The University of Nottingham

UNITED KINGDOM · CHINA · MALAYSIA

Exploring the Impact of Individual-Level Attributes on Fidelity and Return-to-Work Outcomes in a Complex Rehabilitation Trial

Kathryn E Powers

BSc (honours), MSc

Thesis submitted to the University of Nottingham
For the Degree of Doctor of Philosophy
October 2023

Abstract

Background: Randomised controlled trials (RCTs) are held as the 'gold standard' for evaluating intervention efficacy and clinical effectiveness. Many trials of *complex* interventions struggle to demonstrate effectiveness. The existing psychotherapy literature suggests that the attributes of those delivering complex interventions can impact intervention *fidelity*, patient outcomes, and RCT effectiveness findings. Rehabilitation interventions are typically complex and delivered by a range of therapists including physiotherapists, speech and language therapists and occupational therapists. However, beyond psychotherapy studies, there is little evidence of what impact therapist attributes have on patient and trial outcomes. This thesis explored the impact of therapist attributes on fidelity and stroke survivor return-to-work outcomes within the RETurn to work After stroKE trial (RETAKE), an RCT testing the clinical and cost effectiveness of early, stroke specialist vocational rehabilitation (ESSVR) on return-to-work outcomes 12 months after stroke.

Methods: Four interrelated studies were conducted. Study 1 comprised a systematic review exploring the impact of therapist attributes on patient outcomes outside the psychotherapy literature. Findings were synthesised narratively. Study 2 developed an ESSVR-specific fidelity checklist and accompanying guidance notes in consultation with an expert panel, and assessed its interrater reliability. The fidelity checklist was applied to one randomly selected stroke survivor ESSVR records per treating OT in the RETAKE trial in Study 3. Study 4 employed logistic and linear regression to explore OT attributes impacting fidelity and stroke survivor return-to-work outcomes.

Results: Study 1; 12, predominantly physiotherapy studies were included in the systematic review. Therapists' autonomy-supportive behaviours, personality traits and communication skills were suggested to generate change in patients' ability or motivation to adhere to rehabilitation programmes which, in turn, improved patients' pain and disability outcomes. Study 2: The ESSVR-specific fidelity checklist had acceptable interrater reliability and measured modifications in delivery of ESSVR as intended, providing overall, and per-component fidelity ratings. Study 3: 39 records were assessed. Overall fidelity to ESSVR ranged from 30.8 to 100% (Mean: 78.8%, SD: 19.2%), achieving acceptable fidelity. Fidelity to individual components ranged from 12.5 to 97.4%). Linear regression analyses suggested that greater amounts of OT engagement in mentoring were significantly associated with higher rates of fidelity (b = 0.29, 95% CI = 0.05-0.53, $p < 0.05$). Study 4: Logistic regression analyses found that greater OT fidelity to ESSVR (OR = 1.06, 95% CI = 1.01-1.1, p = 0.01) and more stroke rehabilitation experience (OR = 1.17, 95% CI = 1.02-1.35) were associated with an increased likelihood of participant return-to-work.

Conclusion: Interrelationships between therapist attributes, fidelity and patient outcomes are complex and under researched in rehabilitation trials. Therapist fidelity is often not reported. Therapist attributes associated with autonomy-supportive behaviours may be associated with improved patient outcomes. In the context of the RETAKE trial, mentoring facilitated OT fidelity to ESSVR, which, combined with greater stroke rehabilitation experience, increased the likelihood of participant return to work. These findings suggest that stroke specific experience is important and that support beyond the initial training is needed to implement a complex VR intervention with fidelity to optimise trial outcomes. This small study needs to be replicated. Future research should explore how therapists'

attributes influence fidelity and participants outcomes in other complex rehabilitation intervention trials.

Related Outputs

Peer Reviewed Publications

*Powers, K., das Nair, R., Phillips, J., Farrin, A. & Radford, K. Exploring the association between individual-level attributes and fidelity to a vocational rehabilitation intervention within a randomised controlled trial. *International Journal of Environmental Research and Public Health. 20*, 6 (2023). https://doi.org/10.3390/ijerph20064694

*Powers, K., Clarke, S., Phillips, J. *et al.* Developing an implementation fidelity checklist for a vocational rehabilitation intervention. *Pilot & Feasibility Studies.* **8**, 234 (2022). https://doi.org/10.1186/s40814-022-01194-x

Radford KA, McKevitt C, Clarke S, et al. RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed- methods process evaluation using normalisation process theory. BMJ Open 2022;12:e053111. doi:10.1136/ bmjopen-2021-053111

Craven, K., Holmes, J., Powers, K. et al. Embedding mentoring to support trial processes and implementation fidelity in a randomised controlled trial of vocational rehabilitation for stroke survivors. BMC Med Res Methodol 21, 203 (2021). https://doi.org/10.1186/s12874-021-01382-y

Radford, K.A., Craven, K., McLellan, V. et al 2020. An individually randomised controlled multi-centre pragmatic trial with embedded economic and process evaluations of early vocational rehabilitation compared with usual care for stroke survivors: study protocol for the RETurn to work After stroKE (RETAKE) trial. Trials 21, 1010 https://doi.org/10.1186/s13063-020-04883-1

*Included as a chapter within this thesis

Conference Abstracts, Posters and Presentations

*Powers, K. das Nair, R., Farrin, A. Radford, K. Exploring the association between therapist attributes, implementation fidelity and return-to-work outcomes in the Return to Work after Stroke (RETAKE) trial. Accepted as a poster presentation at the 12th World Congress for Neurorehabilitation (December 2022).

*Trusson, D., Powers, K., Phillips, J., Holmes, J., Lindley, R., McKevitt, C., Bowen, A., Watkins, C., O'Connor, R., Farrin, A., Cundill, B., Sach, T., Day, F., Stevens, J., Murray, J., Radford, K., Clarke, D. Comparing return-to-work related experiences between participants in an individually randomised trial of Early Stroke Specialist Vocational Rehabilitation versus usual care only. Accepted as a poster presentation at the 12th World Congress for Neurorehabilitation (December 2022).

*Powers, K. das Nair, R., Farrin, A. Radford, K. Exploring the association between therapist attributes, implementation fidelity and return-to-work outcomes in the Return to Work after Stroke (RETAKE) trial. Accepted for an e-poster presentation at UK Stroke Forum 2022 (November 2022).

Trusson, D., Powers, K., Phillips, J., Holmes, J., Lindley, R., McKevitt, C., Bowen, A., Watkins, C., O'Connor, R., Farrin, A., Cundill, B., Sach, T., Day, F., Stevens, J., Murray, J., Radford, K., Clarke, D. Experiences of return-to-work support: A case-study comparison between recipients of Early Stroke Specialist Vocational Rehabilitation and stroke survivors receiving usual care only. Accepted for an e-poster presentation at the UK Stroke Forum 2022 (November 2022).

Trusson, D., Powers, K., Phillips, J., Holmes, J., Lindley, R., McKevitt, C., Bowen, A., Watkins, C., O'Connor, R., Farrin, A., Cundill, B., Sach, T., Day, F., Stevens, J., Murray, J., Radford, K., Clarke, D. Evaluating the use of Normalisation Process Theory to explore participants' experiences of a complex intervention in the RETurn to work After stroKE (RETAKE) trial. Accepted for an e-poster presentation at the UK Stroke Forum 2022 (November 2022).

*Powers, K. das Nair, R., Farrin, A. Radford, K. Exploring the association between therapist attributes, implementation fidelity and return-to-work outcomes in the Return to Work after Stroke (RETAKE) trial. Accepted for a quick-fire talk and poster presentation at OPSYRIS Annual Meeting 2022 (September 2022).

Trusson, D., Powers, K., Phillips, J., Holmes, J., Lindley, R., McKevitt, C., Bowen, A., Watkins, C., O'Connor, R., Farrin, A., Cundill, B., Sach, T., Day, F., Stevens, J., Murray, J., Radford, K., Clarke, D. Comparing return-to-work related experiences between participants in an individually randomised trial of Early Stroke Specialist Vocational Rehabilitation versus usual care only. Accepted for an oral and poster presentation at OPSYRIS Annual Meeting 2022 (September 2022).

Trusson, D., Powers, K., Phillips, J., Holmes, J., Lindley, R., McKevitt, C., Bowen, A., Watkins, C., O'Connor, R., Farrin, A., Cundill, B., Sach, T., Day, F., Stevens, J., Murray, J., Radford, K., Clarke, D. Evaluating the use of Normalisation Process Theory to explore participants' experiences of a complex intervention in the RETurn to work After stroKE (RETAKE) trial. Accepted for a poster presentation at OPSYRIS Annual Meeting 2022 (September 2022).

Holmes, J., Phillips, J., Powers, K., Craven, K., Bowen, A., O'Connor, R., Stevens, J. & Radford, K. Evaluating occupational therapist' competence to deliver early stroke specialist vocational rehabilitation (ESSVR) in the return to work after stroke (RETAKE) trial: A feasibility study. Accepted as a poster presentation for the Royal College of Occupational Therapists Annual Conference 2022 (June 2022).

*Powers, K., das Nair, R., Farrin, A., Phillips, J., Holmes, J., Watkins, C., Murray, J. & Radford, K. Exploring the association between individual-level attributes and fidelity to a vocational rehabilitation intervention in a randomised trial. Accepted as a poster presentation for the Royal College of Occupational Therapists Annual Conference 2022 (June 2022).

Craven K, Holmes J, Powers K, Clarke S, Cripps R, Lindley R, Phillips J, Tyerman R, McKevitt C, Clarke D, Radford K. Embedding mentoring to support trial processes and implementation fidelity in a randomised controlled trial of vocational rehabilitation for stroke survivors, International Journal of Stroke, https://doi.org/10.1177/17474930211059996

Clarke S, Craven K, Phillips J, McKevitt C, Powers K, Cripps, Farrin A, Watkins C, McLellan V, Bowen A, Hartley S, Holmes J, Holloway I ,Murray JD, O'Connor R, Stevens J, Sach T, Tyerman R, Walker MF, Clarke D, Radford KA, Measuring contamination in the RETurn to work After stroKE (RETAKE) trial, International Journal of Stroke, 16;3_SUPPL:44 (2021) https://doi.org/10.1177/17474930211059996

Holloway I, V McLellan V, Thompson E, Arfan M, Hartley S, Farrin A, Radford K, Winners and losers in post-COVID-19 stroke research; impact, solutions, lessons learned, and implications for future research, International Journal of Stroke,*16(3_SUPPL):46-46, 2021.* https://doi.org/10.1177/17474930211059996

Powers K, Clarke S, Phillips J, Holmes J., Cripps R, Craven K, Farrin A, das Nair R, Radford K. Developing and testing an implementation fidelity checklist for a complex vocational rehabilitation intervention, International Journal of Stroke, *16(3_SUPPL):46-46, 2021.* https://doi.org/10.1177/17474930211059996

*Powers K, Clarke D, Clarke S, Lindley R, Statham A, Radford K. Stroke survivor experience in being supported to return-to-work: A case study series, accepted as a poster presentation for OPSYRIS 2021

Holmes J, Phillips J, Powers K, Bedekar Y, Terry J, Tyerman R, Stevens J, Murray J, Walker M, Farrin A, Radford K. 'Developing a method to evaluate therapists' competence to deliver a complex vocational rehabilitation intervention in the RETurn to work After stroKE (RETAKE) trial'. Synapse, September 2020. [Abstract accepted as a Poster presentation ACPIN 30 April – 1 May 2020, Newport, UK [Conference cancelled due to Covid]].

Radford KA, McLellan V, Bowen A, Fletcher M, Hartley S , Holmes J, Holloway I McKevitt C, Morris T, Murray JD, O'Connor R, Phillips J, Powers K, Stevens J, Sach T, Walker MF, Watkins C, Farrin A, RETurn to work After stroKE (RETAKE), Ongoing Trials, UKSF, Telford, 2-4 December 2019., unpublished conference proceedings

Holmes J. Phillips J, Powers K, Bedekar Y, Terry J, Tyerman R, Stevens J, Murray J, Walker MF, Farrin A, Radford K, on behalf of the RETAKE team. Evaluating occupational therapists (OTs) competence to deliver a complex vocational rehabilitation intervention in the RETurn to work after stroke (RETAKE) trial, Presented as an oral presentation and awarded the top scoring abstract prize, UKSF Telford, 2-4 December 2019. International Journal of Stroke 2019 14 (4_Supplement),9-9 https://doi.org/10.1177/1747493019882907

Cripps R, Powers K, Bell B, McKevitt C, Radford, K. Return to work after stroke: a systematic review and evidence synthesis. Poster presentation, UKSF Telford, 2-4 December, 2019

R Cripps. K Powers, B Bell, J Holmes, C McKevitt, K Radford. Return to work after stroke: a systematic review and evidence synthesis. Poster presentation Opsyris Conference, 4th October 2019 Oxford.

J Holmes, J Phillips, K Powers, Y Bedekar, J Terry, R Tyerman, J Stevens, J Murray, M Walker, A Farrin, K Radford. Evaluating occupational therapists (OTs) competence to deliver early stroke specialist vocational rehabilitation in the RETurn to work After stroKE (RETAKE) trial. Oral presentation Opsyris Conference, 4th October 2019 Oxford.

*K Powers, J Holmes, J Phillips, A Farrin, R das Nair, K Radford. Exploring occupational therapist (OT) attributes on trial outcomes and determining competence to deliver early stroke specialist vocational rehabilitation. Work in Progress presentation Opsyris Conference, 4th October 2019 Oxford.

*J Holmes, J Phillips, K Powers, Y Bedekar, J Terry, R Tyerman, J Stevens, J Murray, M Walker, A Farrin, R das Nair, K Radford. Exploring occupational therapist (OT) attributes on trial outcomes and determining competence to deliver early stroke specialist vocational rehabilitation. Presentation Opsyris Conference, 4th October 2019 Oxford.

J Holmes, J Phillips, K Powers, Y Bedekar, J Terry, R Tyerman, J Stevens, J Murray, M Walker, A Farrin, K Radford. Evaluating Therapist Competence to Deliver Vocational Rehabilitation in the Return to Work After Stroke (RETAKE) Trial: Work in Progress Poster at the Society of Research in Rehabilitation (SRR) Conference Meeting held in Nottingham, 5 February 2019.

*Abstracts and presentations that I presented.

Acknowledgements

I would like to thank everyone who has formally or informally supported me through my PhD. Firstly, I would like to thank my supervisors, Professor Kate Radford, Professor Roshan das Nair and Professor Amanda Farrin, for their ongoing, unwavering support and for challenging me in ways that have stretched me as an individual and as a researcher. I am so grateful to have had your time, interest, and valuable guidance.

I would like to thank the stroke survivors and occupational therapists across the RETAKE study sites for their participation in the trial. Thank you to the fabulous RETAKE team I was privileged to be a part of, led by Professor Kate Radford. Thank you to Dr Julie Phillips, Dr Jain Holmes, Patricia Dziunka, Dr David Clarke, Dr Diane Trusson and Kristelle Craven for your knowledge, guidance, and emotional support. I have thoroughly enjoyed being part of such a dynamic, knowledgeable, and friendly team. Thank you to my numerous peers and colleagues who have given me coffee-fuelled pep talks (and pep walks) and encouraged me to keep pushing forward. Special shout-outs to Blanca, Rachel, Rupinder, Meri, Jo and Annabelle for creating such a supportive and compassionate environment.

Thank you to Ossie Newell, who gave me the opportunity to pursue this research through the funds raised by his charity the Ossie Newell Foundation. I am honoured to be able to carry your legacy forward.

I'd like to thank the myriad of close friends who brought levity and fun to my life when I needed it most, but who were also tolerant of when I needed to exercise discipline. Hannah, Tom, Jen, Darren, Abi, Abby, Sudi and Pam, your years of love and friendship mean everything to me.

Most importantly, I would like to thank my family. My wonderful husband, Richard Swinden, who has endured years of my emotional ups-and-downs during the PhD journey, often providing me with much needed perspective (and coffee). Jan and Kenny Luciano for always lending a listening ear, encouraging me to strive for excellence and being exemplary role

models for what can happen when you mix hard work and positivity. Lastly, I would like to thank my father, Tom Powers, who didn't live to see me progress through my PhD journey, but who was always the self-professed 'number-one fan' of my academic pursuits.

This thesis is a testament to all who supported me. I wouldn't be here without you.

Financial Acknowledgements

This research, conducted from 2018-2023, received funding via the Ossie Newell Foundation and the University of Nottingham.

RETAKE was funded by the National Institute for Health Research Health Technology Assessment (ISRCTN, ISRCTN12464275. Registered on 13th March 2018). The views and opinions in this thesis are those of the author(s) and do not necessarily reflect the views and opinions of the HTA, NIHR, NHS, University of Nottingham or the Ossie Newell Foundation.

Table of Contents

List of Abbreviations

ANOVA	Analysis of Variance
CASP	Critical Appraisal Skills Programme
CFIF	Consolidated Framework for Implementation Fidelity
CI	confidence interval
COM-B	Capability, Opportunity, Motivation, Behaviour Model of Behaviour Change
COVID-19	Coronavirus Disease 2019
CPD	continuing professional development
CRF	case report forms
EBP	evidence based practice
EBPAS	Evidence Based Practice Attitudes Scale
EIVR	Early Intervention Vocational Rehabilitation
EPIC	Evidence Based Practice Confidence Scale
ESD	early supported discharge
ESSVR	Early Stroke Specialist Vocational Rehabilitation
ESTVR	Early Specialist Traumatic brain injury Vocational Rehabilitation
FRESH	Facilitating Return to work through Early Specialist Health-based interventions
GP	general practitioner
HCP	healthcare provider
HCPC	Health and Care Professions Council
HRQOL	health related quality of life
HTA	Health Technology Assessment
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
OR	odds ratio
OT	occupational therapist
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomised controlled trial
RETAKE	RETurn to work After stroKE trial
RTW	return to work
SD	standard deviation
SDT	Self Determination Theory
SE	standard error
TBI	traumatic brain injury
UK	United Kingdom
USA	United States of America
VR	vocational rehabilitation
WHO	World Health Organization

1. Chapter One: Summary of the Research

1.1 Background

Complex intervention studies often struggle to demonstrate efficacy. By evaluating what factors might be influencing the implementation of these complex interventions, we can gain insight that can help us contextualise study results. Currently, there is limited evidence for what individual-level attributes, or characteristics, of both the people delivering and receiving complex interventions, might influence outcomes. The studies within this PhD are aimed at evaluating and understanding what therapist- and patient-level attributes impact fidelity and patient outcomes within complex rehabilitation studies, specifically an early, stroke specialist vocational rehabilitation for stroke survivors.

