بأني أتحدث مع نفس المتصل دائما	5	4	2	1
حبيت فكرة التواصل الهاتفي	5	4	2	1
فترة الاتصال على الهاتف مقبولا	5	4	2	1
تعبئة السجل الأسبوعي كان شيء عملي بالنسبة لي	5	4	2	1
سعيد بالعناية الصحية التي تلقيتها بالهاتف	5	4	2	1
من السهل فهم النصائح المعطاة لي	5	4	2	1
أفضل زيادة عدد المكالمات الهاتفية المستقبلة	5	4	2	1

التثقيف الصحي كان مناسب لحالتي الصحية	5	4	2	1
وقت المكالمة كان كافيا للإجابة على أسئلتي	5	4	2	1
تحدثنا عن أشياء مناسبة لحالتي الصحية	5	4	2	1
المتصل كان دائما ما يزيد من دافعي وثقتي بنفسي	5	4	2	1
أحسست بتحسن بعد تلقي النصائح خلال الهاتف	5	4	2	1
أنصح بالبرنامج التثقيفي لباقي مرضى السكري	5	4	2	1
أشعر بأني أعرف عن السكري أكثر من ذي قبل	5	4	2	1
أعمل بالنصائح الطبية التي تلقيتها على الهاتف يوميا	5	4	2	1
أشعر بأني أسيطر على السكري أكثر من ذي قبل	5	4	2	1
أفضل رؤية الطبيب	5	4	2	1
زاد من مستوى الوعي لدي	5	4	2	1
3 أشهر كانت كافية لتغير من عاداتي الصحية تجاه السكري	5	4	2	1
يجب أن يتم تفعيل البرنامج في المستشفى	5	4	2	1
عدد المكالمات المستقبلة كان كافيا	5	4	2	1