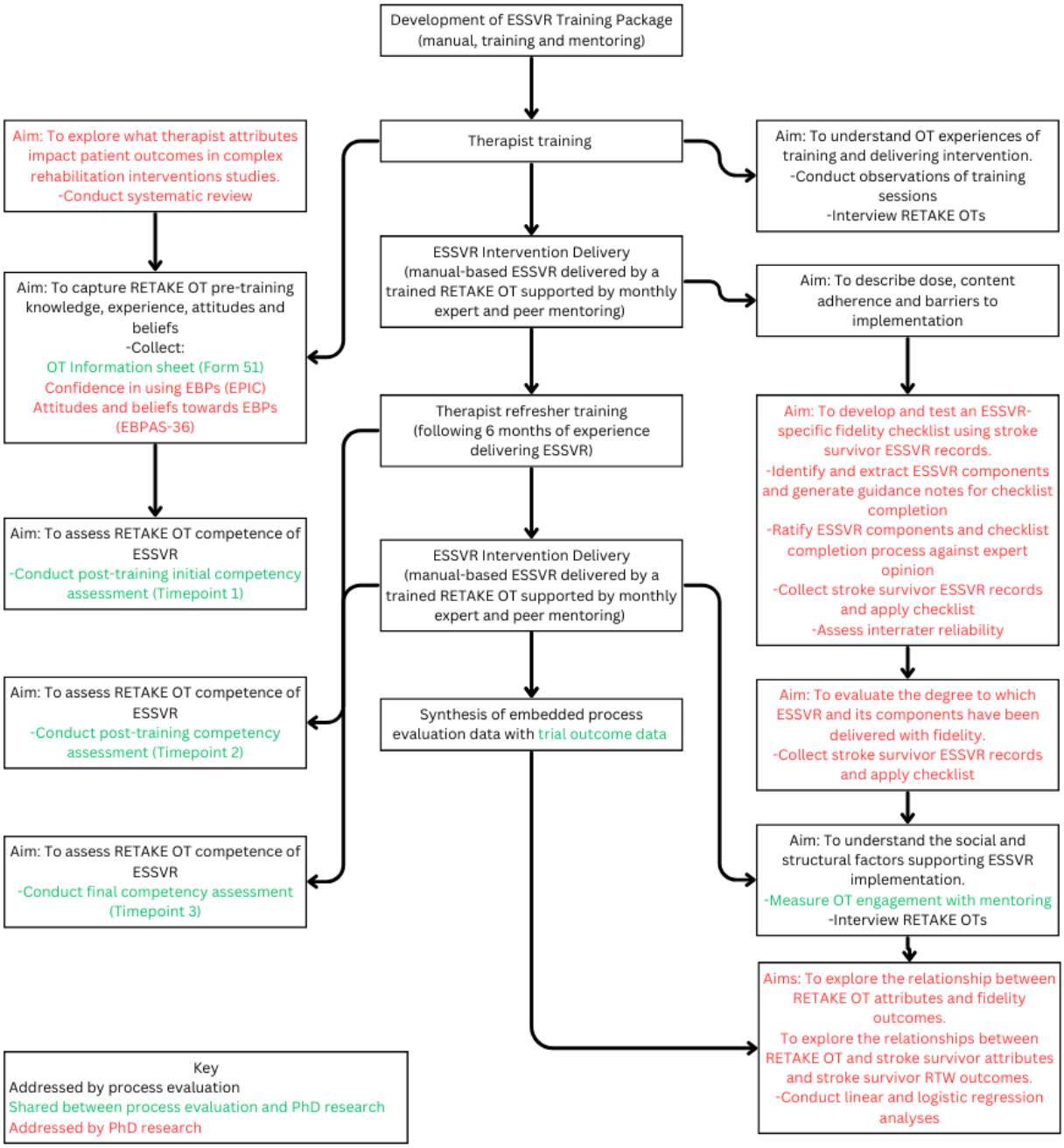
1.2 Context

This research was conducted within the context of a definitive, multi-centre randomised controlled trial (RCT), the RETurn to work After stroKE (RETAKE) trial (Trial Registration: ISRCTN12464275) that is currently underway. RETAKE's aim is to determine whether Early, Stroke Specialist Vocational Rehabilitation (ESSVR) in addition to usual National Health Service (NHS) rehabilitation is more clinically and cost-effective at returning stroke survivors to work at 12 months post-randomisation than usual NHS rehabilitation alone. The trial takes place in 16 study sites across England and Wales. ESSVR was delivered to community-dwelling stroke survivors who had been randomised to the trial's intervention arm, their families, and their employers by specially trained Occupational Therapists (OTs). ESSVR was offered to stroke survivors for up to 12 months following randomisation.

I was employed on the RETAKE trial as a Research Assistant from November 2017-August 2023 where my main research activities were within the trial's embedded process evaluation. I began my PhD studies in October 2018 and used my knowledge of the trial and process evaluation to generate and collect data to answer my research questions. Figure 1-1 maps the aims within my PhD research onto relevant aims within the RETAKE process evaluation and RETAKE study processes to demonstrate separation and overlap between studies.

Figure 1-1.

RETAKE Process Evaluation and PhD Flow Diagram

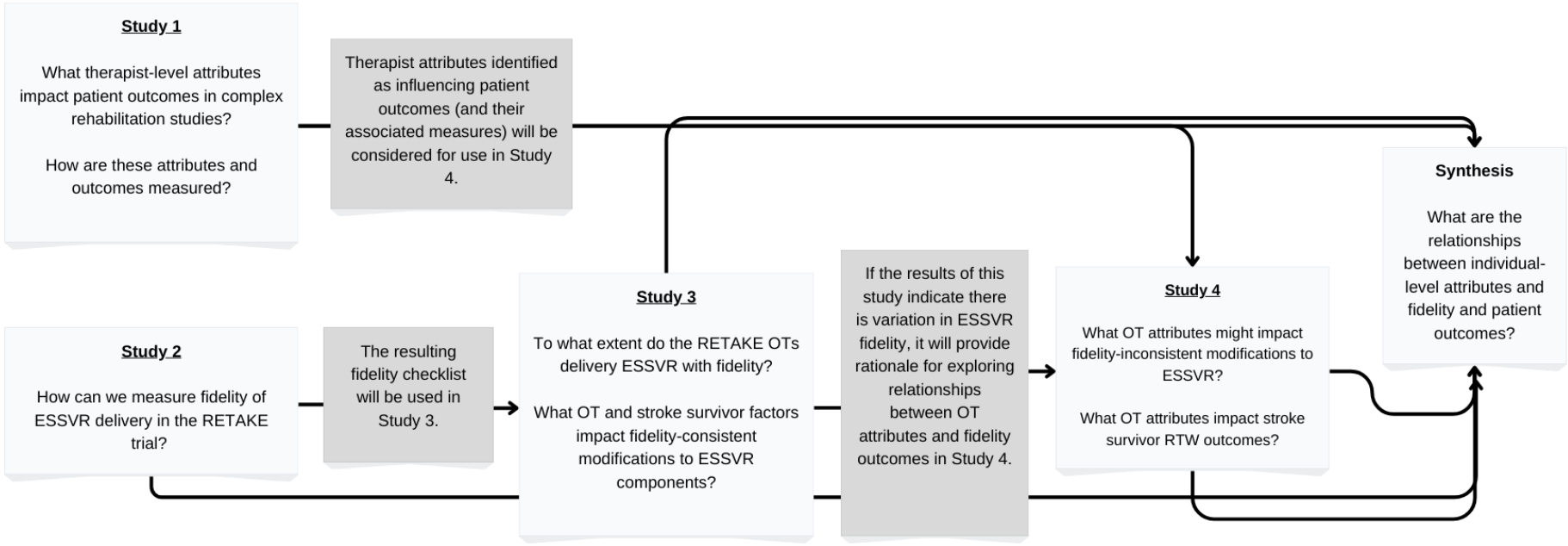


Abbreviations: EBPs, Evidence-based practices; EBPAS-36, Evidence-Based Practice Attitudes Scale-36; EPIC, Evidence-Based Practice Confidence Scale; ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

1.3 Research Approach

The overarching approach I took to designing my research was to conduct a series of interrelated studies, where the results of each study iteratively informed the design and execution of the next (see Figure 1-2). The analyses within this research are largely quantitative but draw on both quantitative and qualitative data sources to explore the complex relationships between individual-level attributes, implementation fidelity, and stroke survivor return-to-work outcomes.

Figure 1-2
PhD Study Design Diagram



Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

1.4 Research Questions

My research aimed to provide insight for future complex rehabilitation intervention studies by highlighting specific implementation considerations using the example of ESSVR delivery in the RETAKE trial. The studies within my PhD were designed and conducted to explore the relationships between individual-level attributes and fidelity and stroke survivor return-to-work outcomes. The research questions underpinning these studies were:

1: What therapist-level attributes have been identified in previous complex rehabilitation intervention trials as impacting patient outcomes and how were they measured?

2: How can we develop an intervention-specific measure of fidelity?

3: To what extent did OTs deliver ESSVR with fidelity in the RETAKE trial and what OT and stroke survivor factors impact fidelity-consistent modifications?

4: What OT-level attributes impact fidelity outcomes?

5: What OT attributes impact stroke survivor return-to-work outcomes?

The research questions, studies, key methods and associated manuscripts or publications are summarised in Table 1-1.

Table 1-1

Summary of key research questions, studies, data sources and analysis methods mapped against chapters in this thesis.

Research Questions	Study	Data Sources	Methods Used	Thesis Chapter
What therapist-level attributes have been explored for their impact on patient outcomes in complex rehabilitation studies? How have these attributes and outcomes been measured?	One	Studies of complex rehabilitation interventions	Systematic Review Narrative synthesis	Three
How can we measure fidelity of ESSVR delivery in the RETAKE trial?	Two	Previous fidelity checklists (qualitative), Proceedings from expert panel (qualitative), Stroke survivor ESSVR records, Completed fidelity checklists (quantitative & qualitative)	Interrater reliability analysis Document analysis: • Thematic analysis • Content analysis	Four
To what extent do the RETAKE therapists deliver ESSVR with fidelity? What individual-level factors impact fidelity-consistent and fidelity-inconsistent modifications to ESSVR components?	Three	Stroke survivor ESSVR records (qualitative), Completed fidelity checklists (quantitative & qualitative)	Document analysis: • Thematic analysis • Content analysis	Five
What OT-level attributes might impact ESSVR fidelity? What OT attributes impact stroke survivor RTW outcomes?	Four	Therapist details forms (quantitative), EBPAS-36 (quantitative), EPIC (quantitative), Mentoring records (quantitative), Competency assessment (quantitative), Completed fidelity checklists (quantitative) Stroke survivor age, sex, marital status and job sector (quantitative)	Linear regression analysis Logistic regression analysis	Six

Abbreviations: EBPAS-36, Evidence-Based Practice Attitudes Scale-36; EPIC, Evidence-Based Practice Confidence Scale; ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

The final chapter of the thesis provides an overall synthesis of the studies. This chapter includes a discussion of the overall findings, their implications, the strengths and limitations of the research, a critical description of their methodological considerations, a summary of the impact COVID-19 had on the research, and recommendations for future research. It ends with an overall conclusion.

2. Chapter Two: Background Literature Review

2.1 Chapter Overview

This chapter presents the background to the three interrelated studies that comprise this programme of research. It outlines important considerations relating to complex interventions and the factors affecting their successful implementation using the example of a complex vocational rehabilitation intervention delivered by occupational therapists (OTs) that aims to support people in returning to and staying in work following a stroke.

2.2. Rehabilitation

The term 'rehabilitation' is broadly defined by the World Health Organization (WHO) as 'a set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with their environment' (WHO, 2021). The interventions that make up rehabilitation can be delivered by a range of professionals in a range of settings which can include healthcare and non-healthcare settings. Rehabilitation is a process, driven by goal-setting, whereby the professional delivering the rehabilitation intervention and the service user receiving the intervention agree on measurable steps that seek to address the overall aim of the rehabilitation (Duncan et al., 2005; Wade, 2021; Young & Forster, 2007).

The National Health Services (NHS) in the United Kingdom, describes itself as a modern healthcare system responsible for the provision of rehabilitation services (NHS England, 2016). The guidance around commissioning of rehabilitation services, published by the NHS, emphasises the wide scope of rehabilitation and its delivery to not only the person experiencing the health condition directly, but also those important to the service user and

their effective rehabilitation, otherwise known as ‘key stakeholders’, who can include family members, friends, colleagues, and employers. The NHS guidance also clarifies that rehabilitation services should support the service user to engage with not only their domestic environment but should also support meaningful reintegration and participation within the services users’ community, leisure, employment, and education contexts (NHS England, 2016).

Wade (2020) highlights the commonalities in processes among rehabilitation studies showing patient benefit. According to Wade’s (2020a) synthesis of rehabilitation studies, studies showing patient benefit include those that are person-centred; providing relevant information to patients and their families (Langhorne & Pollock, 2002) and incorporating goal-setting and shared decision making (Rose et al., 2017). Beneficial rehabilitation is also delivered by a multidisciplinary team comprising a range of healthcare professionals who apply structured protocols based on addressing commonly experienced problems, but contain enough flexibility to provide a person-centred approach (Wade, 2020a, 2020b). Perhaps the most central rehabilitation process described by Wade (2020a) is the incorporation of the biopsychosocial model of illness (Wade & Halligan, 2017), which considers and addresses a patient's presenting problems from a medical, psychological and social perspective, as opposed to a single, medical perspective.

On the whole, rehabilitation interventions have been shown to be effective across many contexts (Wade, 2020a). Reviews of studies examining the effectiveness of rehabilitation interventions have suggested that there may be positive outcomes for the service users in a

number of patient groups including (but by no means limited to) people living with cardiac complications (Sumner et al., 2017), Guillain-Barre syndrome (Sulli et al., 2021), and stroke survivors (Eraifej et al., 2017; Nelson et al., 2017; Wray et al., 2018) however, it is difficult to draw definitive conclusions regarding effectiveness.

While rehabilitation interventions have strong face validity (Hart, 2009a), the mounting pressure on researchers to produce empirical evidence of interventions' effectiveness presents some challenges. One such challenge is the fact that rehabilitation interventions can be delivered by a variety of healthcare professionals, with several interventions being delivered at the same time. Whilst this is largely considered to be a strength of rehabilitation (Wade, 2020a; 2020b), the lack of a shared taxonomy across disciplines creates difficulties in describing and defining these interventions and their active ingredients or components and comparing effectiveness of interventions across studies (Hart et al., 2019; Wade, 2005; Whyte & Hart, 2003). Rehabilitation interventions also require individualisation to suit the needs and changing contexts of those receiving them (Chorpita & Daleiden, 2014; Stirman et al., 2019), which makes it difficult to know if the intervention components are being delivered as intended or if the intervention has morphed into something entirely different. This creates further difficulties in drawing conclusions regarding an intervention's effectiveness in research contexts.

The difficulties that researchers have in defining, replicating, and testing the efficacy of rehabilitation interventions contribute to our understanding of rehabilitation interventions as 'complex' interventions (Creek, 2009; Creek et al., 2005; Hart, 2009; Whyte & Hart, 2003). Understanding the underpinnings of complex interventions and what factors affect their

delivery and receipt, might help us to build a body of evidence for the efficacy of rehabilitation interventions, which is key for translating potentially life-changing interventions into routine practice.

2.3 Complex Interventions

The success of a complex intervention is thought to be dependent on the quality of its implementation (Durlak, 2015; Durlak & DuPre, 2008; Lockett et al., 2018; Nilsen, 2020). A complex intervention is defined by the Medical Research Council (MRC) as having:

- Number of and interactions between components and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention (e.g., intervention recipients, their families, their employers, etc.)
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

(Craig, et al., 2008; Skivington et al., 2021)

Complex interventions also tend to be individualised to the needs and contexts of the person receiving the intervention, which means that, often, core components of an intervention require a sense of flexibility or modification (Chorpita & Daleiden, 2014; Wiltsey Stirman et al., 2013). Whilst individualisation and modification of the intervention's components are essential, there is debate about the effects this may have on an intervention's receipt and overall effectiveness (Stirman et al., 2019; Von Thiele Schwarz et al., 2018). For example, in the psychotherapy literature, there is evidence that modifications

to an intervention can result in care that provides a better 'fit' to its recipient (Wiltsey Stirman et al., 2015, 2017). There is also research to suggest that these modifications may lead to better clinical outcomes for those receiving the intervention as well as promoting the clinician's likelihood to adopt the intervention into their usual practice (Chambers et al., 2013). In contrast, modifications can also present difficulties in ensuring that the clinicians are delivering the intervention as it was intended to be delivered and that the modifications are consistent with the planned intervention (Blakely et al., 1987; Wiltsey Stirman et al., 2015), which can lead to an intervention being shown to be less effective (Kumpfer et al., 2020; Pérez et al., 2016).

An additional consideration that contributes to the difficulty in exploring a rehabilitation intervention's effectiveness is the fact that there tend to be several factors that can impact or moderate outcomes (Aarons et al., 2011; Carroll et al., 2007; Klaic et al., 2021). Exploring which factors might impact key outcomes and affect intervention effectiveness is one of the main aims of implementation research.

2.4 Implementation Research

While many healthcare interventions have strong face validity, it can sometimes be difficult to demonstrate their effectiveness in research (Abdul Latif et al., 2011; Castellini et al., 2016; Gianola et al., 2019; Grol & Grimshaw, 2003; Lau et al., 2015). The challenge to empirically prove effectiveness may be due to the way an intervention is implemented, or delivered in practice (Breitenstein et al., 2010). The goal of implementation research is to unpick the complex processes that may impact patient and study outcomes (Bhattacharyya et al., 2009; Greenhalgh et al., 2004). Exploring these complex processes lends context to

study outcomes and provides researchers with key information about how to best support the translation of research into practice (Kegeles et al., 2015). Theories, models, and frameworks exist within implementation research, and despite a few distinct differences in their aims and concepts (Nilsen, 2020), researchers often use these interchangeably (Kitson et al., 2008; Rycroft-Malone & Bucknall, 2010). These theories, models and frameworks can be used to underpin studies of intervention effectiveness and provide vital information about what is impinging an intervention's successful implementation and, potentially, its effectiveness.

2.5 Programme Theories and Logic Models

Programme theories, or theories of change, explain how and why a programme, or intervention, is meant to work (Davidoff et al., 2015). Programme theories are developed by key stakeholders and are comprised of both *descriptive* and *prescriptive* assumptions (Chen, 1990, 2015). Descriptive assumptions describe the mechanisms that connect the intervention to the outcomes whereas prescriptive assumptions detail the necessary actions for eliciting and supping the desired changes.

Programme theories can be used to inform logic models. Logic models are graphical representations of an intervention's underlying processes and the desired outcomes. They are built with input from key stakeholders whose suggestions form two essential parts of a logic model: programme components and intended outcomes (Wholey, 1979). These two components have been expanded on by the popular United Way of America (1996) description of logic models. This description separates out an intervention's *inputs*

(programme consumables, e.g. staff, money, supplies), *activities* (the services provided by the intervention, e.g. education, referral services, work preparation), *outputs* (direct products of the intervention, e.g. number of staff members trained, number of patients treated), and *outcomes* (direct consequences of the intervention, e.g. increased knowledge, improved mood).

There is an element of caution that needs to be exercised in using and interpreting logic models. Logic models exist to explain processes behind interventions, but the interventions do not necessarily work as they are theorised to do. This limitation of logic models, and of programme theories generally, can be addressed through thinking of the model as a living document. The logic model should be adapted as information emerges about the intervention's implementation and both the intended and unintended consequences of the intervention.

Another limitation of logic models is that they don't guarantee that the intervention is carried out as intended. Understanding fidelity of intervention delivery and understanding the reasons for adaptations in the intervention process can provide the intervention developers and researchers indications as to what processes are truly essential for the intervention to produce the desired outcomes. Knowledge about the implementation of the intervention can feed into the intentional, iterative process of creating a logic model. One model that exists to help address these considerations is the action model/change model.

The action model/change model schema, as proposed by Chen (2015), can account for descriptive and prescriptive assumptions required by programme theories, and can be

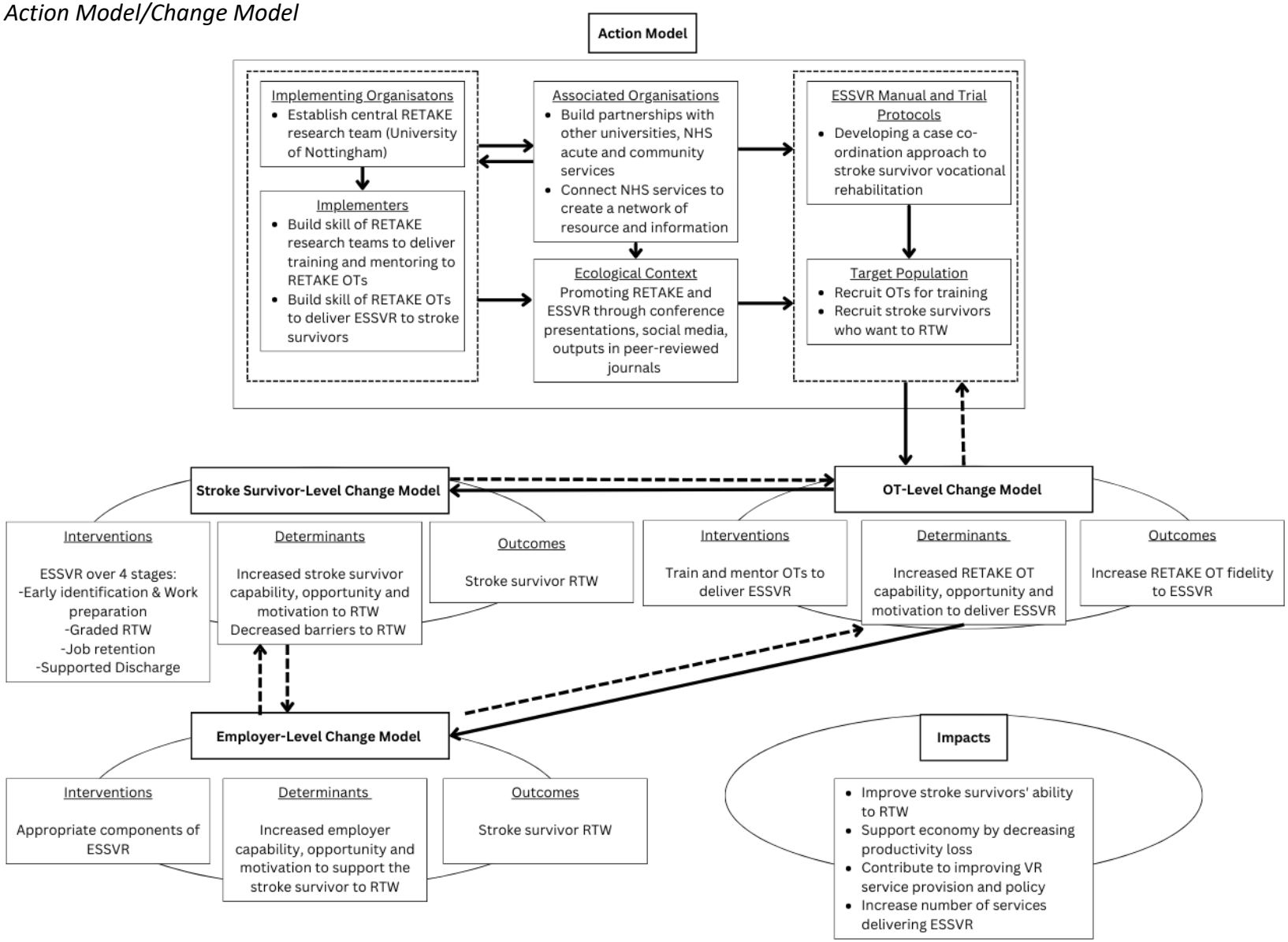
applied to especially complex interventions (Chen, 2015). The schema comprises two models: the action model and the change model.

The action model accounts for prescriptive assumptions through detailing processes of change within an organisation to facilitate recruiting, training and supervision of the people delivering the intervention as well as how each organisation associated with the implementation of the intervention communicates with each other (Chen, 2015). The action model also recommends considering intervention providers' competency in the intervention and other attributes that might potentially affect the quality of intervention delivery. The intervention protocol or manual is also considered under the action model as well as the contextual support that is put in place to support the faithful delivery of the intervention (e.g. training, supervision, mentoring). Finally, the action model prompts the intervention developers to consider the attributes of the population the intervention is being developed for to facilitate its uptake.

The change model describes the series of processes by which the intended changes occur through the intervention's delivery (Chen, 2015). This includes the intended outcomes, or goals, of the intervention, the intervention components geared towards generating those outcomes and the mechanisms that underlie those components to generate the change required to facilitate the desired outcomes. See Figure 2-1 for an ESSVR-specific representation of the Action Model/Change Model.

Figure 2-1

ESSVR Action Model/Change Model



Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; NHS, National Health Service; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work; VR, vocational rehabilitation

2.6 Implementation Theories

Theories exist to inform researchers of the various aspects of implementation and guide the design and evaluation of intervention studies (Nilsen, 2020). Due to the vast number of theories and their different foci, strengths, and weaknesses, choosing the right theories can be difficult (Cane et al., 2012; Rycroft-Malone & Bucknall, 2010). Implementation theories are proposed to inform researchers of the various aspects of implementation and factors that may help or hinder the delivery of an intervention and affect outcomes (*barriers and facilitators*) and their underlying mechanisms of change (Nilsen, 2020).

The research in this PhD programme draws on two main implementation theories: Normalisation Process Theory (NPT) (May & Finch, 2009; May et al., 2009) and the Capacity-Opportunities-Motivation-Behaviour (COM-B) element of the Behaviour Change Wheel (Michie et al., 2011).

2.6.1. Normalisation Process Theory

NPT is an implementation theory that describes a series of processes undertaken by individuals and groups that aid in the adoption of an intervention into routine practice, a phenomenon called *normalisation* (May & Finch, 2009; May et al., 2009). These processes are categorised into four components: 1. Coherence (sense-making); 2. Cognitive participation (engagement); 3. Collective action (work that facilitates intervention delivery); 4. Reflexive monitoring (ongoing appraisal of the intervention) (May & Finch, 2009; May et al., 2009; May et al., 2018; Murray et al., 2010).

2.6.2 Capability-Opportunities-Motivation-Behaviour

Within implementation research, behaviour change frameworks such as the Behaviour Change Wheel (Michie et al., 2011) provide insight into the range of factors that can affect behaviour change in interventions. At the centre of the Behaviour Change Wheel is the COM-B, which illustrates how an individual's capability (capacity to engage in an activity or behaviour), opportunity (external factors that prompt or enable behaviour), motivation (processes that energise and direct behaviour) and behaviour influence each other (Michie et al., 2011). This model posits that an intervention needs to change one or more of the components to elicit change in an individual's behaviour which helps researchers understand what influences intervention and implementation outcomes (Nilsen, 2020), including factors relating to the individuals delivering or receiving the intervention (Aarons et al., 2012; Damschroder et al., 2009; Wiltsey Stirman et al., 2013).

2.7. Determinant frameworks

Closely related to implementation theories are determinant frameworks. Nilsen (2020) distinguishes between these two categories by defining determinant frameworks as tools that identify what specific barriers and facilitators influence or predict implementation outcomes. These frameworks do not seek to explain mechanisms of change or other causal mechanisms like a theory would. The studies within this PhD use the Conceptual Framework for Intervention Fidelity (CFIF; Carroll et al., 2007) to understand the impacts of various factors on a construct known as 'implementation fidelity'.

2.7.1. CFIF

In intervention studies, it can be difficult to know whether interventions have been delivered as intended, or rather, with *fidelity* (Bellg et al., 2004b; Walton et al., 2019). The CFIF proposes four different concepts of adherence or fidelity that ensure that: 1. the components of the intervention are delivered as intended (*content*); 2. All the participants who should be receiving and benefitting from the intervention are doing so (*coverage*); 3. The intervention is being delivered as often as it was intended to be (*frequency*); 4. The intervention is delivered over the period of time it was intended to be (*duration*) (Carroll et al., 2007). Coverage, frequency, and duration combined are also referred to as 'dose'.

The CFIF also proposes 'moderating factors', or factors that may affect fidelity, such as intervention complexity, facilitation strategies, the quality of the intervention delivery and participant responsiveness or engagement.

Following feedback of the original CFIF that criticised its lack of consideration for the effect the wider context of the intervention delivery (i.e., structures and cultures mediating implementation) (Greenhalgh et al., 2004; McCormack et al., 2002; McNulty & Ferlie, 2002), the CFIF was adapted to include *context* as an additional moderating factor, which is defined in the CFIF as *the culture of organisations, social behaviours/interactions among members and social structures* (Hasson, 2010a). This model also included participant recruitment as a moderating factor. This was subsequently acknowledged by studies of surgical safety checklists (Gagliardi et al., 2014) and occupational health (von Thiele Schwarz et al., 2015)

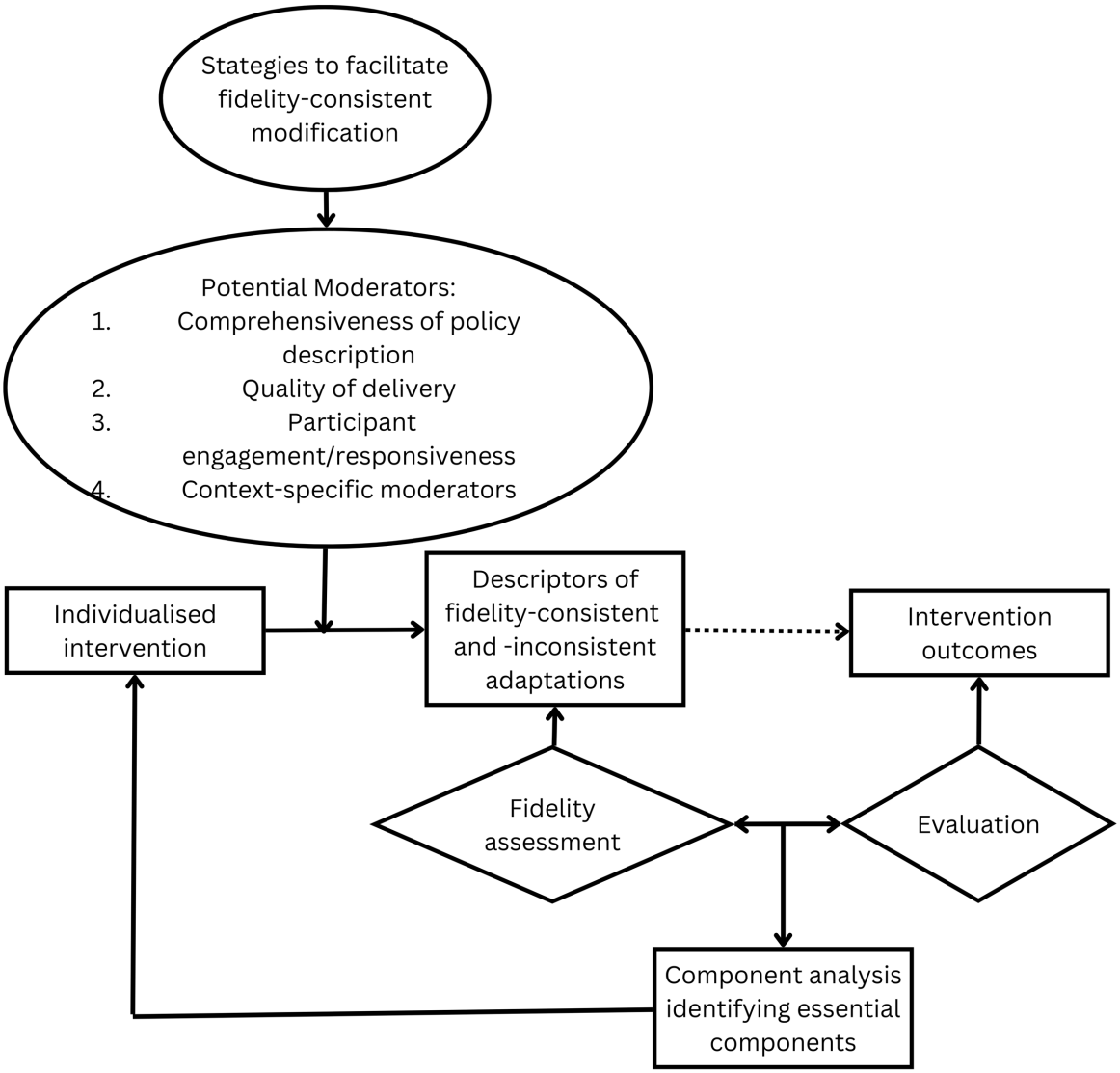
interventions to be an effective tool for evaluating implementation fidelity in complex interventions.

Whilst Carroll et al.'s (2007a) framework acknowledges that adaptations to an intervention are likely to occur during delivery (based on numerous factors), they do not provide guidance on how to measure the impact of these adaptations while simultaneously measuring fidelity. Pérez and colleagues (2016) proposed further amendments to the CFIF that address this criticism (See Figure 2-2). The original CFIF also postulates that the process of identifying essential components aides in exploring adaptation, however there is little guidance about how to effectively identify these components beyond conducting a component or sensitivity analysis (Carroll et al., 2007; Pérez et al., 2016). This issue is not unique to the CFIF and there is a general lack of clear guidance for how best to do this.

In their proposed model of CFIF, Pérez and colleagues (2016) retained the modifications proposed by Hasson et al. (2010), but also criticised the fact that Carroll et al.'s (2007) CFIF upheld adherence as the main indicator of fidelity. To address this, Perez et al. proposed that to understand implementation fidelity, we must also attempt to understand the modifications made to an intervention and to not think of adherence as the 'bottom-line' measurement of adherence.

Figure 2-2

Adaptation of Pérez et al.'s (2016) modified CFIF



Due to the comprehensiveness of this framework and its demonstrated usefulness in other complex intervention studies (Augustsson et al., 2015; Masterson-Algar et al., 2014), CFIF is used in this study to define and describe fidelity in this series of interrelated studies.

2.8. Overview of Implementation Fidelity

Despite the body of literature supporting the importance of fidelity, it is largely under-reported in studies of complex rehabilitation interventions (Hand et al., 2018; Lockett et al., 2018; Walton et al., 2017a). Without information regarding the extent to which an intervention has been delivered with fidelity, it is difficult to know whether the outcomes are due to the effectiveness or ineffectiveness of the intervention (Borrelli, 2011). Fidelity data are necessary to interpret intervention outcomes (Bellg et al., 2004).

2.8.1. Measuring Fidelity

Complex interventions usually contain several 'core components' that are essential for the intervention to have an effect and to be considered as delivered with fidelity (Hasson, 2010a; Lipsey & Cordray, 2000). The higher the level of complexity and individual tailoring of the intervention and its components, the more difficult it may be to measure fidelity (Hand et al., 2018; Hildebrand et al., 2012a; Toglia et al., 2020), thus requiring a more sophisticated method of measurement to avoid drawing conclusions about an intervention that might have been improperly implemented and making Type III errors[1] (Dusenbury, 2003). Measuring fidelity provides insight into which components of an intervention are

[1] Type III errors: When the correct hypothesis is rejected, but for an incorrect reason.

essential for a positive participant outcome (Craig et al., 2008) by establishing what key components were or were not delivered in cases of improved outcomes (Dane & Schneider, 1998).

Fidelity measurement is underpinned by theoretical concepts that emanate from behaviour change theories (Bellg et al., 2004; Cane et al., 2012; Damschroder et al., 2009). Frameworks such as the CFIF (Carroll et al., 2007) have been developed to guide methods for assessing intervention fidelity (Carroll et al., 2007; Hasson, 2010; Masterson-Algar et al., 2014). Some studies use quantitative data collection methods to measure elements of fidelity, such as fidelity checklists, that measure therapist adherence to determine whether core processes have been followed and core intervention components delivered (Lincoln et al., 2020; Walton et al., 2017). Others use qualitative data collection methods such as interviews for capturing acceptability or engagement with the intervention experienced by participants (Holmes et al., 2020; Toglia et al., 2020). These studies often do not include sufficient information regarding either the development of the fidelity measure used or the psychometric properties of the measure, which invites scepticism about quality (Rixon et al., 2016; Schoenwald et al., 2011; Walton et al., 2017; Walton et al., 2020). This emphasises the need for future research to make clear the processes used to assure good psychometric properties of the measure prior to its application.

There is a need for high quality psychometrically robust measures of fidelity, yet there is little agreement on how best to develop these measures (Walton et al., 2017; Walton et al., 2020). Recent guidance suggests that to be considered high quality, the psychometric (e.g., reliability and validity) and implementation properties (practicality) of the measure should

be reported (Walton et al., 2020). Evaluation of a measure's psychometric properties can determine whether the scores consistently measure the intended constructs (Hand et al., 2018; Moncher & Prinz, 1991). Practicality of a fidelity measure, such as ease of use and time taken to complete, is also valuable for researchers to report as these are factors that other researchers and clinicians consider when choosing a measure (Hand et al., 2018; Smart, 2006).

Fidelity checklists are developed by using instructional information (i.e., intervention manuals) that is then distilled into a shortened list of intervention components and used to assess the presence of the components in delivery (Breitenstein et al., 2010; Walton et al., 2020). Fidelity checklists are used in observation of intervention delivery either though in-person or video-recorded observation as the gold standard, which can be time intensive and has other considerations around impact of observation on delivery (Breitenstein et al., 2010; Dumas et al., 2001; Eames et al., 2008). Checklists have the advantage of being simple and quick to administer by those without specialist training in the intervention itself, and in instances where study participants cannot be, or do not wish to be, recorded, or interviewed (Walton et al., 2017). Fidelity checklists have been generated in occupational therapy (Hand et al., 2018; Parvaneh et al., 2015), however, they are typically specific to the interventions they assess and inappropriate for use across studies of other interventions (Craig et al., 2008; Hand et al., 2018).

2.9. Individual-Level Attributes

Implementation science has reiterated the importance of studying other factors that may influence or moderate outcomes as well as fidelity (Carroll et al., 2007; Damschroder et al.,

2009; Hasson, 2010). Of particular interest with regard to complex interventions is the potential impact of individual-level attributes (Wiltsey Stirman et al., 2015). Individual-level attributes are personal characteristics of a person that can be stable, which are thought to stay the same over time (e.g. education, openness to change, critical thinking; Flint-Taylor et al., 2014) or unstable, which are subject to change over time (practice, engagement, illness; Arnkelsson & Smith, 2000). Studies of the factors affecting the implementation of evidence-based practice have shown that attributes of both healthcare professionals and patients may contribute to poor fidelity outcomes, or implementation failure (Grol & Wensing, 2004; Hart & Bagiella, 2012; Solberg, 2000).

2.9.1. Introduction to Therapist Attributes

Many studies of complex interventions require the involvement of several treating therapists. Differences in attributes between therapists have been shown to create variations in outcomes, which is known as 'therapist effect' (Baldwin & Imel, 2013; Johns et al., 2019; Wampold et al., 2017). Therapist effect is pervasive regardless of context whether it be research-based or clinical (Huppert et al., 2001; Johns et al., 2019; Norcross & Lambert, 2019; Saxon & Barkham, 2012) and has been shown to account for roughly 5% of patient outcome variability in psychological treatment studies (Baldwin & Imel, 2013; Johns et al., 2019). Whilst it is understood that this variability exists, the research is not clear regarding *what* about the therapists causes this variability. In the context of an intervention efficacy study, variability in outcomes could lead to conclusions being drawn about an intervention's effectiveness, when the outcome was in fact impacted by the therapists themselves. By understanding the underlying causes of the variability, researchers might be able to provide

extra training or resources to reduce variability and should therefore be a priority for researchers.

Measuring therapist attributes and their impact on outcomes is beneficial to researchers and clinicians for a multitude of reasons. It can help researchers identify which attributes may be more or less conducive to therapists delivering certain interventions (Boswell et al., 2017) and there is even some research to suggest that treatment may be optimised though allocation of therapists to patients based on their attributes (Delgadillo et al., 2020). In cases where a favourable attribute may be modifiable, researchers may be able to design and focus training to enhance that attribute (e.g. knowledge of the impacts of a medical condition) and reduce variability between therapists (Saxon et al., 2017). Reducing variability between therapists is of particular importance, and is a goal reflected in the National Institutes for Care and Clinical Excellence (NICE) guidelines for mental health problems (2011), which operates on the assumption that care is delivered homogenously from therapist to therapist. This is also important in the context of intervention studies where it is important to introduce as little uncontrollable variation as possible (Delgadillo et al., 2020; Johns et al., 2019).

Measures used to assess the predictive ability of therapist attributes can be self-rated, where the therapists themselves complete questionnaires or surveys about themselves, or observer-rated, where a third-party captures information about the therapist based on what they can observe during a session, a series of sessions or an interview with the therapist (Heinonen & Nissen-Lie, 2020). Measures can be specific to a certain profession, such as psychotherapists, but they can also assess broader populations of clinicians.

Therapist attributes are proposed to range across two axes, objective versus subjective and professional versus personal (Heinonen & Nissen-Lie, 2020). Objective therapist attributes, such as therapist age, level of experience and education are easily measured through therapist demographic forms or therapist-completed questionnaires. Subjective therapist attributes are constructs that are comparatively less tangible. This includes therapist personality traits and certain beliefs. Professional therapist attributes are skill-specific and pertain to the ability to implement different therapeutic approaches with patients or clients whereas personal attributes are pervasive regardless of professional or personal context (Beutler et al., 1994; Heinonen & Nissen-Lie, 2020; Nissen-Lie et al., 2023).

Therapist attitudes and beliefs towards evidence-based practice (EPB) (McHugh & Barlow, 2010; Wiltsey Stirman et al., 2015), competency (Branson et al., 2018; Campos-Melady et al., 2017) and self-efficacy (Colquhoun et al., 2017; Eccles et al., 2005) have been found to consistently and considerably affect either fidelity or patient outcome across patient groups, intervention type and setting in a research context (Baldwin & Imel, 2013; Heinonen & Nissen-Lie, 2020; Johns et al., 2019).

Studies have yielded varying results which sometimes contradict each other, but often suffer from smaller numbers of therapist participants. A systematic review by Baldwin and Imel (2013) exploring the impact of therapist attributes found that only two of 25 studies included in the review involved more than 30 therapists, with the median number being nine. Future studies should be designed to include larger numbers of therapists, to

strengthen the statistical analyses performed and enable researchers to be more confident in their findings.

2.9.2. Impacts of Therapist Attributes on Patient Outcomes

Copious systematic reviews conducted in psychotherapy have suggested that objective, more 'static' attributes, such as therapist gender, are not indicative of patient outcomes (Beutler et al., 1994; Boswell et al., 2017; Crits-Christoph et al., 1991; Nissen-Lie et al., 2023; Webb et al., 2010). Therefore, much of the research focuses on subjective personal and professional attributes (Beutler et al., 1994; Heinonen & Nissen-Lie, 2020; Nissen-Lie et al., 2023). Studying therapists' personal and professional attributes can help researchers determine what attributes may be modifiable and amenable to change through training or educational interventions which might, in turn, help researchers produce more reliable efficacy outcomes (Heinonen & Nissen-Lie, 2020).

A recent review conducted by Heinonen & Nissen-Lie (2020) presents the most current research in this area and builds upon the systematic reviews preceding it (Baldwin & Imel, 2013; Johns et al., 2019; Lingiardi et al., 2018). Narratively synthesising the results from 31 studies published between 2000 – 2018 drawing on data from 14,982 patients (range: 18-4980; mean: 483.3; SD: 927.1) and 1,620 therapists (range: 7 – 316; mean: 52.3; SD: 60.4), this review found that the therapist attributes that had the most predictive ability, and thus presented the most promising direction for future research, were professional attributes related to the ability to deliver a specific intervention. Therapist attitudes and beliefs and

ability to communicate were amongst these professional attributes with predictive ability (Heinonen & Nissen-Lie, 2020).

Whilst the results of Heinonen & Nissen-Lie's (2020) review are largely in accordance with previous reviews (Baldwin & Imel, 2013; Johns et al., 2019; Lingiardi et al., 2018) and present researchers with compelling areas of focus for future research, the studies in the review stuffer from a few limitations. The studies within the review that had smaller sample sizes of therapists and patients make it difficult to draw firm conclusions regarding the predictive ability of the attributes. Additionally, the review is affected by publication bias, which is a bias based on the premise that studies with significant findings are more likely to be published (Song et al., 2010). If only the studies that found significant relationships between therapist attributes and patient outcomes were published, this systematic review is vulnerable to making a Type-I error[2]. Further research is warranted to explore these attributes and their potential impact on patient outcomes.

Delgadillo and colleagues (2020) conducted a recent study involving 69 therapists (Psychological Wellbeing Practitioners and Cognitive Behavioural Therapists) treating 4,052 clinically anxious and depressed patients in England. They explored the relationships between therapist competency, as measured by Observed Structured Clinical Examinations and the Cognitive Therapy Scale-Revised (Blackburn et al., 2001), therapist personality traits, as measured by the Revised NEO Personality Inventory (Costa & McCrae, 2008), and patient outcomes, as measured by the Patient Health Questionnaire-9 (Kroenke et al., 2001) and the Generalised Anxiety Disorder Assessment-7 (Spitzer et al., 2006). The results indicated

[2] Type 1 Error: incorrectly rejecting the null hypothesis, also referred to as a 'false-positive'.

that clinical experience and competence was not related to patient outcomes, however, patients treated by Psychological Wellbeing Practitioners with above-average 'agreeableness' personality traits (PHQ-9: B= 0.02, SE=0.01, $p < .05$; GAD-7: B= 0.02, SE= 0.008, $p < .05$) and Cognitive Behavioural Therapists with above-average 'openness to experience' personality traits (PHQ-9: B= 0.04, SE= 0.02, $p < .05$; GAD-7: B= 0.04, SE= 0.02, $p < .05$) had poorer treatment outcomes (Delgadillo et al., 2020). The study is limited by not considering the impact of patient attributes in combination with therapist attributes, such as demographic details or clinical characteristics, which may have produced more precise effect sizes.

Despite its limitations, the results of Delgadillo and colleagues' (2020) study become less surprising when one considers that another study exploring the impact of therapist attributes found that therapists with higher 'openness to experience' scores are also less adherent to treatment protocols (Peters-Scheffer et al., 2013). This highlights the need for researchers to also consider how therapist attributes might alter the way they deliver a treatment protocol with fidelity and how this then might impact patient outcomes.

2.9.3. Impacts of Therapist Attributes on Fidelity Outcomes

Higher levels of fidelity in studies of complex interventions are linked to better patient outcomes (Farmer et al., 2017; McHugo et al., 1999; Strunk et al., 2010). However, there is a lack of studies investigating relationships between fidelity and outcomes within the context of a randomised controlled trial (RCT), and what studies exist are of limited quality (Cox et al., 2019; Perepletchikova et al., 2007; Southam-Gerow et al., 2021). RCTs typically have more participants, which can help researchers draw more confident conclusions due to

higher statistical power (Zhong, 2009), therefore it is important to address concerns about quality and investigate these issues further. It should be considered that whilst RCTs provide researchers with higher statistical power, it can still be difficult to translate an 'effective' intervention into clinical practice, especially in studies of complex interventions (Minary et al., 2019; Wang et al., 2006). Researching what implementation factors support efficacy outcomes can help clinicians prepare to integrate interventions into routine clinical practice.

One way of improving research in this area is to investigate what factors might also impact fidelity, such as individual-level attributes. Investigating the relationship between therapist attributes and fidelity outcomes can help researchers not only contextualise results of intervention efficacy studies, but also impart valuable information about how to improve implementation of an intervention in future research and in clinical practice. Therapist attributes are an essential part of implementation success (Asgary-Eden & Lee, 2012; Sijercic et al., 2020). Studies within implementation research have highlighted the need for thorough investigation into factors which may influence or moderate fidelity outcomes (Carroll et al., 2007; Hasson, 2010). Due to the number of stakeholders involved in the delivery and receipt of complex interventions, the influence of individual-level attributes on fidelity outcomes is of particular interest (Sijercic et al., 2020; Wiltsey Stirman et al., 2015).

Despite the fact that therapist attributes play an essential role in fidelity outcomes, there is conflicting evidence about which specific attributes affect fidelity. Research regarding which therapist demographics (e.g., gender, years of experience, level of education, etc.) impact fidelity outcomes in research is inconsistent and inconclusive (Campbell et al., 2013; Meier et al., 2015; Sijercic et al., 2020). Whilst years of general experience as a practicing therapist

has not demonstrated clear directionality (Campbell et al., 2013; Carpenter et al., 2012; Sijercic et al., 2020), experience in skills related more specifically to an intervention has been shown to improve rates of fidelity (James et al., 2001).

A recently published systematic review considered the impact of therapist attributes on fidelity to psychological treatment protocols (Speers et al., 2022). Across the 66 studies included in the review, Speers and colleagues (2022) found that therapist knowledge of evidence based practices (EBPs), attitudes towards EBPs and clinical experience were related to the therapist's ability to faithfully deliver psychological interventions. The results of Speers and colleagues' (2022) review echo those found in a previous review of the attributes of cognitive behavioural therapists that impacted therapist fidelity conducted by Waller and Turner (2016). However, the studies included in Waller and Turner's (2016) review also found a positive relationship between therapists' competence in specific therapeutic models and their fidelity to that model. While these reviews provide another good starting point for considering what attributes might be important to consider in studies of interventions delivered by other healthcare professionals, the range of attributes considered in these studies, and sparse number of studies assessing the same attributes or measuring these attributes in the same way, meant that the authors were not able to conduct a meta-analysis. Additionally, while there is seemingly an abundance of studies considering these implementation issues in psychotherapy, this research in other disciplines is lacking.

2.9.4. Therapist Attributes Outside of Psychotherapy

While there is a plethora of research within psychotherapy that evaluates the impact of therapist attributes on patient outcomes, professionals specialising in psychotherapy are not the only professionals who deliver complex interventions and whose various attributes may affect patient outcomes. There are very few studies that specifically evaluate the impact on patient outcomes of the attributes of other allied health professionals that commonly deliver complex rehabilitation interventions such as occupational therapists, physiotherapists or speech and language therapists. Of the studies that have been conducted to assess the attributes of these professionals, the results seek only to describe their clinical knowledge (Haesler et al., 2016; Hunt et al., 2021), competence (Jarva et al., 2021), attitudes and beliefs (Benny & Evans, 2020; Gardner et al., 2017), assessment (O'Connor et al., 2016) and intervention practices (Zadro et al., 2019), and in some cases, how these attributes change as a result of a training programme (Richmond et al., 2017). These studies do impart useful information about the different attributes of allied health professionals, but do not explore how the variation in these attributes might translate to clinical practice or impact on patient outcomes. With strong evidence of the impact of psychotherapists' attributes on patient outcome in complex interventions (Baldwin & Imel, 2013; Heinonen & Nissen-Lie, 2020; Johns et al., 2019), it is clear that research should be extended to measure the impact of therapist attributes in other healthcare professions that also regularly deliver complex interventions, such as occupational therapists (Creek, 2009; Creek et al., 2005).

Since the impact of therapist attributes has been demonstrated across different patient groups and settings (Baldwin & Imel, 2013; Crits-Christoph et al., 1991; Johns et al., 2019),

we can also expect variation between therapists from other disciplines that warrant exploration.

2.10. Vocational Rehabilitation

Work is important in obtaining and securing adequate economic resources, but also has considerable implications on an individual's wellbeing and their full participation in society (Dunn & Brody, 2008; Mousteri et al., 2018). Involuntary joblessness and reduced opportunity for employment are often associated with lower rates of life satisfaction (Aragaki et al., 2021; Paul & Moser, 2009). Joblessness is also associated with poorer physical and mental health outcomes (Daly & Delaney, 2013; Goldsmith et al., 1996; Strandh et al., 2014) in both the short- and long-term (Mousteri et al., 2018, 2020). Involuntary joblessness also increases the likelihood for poverty and economic burden (De Neve & Oswald, 2012; Egan et al., 2016; Koltai et al., 2018). Given the benefits of being in work, and the consequences of reduced opportunity for work, when a person's working life is affected by illness, it is important to support the person to retain their employment status or re-enter employment as soon as they are able wherever possible.

Vocational Rehabilitation (VR) supports people in returning to or remaining in work (Waddell et al., 2008) and involves helping people trying to find work, experiencing difficulties at work, and needing support to achieve career progression in spite of illness or disability (Frank & Thurgood, 2006). Supporting someone to return to or remain in work following the onset of a new health condition can increase wellbeing, quality of life and even physical health (Dunn et al., 2022; Waddell et al., 2008; Yasuda et al., 2002). VR is typically delivered through one of three different approaches, or models: programme-based

rehabilitation, supported employment, and case coordination. Programme-based rehabilitation is an approach that focuses on providing the service user with training in skills related to their vocation before placing the service user back in a work environment (Ben-Yishay et al., 1987). Strengths of this approach include the building of service user confidence through training in work related skills and the fostering of service user workplace independence (Fadyl & McPherson, 2009). Programme-based VR is limited by exclusive programme eligibility criteria and the limited opportunity for monitoring service users once they have re-entered the workplace, which can facilitate sustainable return to work (Fadyl & McPherson, 2009).

In contrast, the supported employment model of VR involves very little pre-employment training, but instead focuses on coaching the service user to stay in their role and increase their workplace competencies (Wehman et al., 2000). The strengths of the supported employment model lie in the fact that VR provision can be individualised to the service user and there is typically no limit to the amount of support that can be provided. However, providing high-intensity, prolonged workplace support can also prevent the service user's workplace independence (Fadyl & McPherson, 2009).

Lastly, case coordination adopts of model of VR that is delivered by an individual who acts as an overall 'case coordinator' and runs alongside other rehabilitation the service user might be accessing in the pre-employment period and then supports and monitors the service user through their transition back to the workplace, providing a more system-based support structure (Malec et al., 1995; Malec & Moessner, 2000, 2006). Case coordination can theoretically provide a service user with a smoother transition between different

rehabilitation services and their workplace, with the case coordinator being able to facilitate liaison between all parties (Fadyl & McPherson, 2009). An early systematic review exploring the quality of care for people with disabilities showed that the case coordination model was effective for reducing fragmented care (Lawtheres et al., 2003).

There is no consensus in the literature about which model of VR is most effective for supporting return-to-work outcomes , however, all three approaches are limited by the fact that successful implementation depends on the skills of the staff involved in VR delivery and the capacity of the service to deliver the intervention (La Marche et al., 1995). Despite the lack of consensus about the more effective VR approach, there are realist and systematic reviews in support of VR interventions which include 'early' intervention as a core facet, where 'early' is taken to mean that the VR should begin during a service user's primary rehabilitation phase (Cancelliere et al., 2016; Dunn et al., 2022; Fadyl & McPherson, 2009). This could be as early as two to four weeks following the onset of a health condition (Hilton et al., 2017). A study of VR in people with spinal cord injuries found that people were making decisions about returning to or remaining in work within one month of their injury (Fadyl & McPherson, 2010), which helps to illustrate the need for timeliness in VR delivery in people experiencing long-term neurological conditions.

Due to the many contexts in which VR is delivered (e.g. to patients, their families, and their employers), the knowledge and skills required by therapists to deliver VR and the various outcomes VR can produce, VR is considered a complex intervention. Because of its complexity, it is reasonable to hypothesise that the outcomes of VR might be impacted by the individual-level attributes of those delivering and receiving it. To understand more

about the mechanisms for change within early intervention VR, Dunn and colleagues (2022) conducted a realist review of early intervention VR for people with newly acquired neurological conditions. Realist review is a method that seeks to answer questions about the processes that underlie an intervention and its implementation through the analysis of context of intervention delivery opportunities, the mechanisms by which the intervention operates and the outcomes they produce (Pawson & Tilley, 1997). Dunn and colleagues' (2022) review synthesised data from 37 documents describing the delivery of early intervention VR to people with spinal cord injury, acquired brain injury (including stroke), traumatic brain injury and mixed neurological presentations. The results of the review reveal nine mechanisms underpinning early intervention VR: 1. Ensuring the rehabilitation team's positive attitudes towards VR, 2. The professional's ability to foster hope of returning to work in the service user, 3. The service user's ability to accurately assess their strengths and limitations, 4. The services user's self-efficacy, 5. The service user's preservation of their identity as a worker, 6. The preservation of the relationship between the service user and their employer, 7. The integration of goal-setting into the VR plan, 8. The degree to which the employer engages in the VR process, and 9. The employer's willingness to make adaptations in the workplace to support the service user upon their return (Dunn et al., 2022). The identified mechanisms are suggested to influence outcomes of patient confidence in their ability to work, patient psychological adjustment (as related to their perception of self, identity as a worker, and their perception of disability), and patient/employer engagement in exploring reasonable adjustments (Dunn et al., 2022). Whilst the mechanisms of early intervention VR identified by Dunn et al.'s (2022) realist review suggest that the experience, skills and knowledge of those involved in in the VR process (service users, healthcare providers and employers) influence a service user's work-

related outcomes of confidence in ability to work and ability to engage in reasonable work adjustments, the review did not suggest a way of measuring these individual-level attributes objectively in future studies.

Whilst VR also theoretically, positively impacts the economy, in the context of ESSVR delivered in the RETAKE trial, considerations regarding health economics were examined separately to this thesis by a team of health economists.

2.11. Stroke

2.11.1. Overview and Incidence of Stroke

A stroke occurs when blood flow to the brain is compromised either through a blockage in the vessels of the brain (ischemic stroke) or by bleeding in or around the brain (haemorrhagic stroke). Over 100,000 people suffer stroke every year in the UK (Stroke Association, 2020) and there are currently over one million stroke survivors in the UK (King et al., 2020; Rothwell et al., 2004). With the number of people who will suffer a stroke anticipated to grow by 34% between 2015 and 2035 (Stevens et al., 2017), combined with the advancement of life saving medical interventions, the number of stroke survivors is expected to grow dramatically (King et al., 2020). Consequently, the incidence of stroke in working aged people is rising (Kissela et al., 2012) and roughly a quarter of stroke survivors are estimated to be under the age of 65-years (Stroke Association, 2016).

2.11.1.1. Impacts of Stroke

The impacts that a stroke can have on a person depends on a variety of factors, including the location of the stroke in the brain and the severity of the stroke (Stroke Association,

2021). The fact that these impacts can vary so much between stroke survivors, has considerable implications for their rehabilitation and requires flexibility of any intervention to suit their individual needs. For a summary of the potential impacts of a stroke on an individual, see Table 2-1.

Table 2-1.

Summary of potential impacts of stroke on an individual, adapted from information provided by the Stroke Association (2021).

Physical/Sensory	Communication	Cognitive	Behavioural/Emotional	Economic	Social

• Muscle weakness
• Fatigue
• Blindness
• Hemiparesis
• Hemiplegia
• Foot drop
• Pain
• Spasticity
• Contractures
• Sensation:
  • Hyperesthesia/hypoesthesia
  • Dysesthesia/paraesthesia
	• Aphasia
	• Dysarthria
	• Apraxia
		• Memory impairments
		• Attention
		• Executive dysfunction
		• Global cognition impairments
			• Emotional lability
			• Apathy
			• Depression
			• Anxiety
			• Anger/aggression
			• Euphoria/mania
				• Financial strain
				• Job loss
					• Family problems
					• Divorce
					• Conflict with friends and family
					• Sexual dysfunction
					• Deterioration of leisure activities

2.11.1.2. Stroke Rehabilitation

After a stroke, many people require rehabilitation to help them recover their physical, cognitive, and neurological function, mood, and quality of life. Typically, stroke rehabilitation begins when the stroke survivor is still in hospital, in the acute and inpatient stages of their recovery. Stroke survivors may expect to receive physiotherapy, occupational therapy, speech and language therapy, and psychological services in hospital depending on their needs following their stroke.

Once discharged from hospital, stroke survivors are usually offered Early Supported Discharge (ESD) service, which involves healthcare professionals coming to the stroke survivor's home, assessing, and addressing the needs of the stroke survivor. At this point in the recovery, the stroke survivor might set goals with their ESD team. Goals may range from achieving independence in personal care tasks such as washing and dressing to support to return to daily activities such as leisure activities or hobbies and work. Depending on the resources of the service providing the ESD, the level of rehabilitation required by the stroke survivor and the goals set during rehabilitation, ESD can last anywhere between 6-12 weeks.

Following ESD, a stroke survivor might be referred onto other community services as a continuation of the care they were receiving. These services are vital as stroke survivors may be expected to make substantial, meaningful recovery many years after their stroke (Burton et al., 2014).

2.11.1.3. Return-to-work After Stroke

Many long-term neurological conditions can affect a person's ability to stay in or return to work, including stroke. The ability to successfully return to and stay in work following a stroke has been shown to increase stroke survivors' quality of life (Ashley et al., 2019; Chang et al., 2016; Saeki & Toyonaga, 2010). Increased rates of anxiety and depression have been found in stroke survivors who do not return-to-work (Arwert et al., 2017; van der Kemp et al., 2019).

Studies of return-to-work after stroke have found that less severe strokes (Ashley et al., 2019), increased ability to independently carry out activities of daily living (Hackett et al., 2012; Tanaka et al., 2014; Waje-Andreassen et al., 2013), having a 'white-collar' or 'qualified worker' job (Bonner et al., 2016; Nascimento et al., 2021; Palstam et al., 2019; van Velzen et al., 2009), higher levels of cognitive ability (Kauranen et al., 2013; Vestling et al., 2003; Westerlind et al., 2017) and fewer or less severe neurological deficits (Ntsiea et al., 2015b; Saeki & Toyonaga, 2010; Tanaka et al., 2014) to be significant predictors of return-to-work. There is also some research that suggests that men are more likely to return-to-work than women (Hackett et al., 2012; Palstam et al., 2019; Waje-Andreassen et al., 2013).

The literature around what factors predict successful return-to-work outcomes suffers from inconsistencies in the definition of 'return-to-work', which create difficulties in cross-study comparisons (J D Edwards et al., 2018). The literature also comes from many countries which differ in their sickness, disability and retirement policies and benefits, which undoubtedly influences return-to-work outcomes. Likelihood of return-to-work does improve over time, up to two years (J D Edwards et al., 2018), but after two years the

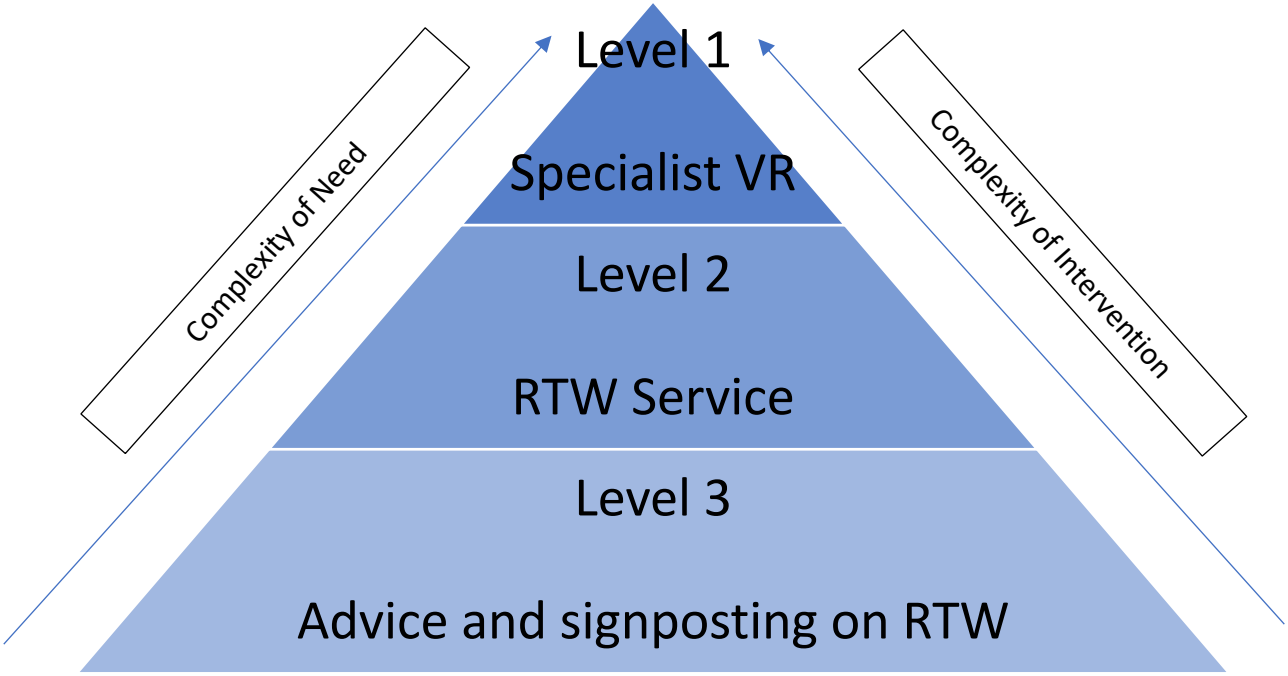
likelihood of returning to work decreases (Ashley et al., 2019; J D Edwards et al., 2018) making early intervention to support people back to work a priority.

2.11.1.4. Vocational Rehabilitation for Stroke Survivors

The National Stroke Service Model: Integrated Stroke Delivery Networks (2021) emphasises the need for vocational rehabilitation to be offered to all stroke survivors in some form regardless of their age or the complexity of their needs and proposes a three-level system which stroke survivors can move through flexibly in a way that addresses their changing individual needs and circumstances. According to the model, Stroke survivors should be able to move between the levels in accordance with their changing needs, requiring services to practice, individualised, flexible care in a 'timely and responsive way' (see Figure 2-3).

Figure 2-3

Adaptation of the National Stroke Service Model Integrated Stroke Delivery Networks; NHS, 2021) proposed model of VR provision for stroke survivors.



Abbreviations: RTW, return-to-work; VR, vocational rehabilitation

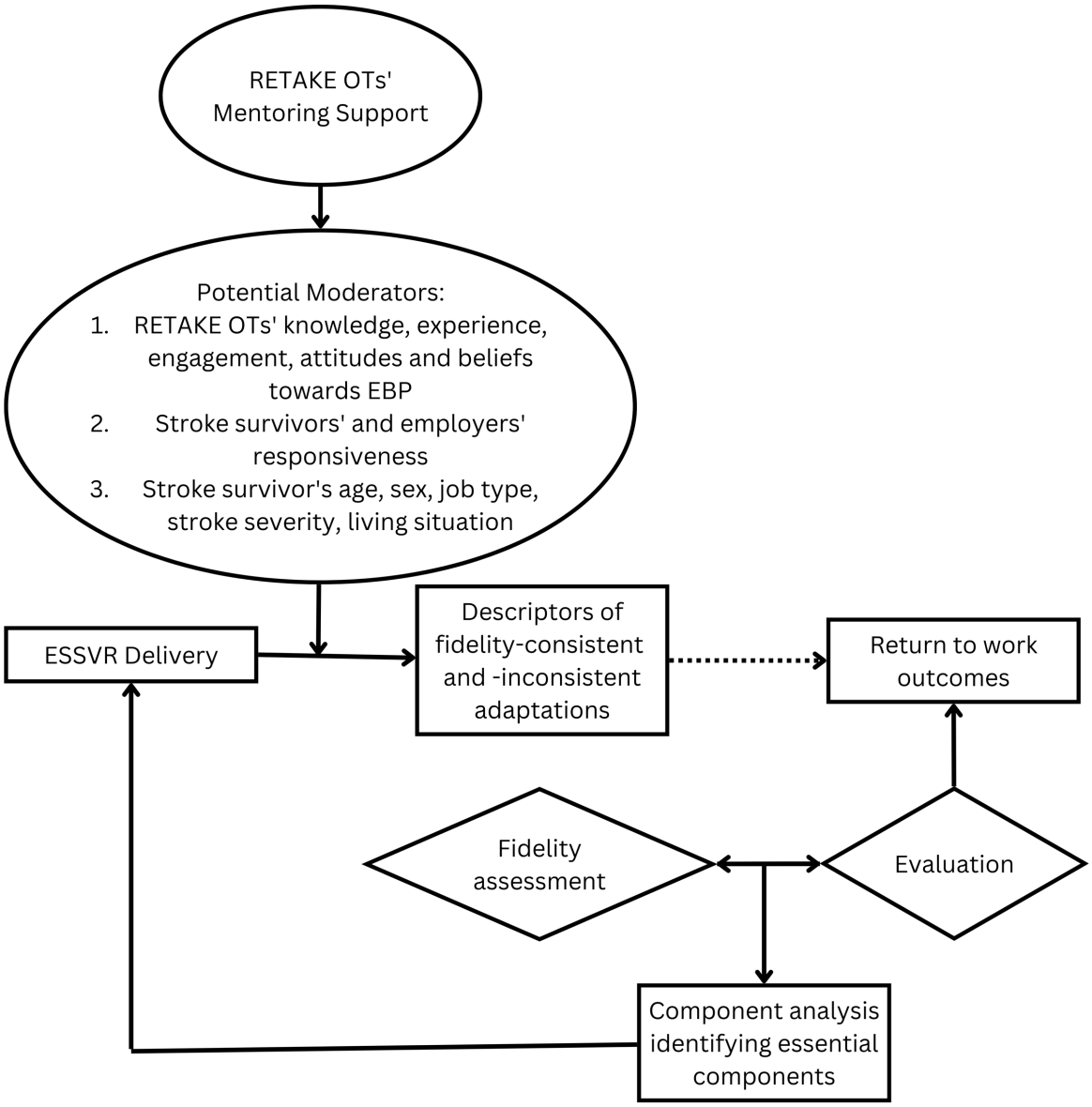
While there have been studies of the effectiveness of different vocational rehabilitation interventions for stroke survivors, there is still debate over what elements, or components, of the interventions make for successful return-to-work outcomes as well as what individual-level attributes might contribute to a successful return to work (Baldwin & Brusco, 2011). A systematic review, conducted by Baldwin and Brusco (2011), collated and compared VR interventions delivered to stroke survivors. The review included results from six studies, all of which used a retrospective single cohort design and reported return-to-work rates ranging from 12%-49% (Baldwin & Brusco, 2011). The lack of high-quality evidence made it difficult to draw any conclusions or recommendations beyond calling for the need for large, multi-centre randomised controlled trials (RCTs) of VR for stroke survivors.

Since Baldwin and Brusco's (2011) review, one RCT was been conducted to determine the effectiveness of a workplace intervention programme for stroke survivors in South Africa (Ntsiea et al., 2015). Eighty stroke survivors were recruited to the study and the results demonstrated that 60% of the stroke survivors in the VR group of the study returned to work compared to 20% of the stroke survivors in the usual-care group at the six-month follow-up point. The results of the study also described factors facilitating and creating barriers to return-to-work such as the unwillingness of the employers to engage in the return-to-work process and the motivations of the stroke survivors to return to employment. While this study demonstrated the effectiveness of their VR intervention, it was conducted within the cultural and economic context of South Africa and, thus, is not generalisable on an international level.

A feasibility RCT of a VR intervention for stroke survivors was conducted in the United Kingdom (Grant, 2016). This feasibility RCT recruited 46 stroke survivors who had experienced largely mild to moderate strokes, 23 of which were randomised to receive stroke specific VR. The results of this small feasibility RCT demonstrated that twice as many stroke survivors returned to work in the intervention group than the control group who were receiving usual care. Whilst this result demonstrated potential for the stroke specialist VR to support return-to-work outcomes and the feasibility of delivering a trial of this nature, a larger trial was needed to demonstrate efficacy. Grant and colleagues' (2020) study helped to lay the foundation for the RETAKE trial, a large, multi-centre, definitive RCT determining the effectiveness and cost-effectiveness of ESSVR (Radford et al., 2020), which also provides the context for this PhD research. The evaluation of ESSVR implementation can be illustrated as follows in this further adaptation of Perez et al.'s modified CFIF (see Figure 2-4.)

Figure 2-4

Perez et al.'s (2016) modified CFIF adapted for ESSVR



Abbreviations: EPB, evidence based practice; ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

2.12. Justification for the Current Study

Investigation of implementation considerations such as fidelity and potential impact of individual-level attributes on outcomes is imperative for enabling researchers to draw conclusions about intervention effectiveness. This research also helps generate relevant recommendations about what interventions might work best for which people and provide people with the best care suited to them. Without information regarding the context around intervention delivery, confident conclusions regarding study results and intervention effectiveness are not possible and the likelihood of patients receiving potentially life-changing intervention is diminished.

2.13. Research Aims & Objectives

Using data associated with a randomised controlled trial (RCT) assessing return to work outcome following receipt of ESSVR (Radford et al, 2020), this PhD research aims to:

- Identify attributes of occupational therapists (OTs) which may impact their ability to deliver a complex rehabilitation intervention with fidelity.
- Assess the fidelity of ESSVR delivery and consider what factors might affect the delivery of ESSVR components.
- Identify which individual-level attributes may contribute to successful return to work outcomes.
- Investigate the relationship between fidelity and stroke survivor return to work outcomes.

Study 1 aims to explore whether therapist-level attributes impact patient outcomes within complex rehabilitation interventions by:

1. Synthesising the existing research around the impact of therapist-level attributes in studies of complex rehabilitation interventions.
2. Reporting the therapist-level attributes that have been measured against patient outcomes.
3. Reporting the tools used to measure the therapist-level attributes used in the studies
4. Evaluating the studies' strengths and limitations.

Study 1 was conducted first to inform the selection of therapist attributes and associated measures for use in Studies 3 and 4.

Study 2 aims to develop a fidelity checklist and guidance notes for measuring fidelity of ESSVR delivery required for Studies 3 and 4 by:

1. Identifying core intervention components and generate guidance notes to assess their delivery within the RETAKE trial.
2. Ratifying the checklist components and guidance notes against expert opinion.
3. Field-testing the checklist.
4. Assessing inter-rater agreement in fidelity checklist completion.

Study 3 aims to determine the fidelity the ESSVR process, evaluate the extent to which each ESSVR component was delivered with fidelity, and explore factors leading to fidelity-consistent modifications by:

1. Applying the fidelity checklist to stroke survivor ESSVR records.

2. Determining the overall fidelity of ESSVR delivery within and across OTs.

3. Determining the fidelity of the delivery of each ESSVR component.

4. Assessing stroke survivor and therapist factors that result in fidelity-consistent modifications.

Individual RETAKE OT fidelity assessment scores determined through this study were used in Study 4.

Study 4 aims to explore the impact of OT attributes on fidelity outcomes stroke survivor return-to-work status at 12 months by:

1. Measuring OT (Knowledge, experience, engagement with mentoring, confidence, and attitudes and beliefs towards evidence-based practice) and stroke survivor (age, sex, job type and living situation) attributes.
2. Measuring fidelity of ESSVR delivery and stroke survivor return-to-work outcome.
3. Analysing OT attributes against fidelity outcomes through linear regression.
4. Analysing OT attributes against return-to-work outcome through logistic regression.

2.14 Research Approach

To address the aims and objectives, this thesis contains a series of interrelated, iteratively developed studies using an overarching, mixed-method design. The results of each study informed the next study, which is described in each chapter's preamble. The studies themselves consider several methodologies and draw on both qualitative and quantitative data to answer the research questions. The discussion section of this thesis provides a

narrative synthesis of the results of these studies. These methods are described in the individual chapters, but the rational, strengths, and limitations of employing a mixed-methods research approach are described here.

2.14.1 Mixed-Methods Approach

The practice of combining qualitative and quantitative methods within research is called method integration. Using a mixed-methods approach is a method integration that involves the intentional synthesis of qualitative and quantitative data to answer a research question (Johnson & Onwuegbuzie, 2007). Qualitative and quantitative approaches normally sit within their own paradigms (Johnson & Onwuegbuzie, 2007). Mixed-methods approaches create a third paradigm where both qualitative and quantitative data collection and analyses are combined to answer a research question from different perspectives (Knappertsbusch et al., 2021; Plano Clark & Ivankova, 2016).

2.14.2. Strengths

Mixed-methodology provides a well-rounded and robust approach to answering complex research questions in healthcare research (O'Cathain et al., 2010). In complex intervention implementation studies, it is one approach to answering a research question to elicit a perspective that adequately captures the issues underpinning implementation (Skivington et al., 2021). Mixed-methods approaches benefit from the strengths of both qualitative and quantitative research, for example, a researcher can collect rich contextual information through qualitative data that speak to precise results generated by quantitative data analysis (Robins et al., 2008).

2.14.3. Limitations

Despite its strengths, methodological diversity is not always embraced. Some researchers reject mixed methods approaches, citing that qualitative and quantitative paradigms are built on a 'methodological dualism' and are therefore incompatible based in their epistemology (Greene & Caracelli, 1997; Guba & Lincoln, 1989). In answer to these criticisms, many mixed-methods designs have been proposed along with how best to synthesise data within this third paradigm and bridge the gap between these seemingly epistemologically-opposed approaches (Creswell & Clark, 2017; Teddlie & Tashakkori, 2009).

2.14.4. Mixed-Methodology in Complex Intervention Research

The Medical Research Council (MRC), which funds research aimed at developing interventions to improve health and wellbeing, calls for greater priority to be given to using mixed-methods in complex intervention research to answer questions beyond an intervention's effectiveness (Craig et al., 2008; Skivington et al., 2021). Mixed-methods designs are increasing used in attempts to understand and address barriers in intervention implementation (Palinkas et al., 2011; Proctor et al., 2009). Qualitative methods provide depth which can help implementation researchers unpick why an intervention might have failed or what factors aided its success, whereas quantitative data can provide a way to test hypotheses of what factors predict successful implementation outcomes (Teddlie & Tashakkori, 2009). Due to the exploratory nature of my PhD research a mixed-methods design was considered appropriate for determining what OT- and stroke survivor-level attributes might impact fidelity and return-to-work outcomes in the context of the RETAKE trial.

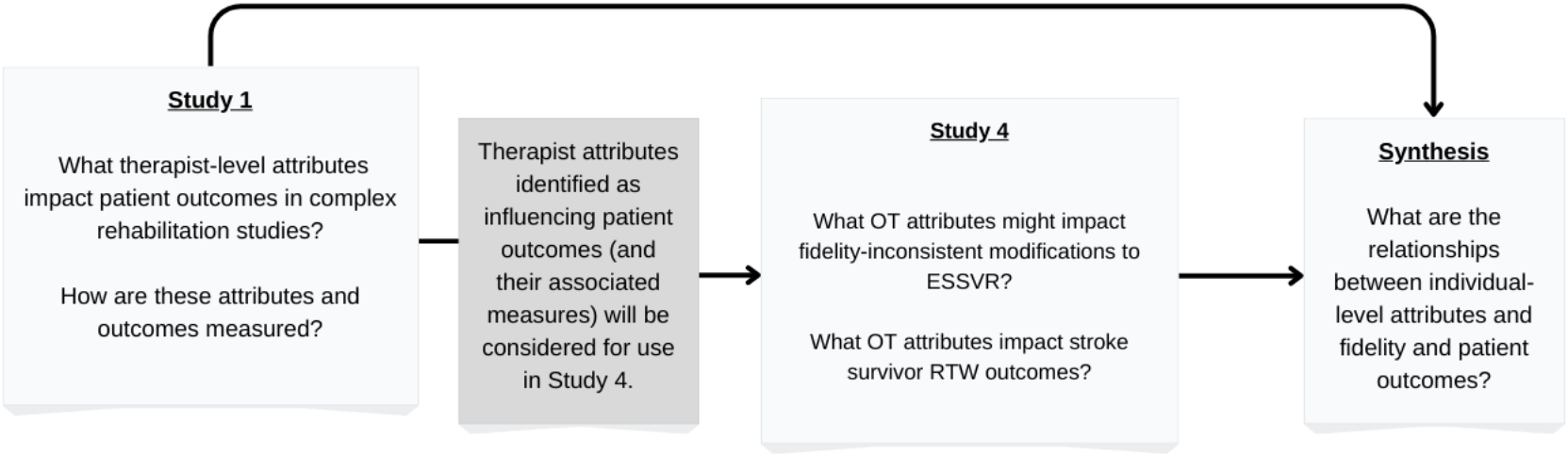
3. Chapter Three: Do therapist attributes impact patient outcomes within studies of complex rehabilitation interventions? A systematic review.

3.1 Preamble

The first aim of this thesis was to explore whether therapist attributes impact patient outcomes in the context of complex rehabilitation intervention studies. To address this aim, this chapter reports the methods, analysis, and key findings from a systematic review of literature seeking to understand the relationships between therapist attributes and patient outcomes outside of the psychotherapy literature. Research and clinical implications are highlighted in the chapter's discussion section. This chapter has been submitted to *Physiotherapy* and therefore, some repetition of literature discussed in the background literature review chapter will be evident. See Figure 3-1 for a visual representation of how the results of this study contribute to other studies within this thesis.

Figure 3-1

The interrelationships between Study One, Study Four and the overall synthesis of studies within this thesis



Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; NHS, National Health Service; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

3.2 Abstract

Objective(s): To investigate the relationship between therapist attributes and patient outcomes in studies of complex rehabilitation interventions.

Data Sources: MEDLINE, EMBASE, PsycINFO, CINAHL and the Cochrane Collaboration Library databases were searched from inception to May 2023.

Study Selection: Studies measuring at least one therapist attribute (e.g., communication skills) and exploring the attribute's impact on outcomes of patients receiving complex rehabilitation interventions were included. Identified studies were independently screened by two researchers against inclusion/exclusion criteria.

Data Extraction: Data regarding therapist attributes and patient outcomes, how they were measured and the impact of the therapist attributes on outcomes were independently extracted by two reviewers, who agreed and verified the extraction, and resolved conflicts through discussion. Critical Appraisal Skills Programme checklists were used to assess quality.

Data Synthesis: Searches resulted in 1861 titles and 128 full texts which were screened; yielding 11 studies describing rehabilitation interventions for musculoskeletal and neurological conditions. Narrative synthesis was used to describe and compare the studies to each other and the existing literature on therapist attributes. Their impact on patient outcomes were mapped onto the Capability-Opportunities-Motivation-Behaviour (COM-B) model of behaviour change. Therapist communication skills, personality traits and

autonomy-supportive behaviours were found to significantly predict aspects of patient capability, motivation, behaviour, and clinical outcomes. Measures for assessing attributes and outcomes were recorded.

Conclusions: Therapist attributes that create change in patients' capability and motivation to take the lead in and adhere to their rehabilitation might improve patients' clinical outcomes. Further research exploring how therapist attributes influence clinical outcomes in complex rehabilitation intervention studies is warranted.

Keywords: Systematic Review; Rehabilitation Research; Implementation Science; Complex interventions

3.3 Introduction

As the demand to develop and implement evidence-based interventions grows, so does the expectation on researchers and clinicians to produce good quality research. In rehabilitation, interventions tend to be complex, often with behavioural, or experience-based components that make them difficult to regulate and contextualise when compared to more passive treatments like medication or surgery (Craig et al., 2008; Skivington et al., 2021). Complex rehabilitation interventions have many interacting parts, can produce a variety of outcomes and require certain behaviours of those delivering and/or receiving them (Craig et al., 2008; Hart, 2009; Skivington et al., 2021). They can be delivered to many key stakeholders (e.g., patients, their families, and their employers) in many contexts (e.g., in hospital, at home, and at work) and are often individually tailored to the patients' unique requirements, contexts and goals with the aim of restoring or improving health after illness or addiction (Hart, 2009).

The many interacting parts of interventions makes standardisation of study design and intervention delivery difficult (Craig et al., 2008; Skivington et al., 2021) Results of complex intervention studies are underpinned by complicated causal chains and interrelationships, creating tenuous links between intervention and outcomes that are not fully assessed or understood (Abdul Latif et al., 2011; Lau et al., 2015). Exploring these complex interrelationships provides contextual information that can help researchers and clinicians better understand the factors that affect the outcomes within a study.

Implementation frameworks and theories have been proposed to identify factors that affect an intervention's delivery, receipt, and outcomes (Carroll et al., 2007; Michie et al., 2011).

Their implementation and success often relies on the people delivering or receiving the intervention behaving in a specific way (Craig et al., 2008; Skivington et al., 2021). Behaviour change models have been created to help researchers conceptualise how an intervention might generate intended changes. One such model is the Capability-Opportunity-Motivation-Behaviour (COM-B) model, which illustrates how an individual's capability (capacity to engage in an activity or behaviour), opportunity (external factors that prompt or enable behaviour), motivation (processes that energise and direct behaviour), and behaviour influence each other (Michie et al., 2011). This model posits that an intervention needs to change one or more of the components to elicit change in an individual's behaviour. The COM-B helps researchers understand what influences intervention and implementation outcomes (Nilsen, 2020), including the individual-level attributes of people delivering or receiving the intervention (Aarons et al., 2012; Damschroder et al., 2009; Wiltsey Stirman et al., 2013).

Individual-level attributes are personal characteristics of a person that can be stable, i.e., thought to stay the same over time (e.g., education, openness to change, critical thinking; Flint-Taylor et al., 2014) or unstable, which are subject to change over time (practice, engagement, illness; Arnkelsson & Smith, 2000). Studies of the factors affecting implementation of evidence-based practice have shown that attributes of both the healthcare professionals delivering (referred to as 'therapists' in this study) and the patients receiving interventions contribute to poor fidelity outcomes, or implementation failure (Grol & Wensing, 2004; Hart & Bagiella, 2012; Solberg, 2000). Therapist attitudes and beliefs towards evidence-based practice (McHugh & Barlow, 2010; Miller et al., 2020), competency (Branson et al., 2018; Campos-Melady et al., 2017), training success (Lim et al., 2012; Liness

et al., 2019), clinical experience (McHugh et al., 2009), and self-efficacy (Colquhoun et al., 2017; Eccles et al., 2005) have consistently been found to affect either fidelity or patient outcomes across patient groups, intervention type and setting (Heinonen & Nissen-Lie, 2020a; Johns et al., 2019; Nissen-Lie et al., 2023).

While there is a plethora of research within psychotherapy that evaluates the impact of therapist attributes on patient outcomes, those specialising in psychotherapy are not the only professionals who deliver complex interventions or whose various attributes may affect patient outcomes. There is a lack of research that specifically evaluates the impact of the attributes of other allied health professionals that commonly deliver complex rehabilitation interventions such as occupational therapists, physiotherapists or speech and language therapists and their impact on patient outcome. Of the studies that have measured the attributes of these professionals, the results seek to only describe their clinical knowledge (Haesler et al., 2016), competence (Jarva et al., 2021), attitudes and beliefs (Gardner et al., 2017), evidence-based practice associated behaviours (Zadro et al., 2019), and in some cases, the changes in these attributes following a training programme (Richmond et al., 2017). While these studies impart useful information about the different attributes of allied health professionals, they do not explore how the variation in these attributes might translate to clinical practice or impact on patient outcomes. Given evidence for the impact of psychotherapist attributes on patient outcome in complex interventions (Heinonen & Nissen-Lie, 2020; Johns et al., 2019; Nissen-Lie et al., 2023), research is needed in other professions that also regularly deliver complex interventions.

This systematic review explores the rehabilitation literature to evaluate what therapist attributes have been measured outside of the psychotherapy literature, how they have been measured and whether they affect patient outcomes in studies of complex rehabilitation interventions. We collate the methods used to measure each therapist attribute and patient outcome, and critically appraise the methodology of the papers included in this review in a narrative synthesis. This will help us understand what therapist attributes might affect outcomes in studies of complex rehabilitation interventions and may in turn help identify what contextual factors facilitate measurable improvements in patient outcomes in studies of complex interventions.

3.4. Methods

3.4.1. Database Search and Search Strategy

A search to identify studies relating to the research question was conducted (see Appendix 8.1). Specific keywords around healthcare intervention studies, therapist attributes and complex rehabilitation interventions were identified through a review of the literature and consultation with experts and were used to build a search strategy to be used in the electronic databases. Key 'target' papers were used to test the efficiency of the search. The search strategy was built for Ovid MEDLINE but was further adapted for other databases.

Electronic databases searched include: MEDLINE, EMBASE, PsycINFO, CINAHL and the Cochrane Collaboration Library. Database searches were conducted from inception to May 2023.

Citations from relevant studies were hand-searched and reviewed for inclusion.

3.4.2. Screening

Studies were included if they: (i) reported a therapist attribute that was (ii) reported in relation to a patient outcome in a (iii) study of a complex rehabilitation intervention delivered to (iv) adults (18+), and the study was (v) published in English and (vi) peer reviewed.

Studies were excluded if they were: (i) purely qualitative, (ii) group-based interventions or, (iii) study protocols. Due to the wealth of literature in the measurement of therapist

attributes in psychotherapy, we also excluded psychotherapy interventions delivered by psychotherapists.

No restrictions were placed on the type of patients or health conditions.

One researcher (KP) conducted the searches of the databases and removed duplicates. All remaining titles and abstracts were screened and filtered independently (KP & BD) using screening and filtering tools (Appendix 8.2) created by KP and appraised by the review team. Where it was not possible to determine a record's eligibility by title and abstract alone, the full text was obtained and reviewed. The researchers then discussed eligibility and the decisions were documented.

3.4.3. Data extraction

For titles and abstracts that passed the initial screening, full texts were obtained and read by two reviewers (KP & BD) independently to assess inclusion in the review. A data extraction table was created to capture in each study (i) therapist attributes reported and how they were measured, (ii) patient outcomes and how they were measured, and (iii) what effect the attribute had on patient outcome (Appendix 8.3). The two reviewers independently extracted the data and met to discuss any discrepancies in their data extraction tables and agree on their findings.

3.4.4. Quality Assessment

The Critical Appraisal Skills Programme Checklists (CASP), based on study design, were used to evaluate the quality of the included studies. Due to the recommendations against

excluding or weighing studies based on quality rating studies were not excluded based on quality (Carroll & Booth, 2015). Instead, limitations of the studies and how these might have influenced the results are discussed.

3.4.5. Study synthesis

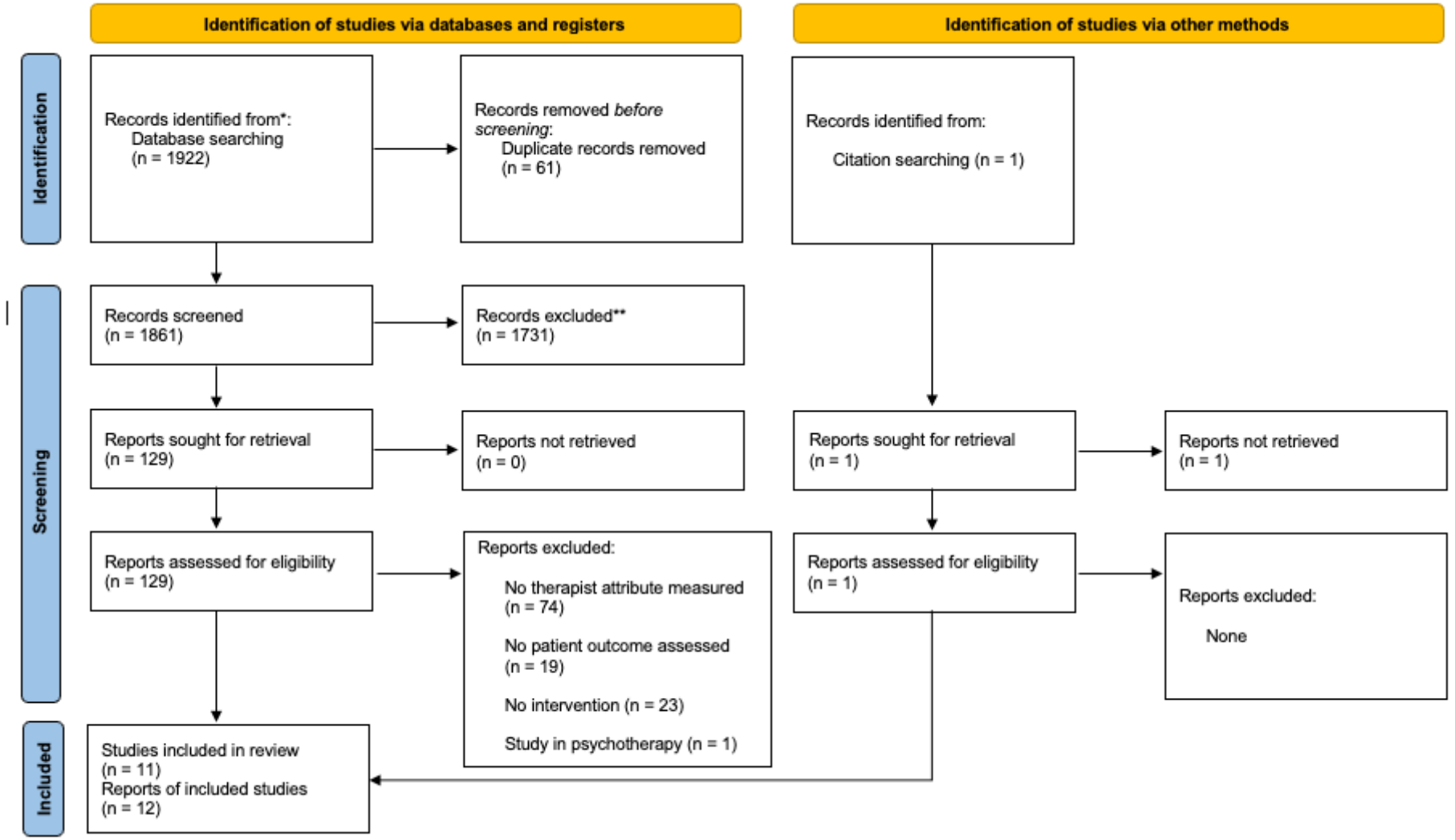
Due to the heterogeneity in the designs, purpose and outcomes measured in the studies, it was not possible to conduct a quantitative meta-analysis. A narrative synthesis approach was used to describe, critically evaluate, and compare the studies. The Capability-Opportunity-Motivation-Behaviour model (COM-B) of the Behaviour Change Wheel was used to structure and aid the synthesis by categorising therapist attributes and patient attributes and outcomes in an attempt to understand their complex interrelationships.

3.5. Results

Of the 1,861 titles and abstracts and the 128 full texts screened, 11 individual studies met the inclusion criteria. The primary search strategy identified 10 of the studies and one was identified using the snowball method. See Figure 3-2 for a flow diagram detailing screening at each stage.

Figure 3-2

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram illustrating study selection.



3.5.1. Descriptions of patients and patient-level interventions

Across the 11 studies included in this review, 4,455 patients (age range 18-94) received interventions addressing rehabilitation related to musculoskeletal pain (n=3,754; Baker et al., 2012; Chan et al., 2009; Chipchase et al., 2016; Jackson et al., 2001; Lonsdale et al., 2017; Overmeer et al., 2011), chronic diseases (n=393; Buining et al., 2015), laryngectomy (n=124; Feiner et al., 2021), traumatic brain injury (n=40; Tomaszewski, 2012; Tomaszewski et al., 2013), and dementia (n=71; Dopp et al., 2015).

Brief descriptions of patient-level interventions are given in Table 3-1.

3.5.2. Characteristics of Therapists

Within the 11 studies, nine reported interventions delivered by physiotherapists only (n=418; Baker et al., 2001; Chan et al., 2009; Jackson et al., 2012; Lonsdale et al., 2017; Overmeer et al., 2011; Tomaszewski et al., 2013), one study by occupational therapists only (n=94; Dopp et al., 2015), and one study by speech and language pathologists only (Feiner et al., 2021). Three studies did not report the number of individual therapists involved in the delivery of the intervention (Chan et al., 2009; Feiner et al., 2021; Tomaszewski, 2012; Tomaszewski et al., 2013).

3.5.3. Therapist Attributes

Therapist attributes were categorised within the COM-B model domains as being related to the therapists' 'capability', 'opportunity', 'motivation', or 'behaviour' (Michie et al., 2011). The attributes were captured using 13 measures across the 11 studies, with six of the

measures having previously demonstrated reliability and validity. See Table 3-2 for a list of measures assessing therapist attributes.

3.5.3.1. Therapist Capability

3.5.3.1.1. Participation in training

In addition to interventions delivered to patients, five studies also included interventions delivered to therapists. These interventions were training programmes targeted at improving therapist communication skills (Lonsdale et al., 2017; Tomaszewski, 2012; Tomaszewski et al., 2013), condition-specific knowledge (Chipchase et al., 2016; Dopp et al., 2015), and understanding of the biopsychosocial model of rehabilitation (Overmeer et al., 2011). Participation in the training was measured by attendance records.

3.5.3.1.2. Therapist confidence and competence

Therapist confidence to deliver aspects of the interventions was measured using a questionnaire in two studies (Chipchase et al., 2016; Jackson et al., 2012). Competence, or therapist skill and knowledge, was assessed in one study, however the method for doing so was not reported (Overmeer et al., 2011).

3.5.3.2. Therapist Opportunity

Therapist access to extra training sessions was explored for its association with patient outcomes in one study (Chipchase et al., 2016). Therapists in this study were assigned to one of two groups. The intervention group had the opportunity to access additional, 'refresher' training sessions following an initial training session. The control group only had access to the initial training session.

3.5.3.3. Therapist Motivation

3.5.3.3.1. Therapist attitudes and beliefs

Therapist beliefs about collaborative goal-setting (Baker et al., 2001) and the biopsychosocial model of rehabilitation (Overmeer et al., 2011) was measured through therapist-completed questionnaires.

3.5.3.3.2. Therapist personality traits

Therapist 'Big Five' personality traits were measured using the Big Five Inventory (Denissen et al., 2008) in two studies (Buining et al., 2015; Kooijman et al., 2020). Patient-rated therapist likeability was measured in one study using a five-point Likert scale where a rating of one meant 'not at all likeable' and a rating of five meant 'extremely likable' (Feiner et al., 2021).

3.5.3.4. Therapist behaviours

Therapist practice behaviours were the most commonly measured attributes. Therapist autonomy-supportive behaviours, or those that encourage or motivate patients to take the lead in their rehabilitation, were measured in four studies (Baker et al., 2001; Chan et al., 2009; Jackson et al., 2012; Lonsdale et al., 2017). These behaviours were measured by instruments completed through observation (Baker et al., 2001; Lonsdale et al., 2017), patient report (Chan et al., 2009; Jackson et al., 2012), and therapist report (Jackson et al., 2012).

Therapeutic approach to neck pain rehabilitation was measured through therapist-completed questionnaires in one study (Chipchase et al., 2016).

One study measured therapist engagement in mentoring or supervision from experts. Mentoring and supervision aimed to support the therapists to deliver the intervention as intended. The amount of mentoring and supervision the therapists received was recorded (Dopp et al., 2015).

Therapist adherence to the intervention protocol was measured in one study through therapist completion of written vignettes (Dopp et al., 2015).

Table 3-1

Characteristics of included studies

Article(s)	Country	Study Design	Aim	Population (number of participants)	Type of Therapist (number of therapists)	Intervention	Therapist Attribute Measured	Patient Outcomes Measured	Results
Baker et al. (2001)	USA	Cohort study	To examine whether therapists seek to involve patients in goal setting and, if so, what methods they use. Therapists' attitudes toward participation and patient satisfaction with the examination were also examined.	Geriatric rehabilitation patients (n=73)	Physiotherapists (n= 22)	Goal-driven, individualised geriatric patient rehabilitation	Therapist approach, attitudes and beliefs toward goal-setting	Patient satisfaction	Nonparametric correlations were computed using Spearman rank correlation coefficients. An analysis of variance (ANOVA) was applied to the therapist and patient data. (-) No significant relationship between therapists' approach[a], attitudes and beliefs toward goal setting and clinical practice[a] nor participant satisfaction[a]. (+) Therapists' explanation of the relationship of the intervention to the participants' rehabilitation goals was correlated with participant satisfaction (*r* =.43, *P*=.05)

Buining et al. (2015)	The Netherlands	Cohort study	To explore the influence of therapist personality traits on treatment outcomes of patients with chronic diseases.	Patients with chronic diseases (n = 393)	Physiotherapists (n = 39)	Individualised physiotherapy for improving pain in chronic diseases.	Therapists' 'Big Five' personality traits	Treatment outcome (severity of complaint)	Data was analysed using multi-level linear regression. (+) Therapist neuroticism was found to have a significant association with patient treatment outcome (F=0.71, *P*=0.01). Patients treated by therapists with lower neuroticism scores have greater reduction in severity of their complaint.
Chan et al. (2009)	China	Cohort study	To investigate the impact of physiotherapists' autonomy-supportive behaviours on patients' motivation and rehabilitation after anterior cruciate ligament (ACL) reconstruction surgery.	Post-surgery ACL patients (n=115)	Physiotherapists (n=115)[b]	Sports injury physiotherapy rehabilitation for anterior cruciate ligament	Physiotherapists' autonomy-supportive behaviours	Patient treatment motivation and self-reported rehabilitation adherence	Mediation analysis was conducted by first using a direct effect model, then a mediation model and last a combined effects model. *Direct effects model:* (+) Autonomy support predicted rehabilitation adherence (γ=.26, *P*<.05). *Mediation model:* (+) Autonomous treatment motivation predicted rehabilitation adherence (β=.62, *P*<.05) (+) Autonomous treatment motivation positively

									associated with autonomy-supportive behaviours (γ=.22, *P*<.05). *Combined effects model:* (+) Significant indirect effect of autonomy-supportive behaviours on rehabilitation adherence (γ=.16, *P*<.05).
Chipchase et al. (2016)	Australia	RCT	To determine whether a traditional CPD workshop with a follow-up session with the educator is more likely to change physiotherapists' practice behaviour and patient outcomes than a traditional workshop with no opportunity for follow-up.	Neck pain patients (158)	Physiotherapists (23)	Therapist: Continuing professional development workshop with opportunity for follow-up session Patient: Research-informed multimodal therapeutic exercise program	Confidence and practice behaviour	Patient clinical outcome	Repeated measures ANOVA: (-) No significant differences in patient ratings of neck pain between groups of therapists (Neck Disability Index: F=.36, *P*=.56)
Döpp et al. (2015)	The Netherlands	Cluster RCT	To evaluate the effectiveness of a training package to implement a	People with dementia (71)	Occupational Therapists (94)	Therapist: Extra training, coaching and ongoing	Adherence to programme delivery, amount of coaching	Patient daily functioning, self-perceived performance	Mixed-model analysis and covariate analyses:

			community occupational therapy programme for people with dementia and their caregiver.			support in delivery of intervention Patient: Client-centred and home-based occupational therapy programme	received, knowledge of dementia, experience of delivering intervention (number of patients), support from occupational therapy colleagues.	in meaningful daily activities and quality of life	(+) Positive relationship between amount of coaching and therapist adherence (*b*= 0.3, SE *b*= 0.2, *p*=0.03, CI 95% 0.03 to 0.62) (+) OTs with more experience of delivering the intervention previous to the study had lower adherence ratings (*b*= -0.9, SE *b*= 0.4, *p*= 0.03,CI 95% -1.69 to -0.07) (-) No relationship between successful training completion and client or caregiver outcomes.
Feiner et al. (2021)	Germany	Cohort study	To assess the association between therapist likeability and patient speech intelligibility following a laryngectomy.	Patients who had recently undergone laryngectomy (124)	Speech and language therapists in 13 centres[b]	Post-laryngectomy speech and language therapy	Patient-rated therapist likeability	Patient objective and subjective speech intelligibility.	(-) Therapist likeability was not significantly associated with objective (OR= 3.1; 95% CI = 0.78-2.18; p=0.32) or subjective (OR = 1.01; 95% CI = 0.60-1.72; p=0.96) speech intelligibility
Jackson et al. (2012)	Australia	Cohort study	To explore the potential relational outcomes, between	Patients with lower-limb musculoskeletal disorder (n=68)	Physical therapists (n=68)	One-to-one, clinic-based exercise programme	Therapist self-efficacy beliefs, therapist 'other-efficacy' beliefs, therapist	Client self-, other- and relation inferred self-efficacy	Actor-Partner Interdependence Model (+) Clients viewed their relationship more positively

			therapists, clients, associated with "tripartite efficacy framework" in a rehabilitation context.			with consultation	relation inferred self-efficacy beliefs	beliefs, perception of the relationship with therapist and client engagement	when their therapist was highly confident in the client's ability (*b*= .59, t_{61}= 3.22, *p*=.002).
Kooijman et al. (20200	The Netherlands	Cohort study	To explore the relationship between therapist personality and patient outcome.	Patients with shoulder pain (n=2814)	Physiotherapists (n=56)	Individualised physiotherapy for shoulder pain	Therapist 'Big 5' personality traits	Patient-reported severity of shoulder complaint	Univariate and multi-level regression analyses were used. Therapist extraversion was significantly associated with change in patient treatment outcome (B=-0.57; 95% CI = -1.07-0.06; p=0.03).
Lonsdale et al. (2017)	Ireland	Cluster RCT	To assess the effect of an intervention designed to enhance physiotherapists' communication skills on patients' adherence to recommendations regarding home-based rehabilitation for chronic low back pain.	Patients with chronic low back pain (n=255)	Physiotherapists (n=53)	Therapist: 8-hours of training in enhancing communication skills Patient: Individualised, physiotherapy care for chronic low-back pain.	Therapist participation in communication skills training, motivational orientation personality style	Patient-reported adherence, pain and pain-related function	Linear Mixed-model Analysis: (+) Therapist training had a positive effect on patient self-reported home-based exercise adherence (*d*=.28, *p*= .01) (-) Therapist training had no significant effect on in-clinic adherence (-) Therapist training had no significant effect on physical activity

									(-) Therapist training had no significant effect on clinical outcomes (pain, function and satisfaction with treatment) (-) Therapist training had no significant effect on patient quality of life. (+) Therapist training had a positive effect on patients' perceptions of competence to follow their physiotherapists' recommendations (*d*=.66, *p*<.01) (+) Therapist training had a positive effect on patients' amotivation (*d*=-.42, *p*=.01) (-) Therapist training had no significant effect on controlled motivation (*p=.71)* (-) Therapist training had no significant effect on fear-avoidance beliefs (*p*=.36)

Overmeer et al. (2011)	Sweden	RCT	Examine the effects on outcomes (pain and disability) in patients on a course about psychosocial prognostic factors for physical therapists.	Patients with acute and subacute musculoskeletal pain (n=229)	Physical therapists (n=42)	Therapists: Specialised training in the benefits and delivery of biopsychosocial intervention Patients: Biopsychosocial manualised treatment programme	Therapist attitudes and beliefs in biopsychosocial, knowledge and skills, training completion	Patient pain, disability catastrophising and mood	Two-way univariate ANOVA: (-) Therapist training had no significant effect on patient pain (F = 0.85, *df*=1,225, *p*=.9) or disability (F=1.1, *df*1,222, *p*=.3) outcomes. Three-way univariate ANOVA: (-) Therapist training had no significant effect on pain outcomes for patients classified as being in the high-risk (catastrophising and depression) group (F=2.38, *df*=1,221, *p*=.1)
Tomaszewski et al. (2013), Tomaszewski (2012)	Poland	RCT	Evaluate the health-related quality of life in patients aroused from prolonged coma after a severe TBI treated by physiotherapists trained in the 'Academy of Life' programme. (2013)	2013: Patients aroused from prolonged coma (n=40) 2012: Patients with TBI (n=40)	Two teams of physiotherapists working in a rehabilitation clinic (2013) Two teams of therapists working in a rehabilitation clinic (2012)	Therapist: 'Academy of Life' training programme Patient: Multi-phased rehabilitation programme	Therapist participation in communication skills training	Rehabilitation outcome (2013, 2012) Quality of life (2013)	2013: (+) Participants who received rehabilitation from the therapists who had received training experienced significant improvement of Functional Motor Capacity between baseline and the final follow-up time point (x^2=43.91, *p*=.0005). Participants who received rehabilitation from the therapists who had not

			Evaluate the effectiveness of rehabilitation of TBI patients when conducted by therapists who had participated in a training programme on effective patient communication, as compared to rehabilitation administered by therapists without this training. (2012)						received training did not experience significant improvement of functional motor capacity between baseline assessment and the final follow-up time point (x^2=5.51, *p*=.5) (+) Participants who received rehabilitation from the therapists who had received training experienced significant improvement of Social Functions between baseline and the final follow-up time point (x^2=22.253.91, *p*=.001). Participants who received rehabilitation from the therapists who had not received training did not experience significant improvement of functional motor capacity between baseline assessment and the final follow-up time point (x^2=1.146, *p*=1) 2012: (+) Participants who received rehabilitation from the therapists who

									had received training experienced significant improvement of mental and physical comfort between baseline and the final follow-up time point (x^2=45.95, *p*=.0001). Participants who received rehabilitation from the therapists who had not received training did not experience significant improvement of mental and physical comfort between baseline assessment and the final follow-up time point (x^2=3.03, *p*=.8) (+) Participants who received rehabilitation from the therapists who had received training experienced significant improvement in their ability to communicate in social situations between baseline and the final follow-up time point (x^2=27.04, *p*=.001). Participants who received rehabilitation from the therapists who had not

									received training did not experience significant improvement in their ability to communicate in social situations between baseline assessment and the final follow-up time point (x^2=1.41, *p>.5*)

Abbreviations: ACL, anterior cruciate ligament; ANOVA, analysis of variance; CI, confidence interval; CPD, continuing professional development; OR, odds ratio; OT, occupational therapist; RCT, randomised controlled trial; TBI, traumatic brain injury; USA, United States of America

3.5.4. Patient Outcomes

Patient outcomes were categorised within the COM-B model as capturing patient 'capability', 'opportunity', 'motivation', or 'behaviour' in an attempt to map their complex interrelationships with patient clinical outcomes. Eleven studies used at least one measure with established validity and reliability to assess patient outcomes. See Table 3-3 for the measures used to capture each patient outcome.

3.5.4.1 Patient Capability

Patient competence to follow therapist recommendations was measured in one study (Lonsdale et al., 2017).

Patient communication skills were measured in one study (Tomaszewski, 2012; Tomaszewski et al., 2013) using patient-completed questionnaires.

3.5.4.2. Patient Opportunity

Patient opportunity (i.e., available resources and environmental factors) was not measured in any of the included studies.

3.5.4.3. Patient Motivation

3.5.4.3.1. Treatment Motivation

Treatment motivation was measured for patients undergoing rehabilitation following anterior cruciate ligament reconstruction (Chan et al., 2009) and for patients with lower limb degenerative musculoskeletal conditions (Lonsdale et al., 2017) through patient self-reported questionnaires.

3.5.4.3.2. Patient Satisfaction

Patients receiving goal-driven, individualised pain rehabilitation were asked to report satisfaction with their physiotherapist's ability to collaboratively set rehabilitation goals through a patient completed satisfaction survey (Baker et al., 2001).

3.5.4.4. Patient Behaviour

3.5.4.4.1. Patient Adherence to Treatment Programme

Patient adherence to their rehabilitation programmes was measured by patient self-report in three studies, all of which involved a physiotherapy home exercise programme (Chan et al., 2009; Jackson et al., 2012; Lonsdale et al., 2017).

Seven other studies included in the review comprised home-based exercises but did not measure patient adherence to these programmes (Baker et al., 2001; Buining et al., 2015; Chipchase et al., 2016; Feiner et al., 2021; Kooijman et al., 2020; Overmeer et al., 2011; Tomaszewski, 2012; Tomaszewski et al., 2013).

3.5.4.5. Patient Clinical Outcomes

Patient clinical outcomes of pain, function and disability were most commonly measured. These outcomes were measure in eight of the included studies through patient-reported questionnaires assessing pain and disability (Buining et al., 2015; Chipchase et al., 2016; Dopp et al., 2015; Feiner et al., 2021; Kooijman et al., 2020; Lonsdale et al., 2017; Overmeer et al., 2011; Tomaszewski, 2012; Tomaszewski et al., 2013) and quality of life (Dopp et al., 2015; Lonsdale et al., 2017; Tomaszewski, 2012; Tomaszewski et al., 2013).

Table 3-2

Measures of Therapist Attributes Used in the Included Studies

Measure	Reference	Measure Focus	Studies Used
Participation Method Assessment Instrument (PMAI)*	Baker et al. (2001); Northen et al. (1995)	Therapist approach to goal setting	Baker et al. (2001)
Therapist opinion survey	Baker et al. (2001)	Therapist attitudes about participant participation	Baker et al. (2001)
Health Care Climate Questionnaire (HCCQ)*	Williams et al. (1996)	Therapists' autonomy-supportive behaviours	Chan et al. (2009)
Practice behaviour questionnaire	Chipchase et al. (2016)	Therapist practice behaviours and confidence to carry out assessment	Chipchase et al. (2016)
Case vignette	Döpp et al. (2017)	Therapist adherence to the intervention	Döpp et al. (2017)
Coaching attendance records	Döpp et al. (2017)	Amount of intervention coaching received	Döpp et al. (2017)
Therapist questionnaire	Döpp et al. (2017)	Experience of delivering the intervention and knowledge of dementia	Döpp et al. (2017)
Therapist likeability question (5-point Likert scale)	Feiner et al. (2021)	Patient-rated therapist likeability	Feiner et al. (2021)
Relationship Assessment Scale (RAS)*	Hendrick et al. (1998)	Therapist perception of the therapeutic relationship with the patient/client	Jackson et al. (2012)

Measure	Reference	Measure Focus	Studies Used
Tripartite Efficacy Measurement	Jackson et al. (2012)	Therapist self-efficacy, therapist-perceived client-efficacy, relationship with client	Jackson et al. (2012)
Big Five Inventory (Dutch Version)*	Denissen et al. (2008)	Big Five personality traits (extraversion, agreeableness, openness, conscientiousness, and neuroticism	Buining et al. (2015); Kooijman et al. (2020)
Pain Attitudes and Beliefs Scale for Physical Therapists (PABS-PT)*	Ostelo et al. (2003)	Therapist attitudes and beliefs towards psychosocial factors	Overmeer et al. (2011)
Health Care Providers Pain and Impairment Relationship Scale (HC-Pairs)*	Houben et al. (2004); Rainville et al. (1995)	Provider attitudes and beliefs about the relationship between pain and impairment	Overmeer et al. (2011)

*Demonstrated validity and reliability

Table 3-3

Measures of Patient Outcomes in the Included Studies

Measure	Reference	Measure Focus	Studies Used
Patient Satisfaction Survey	Baker et al. (2001)	Patient satisfaction with treatment	Baker et al. (2001)
Treatment Self-Regulation Questionnaire *	Ryan & Connell (1989)	Patient treatment motivation	Chan et al. (2009)
Adapted Sports Injury Rehabilitation Adherence Scale (SIRAS) *	Kolt et al. (2007)	Patient-reported rehabilitation adherence	Chan et al. (2009); Lonsdale et al. (2017)
Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence *	Bassett (2003)	Patient-reported rehabilitation adherence	Chan et al. (2009)
Neck Disability Index (NDI) *	Vernon (2008)	Patient-reported neck pain and disability	Chipchase et al. (2016)
Assessment of Motor Process and Skills (AMPS)*	Fisher (2003)	Patient levels of daily functioning	Döpp et al. (2015)
Interview for Deterioration of Daily Activities in Dementia (IDDD)*	Teunisse & Derix (1997); Voigt-Radloff et al. (2012)	Patient levels of daily functioning	Döpp et al. (2015)
Canadian Occupational Performance Measure (COPM)*	Law et al. (1990)	Patient self-perceived performance in meaningful daily activities	Döpp et al. (2015)
Dementia Quality of Life Instrument (DQOL) *	Brod et al. (1999)	Quality of life in patients with dementia	Döpp et al. (2015)

Measure	Reference	Measure Focus	Studies Used
Post-Laryngectomy Telephone Intelligibility Test*	Zenner (1986); De Maddalena & Zenner (1996); Glunz et al. (2011)	Objective speech intelligibility	Feiner et al. (2021)
Questionnaire for Adjustment after Laryngectomy	De Maddalena et al. (1991)	Subjective speech intelligibility	Feiner et al. (2021)
Relationship Assessment Scale (RAS) *	Hendrick et al. (1998)	Patient/client perception of the therapeutic relationship with their therapist	Jackson et al. (2012)
Tripartite Efficacy Measurement	Jackson et al. (2012)	Client self-efficacy, client-perceived therapist-efficacy, relationship with therapist	Jackson et al. (2012)
International Physical Activity Questionnaire – short form (IPAQ) *	Craig et al. (2003)	Patient level of physical activity	Lonsdale et al. (2017)
Numerical Rating Scale *	Deyo et al. (1998)	Patient ratings of pain intensity and how 'bothersome' the pain is	Lonsdale et al. (2017); Buining et al., (2015); Kooijman et al. (2020)
Global Perceived Effect Scales *	Kamper et al. (2010)	Patient perception of recovery	Lonsdale et al. (2017)
Roland-Morris Disability Questionnaire *	Roland & Fairbank (2000)	Patient reported function and disability	Lonsdale et al. (2017)
Patient-Specific Functional Scale (PSFS) *	Kowalchuk Horn et al. (2012)	Patient reported pain-related function	Lonsdale et al. (2017)
European Quality of Life Questionnaire (EurQoL) *	Hurst et al. (1997)	Patient quality of life	Lonsdale et al. (2017)

Measure	Reference	Measure Focus	Studies Used
Fear-Avoidance Beliefs Questionnaire (FABQ) *	Waddell et al. (1993)	Patient beliefs of how activity affects pain	Lonsdale et al. (2017)
Treatment Self-Regulation Questionnaire (TSRQ) *	Ryan & Connell (1989)	Patient autonomous motivation to follow recommendations	Lonsdale et al (2017)
Orebro Musculoskeletal Pain Screening Questionnaire *	Johnston (2009)	Patient ratings of pain	Overmeer et al. (2011)
Quebec Back Pain Disability Scale *	Kopec et al. (1996)	Patient ratings of back pain and disability	Overmeer et al. (2011)
Pain Catastrophizing Scale (PCS) *	Sullivan et al. (1996)	Patient catastrophising	Overmeer et al. (2011)
Hospital Anxiety and Depression Scale (HADS) *	Zigmond & Snaith (1983)	Patient mood	Overmeer et al. (2011)
Efficacy Assessment Scales for TBI Patients *	Pąchalska & MacQueen (1998)	Patient pain management, mood and communication.	Tomaszewski (2012)
Quality of Life Scale for TBI Patients *	Pąchalska & MacQueen (1998)	Patient quality `of life	Tomaszewski et al. (2013)

*Demonstrated validity and reliability

3.5.5. Impact of Therapist Attributes on Patient Outcomes

Through mapping therapist attributes and patient outcomes onto the COM-B model for behaviour change (Michie et al., 2011), complex interrelationships between therapist attributes and patient outcomes were explored. For a visual representation of the interrelationships between therapist attributes and patient outcomes, see Figure 3-2.

3.5.5.1. Therapist Capability

3.5.5.1.1. Therapist Participation in Training

Success of the therapist training programmes was measured through therapist adherence assessments (Dopp et al., 2015; Lonsdale et al., 2017), competency assessment (Overmeer et al., 2011) and by pre- and post-training questionnaires measuring therapist attitudes and behaviours (Overmeer et al., 2011). Neither training in dementia care nor communication skills was found to influence greater therapist protocol adherence (Dopp et al., 2015; Lonsdale et al., 2017). Training in the biopsychosocial model of rehabilitation was found to significantly improve therapists' attitudes and behaviours towards the biopsychosocial model (Overmeer et al., 2011).

Therapist participation in communication skills training was shown to improve the social functioning (Tomaszewski, 2012; Tomaszewski et al., 2013) and independence in activities of daily living (Tomaszewski et al., 2013) of patients with traumatic brain injury (n=40). This study indicated that the communication skills training programme was intended to improve therapists' patient-supportive behaviour, which might then influence patient adherence to rehabilitation programme and lead to improved patient outcomes, but this was not measured.

3.5.5.1.2 Therapist Competence & Confidence

Chipchase and colleagues (2016) found that physiotherapist confidence to treat patients with neck pain was not associated with differences in practice behaviour (approaches to neck pain rehabilitation), nor was it associated with improvements in patient functional

outcome in 158 patients and 23 physiotherapists. Conversely, Jackson and colleagues (2012) found that higher therapist confidence was associated with more pro-social therapist behaviour.

3.5.5.2. Therapist Motivation

3.5.5.2.1. Therapist Attitudes and Beliefs

Despite finding favourable therapist attitudes and beliefs towards collaborative goal-setting (n=22; Baker et al., 2001) and the biopsychosocial model (n=42; Overmeer et al., 2011), these attitudes were not found to influence changes in clinical practice behaviour (Baker et al., 2001) or patient functional outcomes (n=229; Overmeer et al., 2011). Baker and colleagues (Baker et al., 2001) reflected that therapist (n=22) confidence to implement collaborative goal-setting might have influenced practice behaviour, but this was not measured. Overmeer and colleagues (2011) did not measure practice behaviour in their study.

Döpp and colleagues (2015) hypothesised that both attitudes and beliefs towards evidence-based practice and confidence to deliver the intervention might influence greater levels of protocol adherence in OTs (n=94), but this was not measured.

3.5.5.2.2. Therapist Personality Traits

Patients with chronic diseases (n=393) who were treated by physiotherapists (n=39) with higher neuroticism scores were more likely to have worse treatment outcomes (Buining et al., 2015). Patients with chronic shoulder pain (n=2814) who were treated by physiotherapists (n=56) with higher scores of extraversion were more likely to have better treatment outcomes (Kooijman et al., 2020).

Both Buining et al. (2015) and Kooijman et al. (2020) reflected that physiotherapists with certain personality traits might influence patient adherence to at-home exercise programmes, but patient adherence was not measured in these studies. Similarly, Feiner

et al. (2021) hypothesised that more 'likeable' speech and language therapists would be able to motivate their patients to adhere to at-home rehabilitation and thereby produce better speech intelligibility. However, Feiner et al. (2021) did not measure motivation or patient adherence in their study.

3.5.5.3. Therapist Behaviours

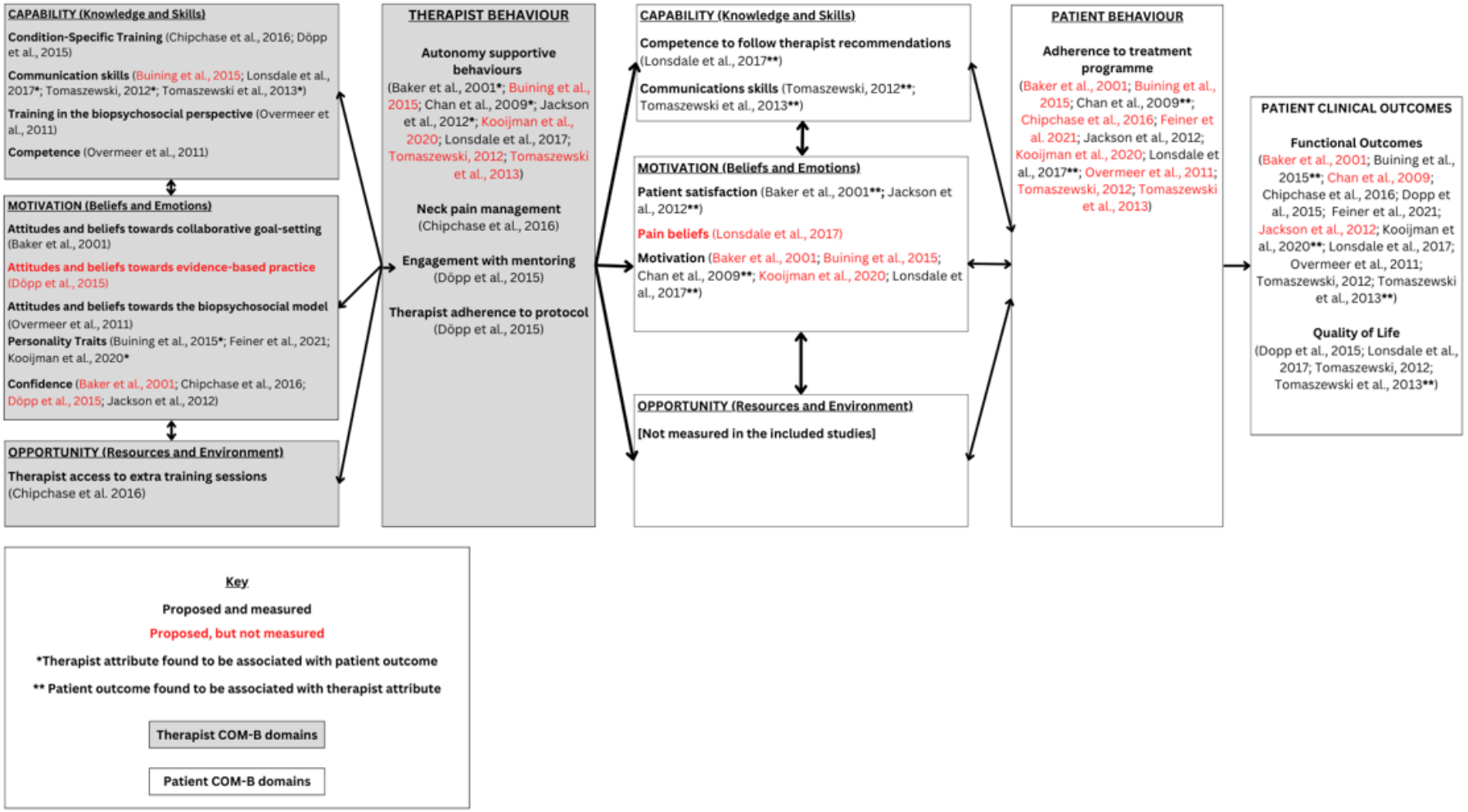
Physiotherapists' increased autonomy-supportive behaviours towards patients was found to be associated with increases in patient motivation to engage in rehabilitation (Chan et al., 2009; Lonsdale et al., 2017) and adherence to at-home rehabilitation (Jackson et al., 2012). Higher ratings of therapist collaborative goal-setting behaviour were not found to influence patient satisfaction in Chan and colleagues' (2009) study, however, all patients reported high levels of patient satisfaction. Chan and colleagues hypothesised that patient satisfaction would in turn influence patient motivation, adherence to home-based exercise and functional outcomes, but these were not measured (Chan et al., 2009).

In Döpp and colleagues' study (Dopp et al., 2015), OT (n=94) engagement with mentoring was found to significantly increase OTs' adherence to protocol, however, adherence was still reportedly low and did not translate to significant improvements in functional or quality of life outcomes for people with dementia (n=71) or their carers (n=71). Similarly, engagement in mentoring did not produce significant changes to physiotherapists' (n=23) approaches to neck pain rehabilitation and subsequently, there were no significant improvements to patients' (n=158) pain and disability outcomes (Chipchase et al., 2016).

Physiotherapist (n=53) adherence to intervention protocol was shown to significantly improve patient (n=255) adherence to home-based rehabilitation for chronic low back pain, but had no significant effect on patient pain, disability, or quality of life outcomes (Lonsdale et al., 2017). The authors propose that patient pain-related fear-avoidant beliefs may have influenced patients' pain and disability outcomes, but this was not measured.

Figure 3-3

Interrelationships between therapist attributes and patient outcomes in the included studies mapped to the COM-B domains (Michie et al., 2011).



Abbreviations: COM-B, Capability-Opportunity-Motivation-Behaviour model of behaviour change

3.5.6. Quality Assessment of Included Studies

The risk of bias in the 12 included studies was low (See Figures 3-3 and 3-4). Quality was quantified based on a scoring system where 'Yes' was awarded two points, 'Cannot Tell' was awarded one point, and 'No' was awarded zero points. Two records (Tomaszewski, 2012; Tomaszewski et al., 2013) were thought to be related publications reporting different outcomes from the same sample of patients due to similarities in the reported demographics of their study participants. The authors of these publications were contacted for confirmation, but no response was received, and the decision was made to retain both records. For the purposes of this review, the data were extracted from these two records and reported as results of the same study with references made to the appropriate publication where needed.

Figure 3-4

Quality assessment of Randomised Controlled Trials using the CASP Checklist

	Chipchase et al., 2016	Dopp et al., 2015	Lonsdale et al., 2017	Overmeer et al., 2011	Tomaszewski, 2012; Tomaszewski et al., 2013
Did the trial address a clearly focused issue?	Y	Y	Y	Y	Y
Was the assignment of patients to treatments randomised?	Y	Y	Y	Y	C
Were all of the patients who entered the trial properly accounted for at its conclusion?	Y	Y	Y	Y	Y
Were patients, health workers and study personnel 'blind' to treatment?	N	N	Y	C	N
Were groups similar at the start of the trial?	Y	C	Y	C	N
Aside from the experimental intervention, were the groups treated equally?	Y	Y	Y	Y	C
Can the results be applied to the local population, or in your context?	C	C	C	C	C
Were all clinically important outcomes considered?	Y	C	Y	N	C
Are the benefits worth the harms and costs?	Y	Y	Y	Y	Y
Total (out of 18 possible points)	**15**	**13**	**17**	**13**	**10**

Y: Yes (2 points) C: Cannot Tell (1 point) N: No (0 points)

Figure 3-5

Quality assessment of cohort studies using the CASP Checklist

	Baker et al., 2001	Buining et al., 2015	Chan et al., 2009	Feiner et al., 2021	Jackson et al., 2012	Kooijman et al., 2020
Did the study address a clearly focused issue?	Y	Y	Y	Y	Y	Y
Was the cohort recruited in an acceptable way?	Y	Y	Y	Y	Y	Y
Was the exposure accurately measured to minimise bias?	Y	Y	C	C	C	Y
Was the outcome accurately measured to minimise bias?	Y	Y	C	Y	C	Y
Have the authors identified all important confounding factors?	C	C	C	C	C	C
Have they taken account of the confounding factors in the design and/or analysis?	C	Y	Y	C	C	Y
Was the follow up of subjects complete enough?	Y	Y	Y	Y	Y	Y
Was the follow up of subjects long enough?	Y	Y	Y	Y	Y	Y
Do you believe the results?	Y	Y	Y	Y	Y	Y
Can the results be applied to the local population?	Y	Y	Y	Y	Y	Y
Do the results of this study fit with other available evidence?	Y	Y	Y	Y	Y	Y
Total (out of 22 possible points)	**20**	**21**	**19**	**19**	**18**	**21**

Y: Yes (2 points) C: Cannot Tell (1 point) N: No (0 points)

3.6 Discussion

This review examined the complex rehabilitation intervention literature to understand the potential for therapist attributes to affect variation in outcomes of patients receiving complex rehabilitation interventions. Eleven studies of healthcare professionals delivering complex rehabilitation interventions to a range of patient groups met the selection criteria for this review. Intervention aims, duration and outcomes varied greatly between the studies. Therapist attributes and patient outcomes were mapped onto the COM-B model of behaviour (Michie et al., 2011) in an attempt to understand the interrelationships between them. The results regarding the impact of therapist attributes on patient outcomes suggested that therapists' autonomy-supportive behaviours, or behaviours that encourage or motivate patients to take the lead in their rehabilitation, influence patient motivation and adherence to at-home rehabilitation programmes, which might lead to improved patient clinical outcomes (e.g., pain and disability). Other attributes found to be associated with improved patient outcomes in this review, such as therapist communication skills and personality traits, were proposed to promote autonomy-supportive behaviours in therapists. This review is the first to our knowledge seeking to understand the impact of therapist attributes on patient outcomes outside of the psychotherapy literature.

Three of the four studies that directly measured autonomy-supportive behaviours reported significant positive effects of therapist autonomy-supportive behaviours on patient satisfaction outcomes (Baker et al., 2001; Jackson et al., 2012;) and patient adherence to their treatment programme (Chan et al., 2009). However, none of these studies measured patient clinical outcomes of function, pain, disability, or quality of life. Within the discussion sections of their publications, Baker and colleagues (2001) and Jackson and colleagues (2012) both reflect that patient satisfaction might lead to greater patient adherence to exercise programmes. Chan and colleagues (2009) similarly reflect that greater patient adherence to exercise programmes should facilitate improvement in

patient pain and disability ratings and quality of life. Two of the three studies that measured therapist personality traits demonstrated that more extraverted (Kooijman et al., 2020) and less neurotic (Buining et al., 2015) therapists are associated with greater improvements in patient ratings of pain. Whilst not measured in either study, both authors suggest that these personality traits lead to the therapist engaging in more pro-social behaviour that might encourage patient adherence to at-home rehabilitation, resulting in the observed improvements in pain ratings. The notion that patient adherence to their at-home exercise programme is inherently linked to functional outcomes is supported by systemic reviews within physiotherapy, which emphasise that adherence is 'central to the success of therapy' (Bachmann et al., 2018; Essery et al., 2017).

The psychotherapy research regarding autonomy-supportive behaviours indicates that these behaviours are helpful in encouraging behaviour-change in patients (Ryan et al., 2011) and that these changes go on to positively affect patient outcomes (Ackerman & Hilsenroth, 2003; Atkins et al., 2017; Martin et al., 2000). Similarly, therapist friendliness and ability to communicate effectively has been found to be associated with better outcomes for patients experiencing depression (Constantino et al., 2008; Coyne et al., 2018; Zuroff et al., 2017). These communication skills are proposed to lead to 'autonomy granting' behaviour, which leads to reduction in depression ratings (Constantino et al., 2021). Taking the results of this review together with findings from the psychotherapy literature, it seems therapist attributes that facilitate therapist autonomy-supportive behaviours, such as therapist communication skills and extraverted personality traits, generate better patient outcomes.

Relating the results of this review to research within psychotherapy, there are some interesting points of comparison. The studies included in this review assess therapist attributes that are more subjective, socio-emotional professional attributes, i.e., attributes regarding the therapist's ability to communicate with or relate to others.

Previous psychotherapy studies have identified these attributes as being more predictive of patient outcomes than more objective professional attributes such as education and experience (Heinonen & Nissen-Lie, 2020; Nissen-Lie et al., 2023). Despite the similarities in the attributes that are measured, the most notable difference is in the sheer number of studies examining the effect of therapist attributes on patient outcome and the range of attributes measured. For comparison, the most recent review of the impact of therapist attributes on patient outcomes in psychotherapy, conducted by Heinonen and Nissen-Lie (2020), included 31 studies published between 2000-2018.

With regards to measurement, this review also found that some therapist and patient domains of the COM-B were more commonly measured than others. Attributes within the therapist behaviours domain were measured most often, which is perhaps because these are the most observable and objective attributes. Similarly, patient clinical outcomes were the most frequently measured patient outcomes. Again, this may be due to the more objective nature of these outcomes when compared with patients' capabilities, opportunities, and motivations. However, patient adherence to their rehabilitation programme was suggested by all eight of the included physiotherapy studies to be essential to improving patient pain and disability, but this was only measured in three (Chan et al., 2009; Jackson et al., 2012; Lonsdale et al., 2017). Future research should seek to routinely include patient adherence as a variable for exploring not only the impact of therapist attributes, but also exploring the impact of adherence on functional outcomes.

Consideration for the therapists' adherence to the intervention they delivered was only given in two of the studies (Dopp et al., 2015; Lonsdale et al., 2017). Therapist adherence to an intervention is an important consideration because without information about what was or was not delivered to the patient, researchers cannot be sure that the variation in results is related to the intervention or to the variation in therapist attributes (Carroll et al., 2007a; Damschroder et al., 2009). Intervention efficacy outcomes rely on

the standardisation of intervention delivery, which is also especially difficult to measure in studies complex interventions as they are often tailored to meet the diverse needs, contexts and goals of the patients receiving them.

Despite the plethora of measures identified in previous systematic reviews of therapist attributes and their impact on patient outcomes in psychotherapy, only six studies within this review included previously established, reliable and valid measures of therapist attributes (Table 3-2; Baker et al., 2001; Chan et al., 2009; Jackson et al., 2012; Overmeer et al., 2011). Most of the studies were also limited in the numbers of patient participants and by the small numbers of therapists delivering the interventions, whose attributes were assessed. To evaluate the potential relationship more effectively between therapist attributes and patient outcome, and help researchers to draw more confident conclusions, larger studies involving greater numbers of therapists are required. Kooijman and colleagues (2020) used a primary care database to access the data of patients treated by therapists who consented to the study (n=56) to achieve their large number of patient participants (n=2814). Kooijman and colleagues' approach to conducting research on the impact of therapist attributes might serve as a model for how to conduct this research in future to achieve higher numbers of therapists and patients.

Another interesting finding of this review was that only one included study was in occupational therapy (Dopp et al., 2015). Occupational therapy is by definition a highly complex rehabilitation intervention (Creek, 2009; Creek et al., 2005) that can involve delivering components of interventions to stakeholders across many different contexts, increasing the number of factors that influence patient outcome (Carroll et al., 2007a; Damschroder et al., 2009). This level of complexity in occupational therapy is what makes assessing outcomes and their interrelationships particularly difficult. Occupational therapy interventions are inherently challenging to observe or record due to the multiple contexts in which the intervention delivery takes place and the multiple stakeholders involved. However, research investigating the effectiveness of occupational therapy

interventions in which these outcome assessments typically occur is still in its infancy in occupational therapy, which may explain the limited number of studies when compared to physiotherapy and psychotherapy studies.

3.6.1. Study Limitations

Whilst the results of this review suggest that therapist autonomy-supportive behaviours impact patient outcomes, the only studies that showed associations between therapist attributes and patient outcomes were physiotherapy studies. Therefore, the results of this review may not be generalisable to other disciplines. This review is also limited by the lack of shared taxonomy between disciplines. It is possible that there are terms referring to therapist attributes that were not picked up by the search strategy. Future research may look to bridge or map taxonomy within and between disciplines to better understand the concepts and processes that surround clinical practice. Publication bias, or withholding research with negative results from publication (Joober et al., 2012), should also be taken into consideration when interpreting these results as there may have been further unpublished studies in this area that did not find a predictive relationship between therapist attributes and patient outcomes.

3.6.2. Future Research

This review highlights some promising avenues for future research. Future studies should consider further exploring the indirect impact therapist attributes might have on patient clinical outcomes to understand the mechanisms and processes by which impact occurs. Using behaviour change frameworks, such as the Behaviour Change Wheel, which comprises the COM-B, can further help researchers understand these indirect impacts of therapist attribute on targeted patient outcomes in complex rehabilitation intervention studies (Michie et al., 2011). These studies should be designed to include greater numbers of therapists to achieve the power needed to better understand what influences the variability in patient outcomes within a trial. Only then will researchers of

complex rehabilitation interventions be able to effectively contextualise the findings of their intervention studies. Investigation of implementation considerations such as the impact of individual-level attributes on outcomes is imperative for enabling researchers to understand what factors affect intervention implementation and effectiveness. This research also helps generate relevant recommendations about what interventions might work best for which people and provide people with the best care suited to them. Without information regarding the context around intervention delivery, confident conclusions regarding study results and intervention effectiveness are not possible and the likelihood of patients receiving potentially life-changing intervention is diminished.

3.7. Conclusions

There is evidence that therapist attributes impact patient outcomes in studies of complex rehabilitation interventions. Therapist attributes, such as effective communication skills and personality traits, facilitate autonomy-supportive behaviours that create change in patients' capability and motivation to take the lead in and adhere to their rehabilitation programme. Patient adherence to their at-home rehabilitation programme might then go on to improve patients' clinical outcomes. Future research should consider further exploring the processes and complex interrelationships between therapist attributes and patient outcomes. To add further strength to this research, researchers should conduct studies that consider the evaluation of implementation fidelity alongside the measurement of therapist attributes to ascertain the causes of variation in patient outcomes more confidently.

4. Chapter Four: Developing an implementation fidelity checklist for a vocational rehabilitation intervention

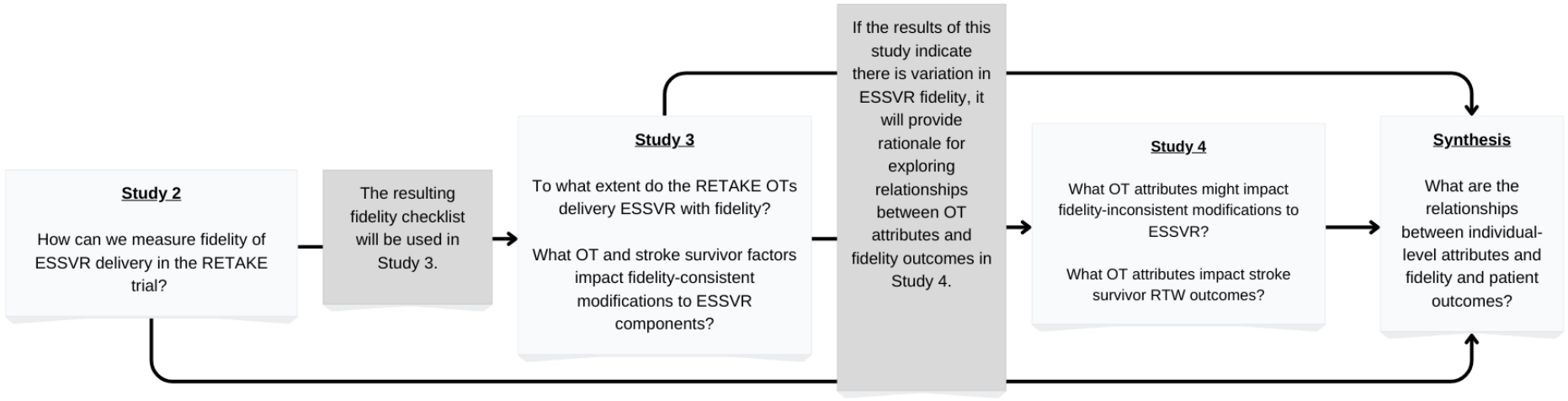
4.1. Preamble

The aim of this study (Study Two) was to develop an ESSVR-specific fidelity checklist and accompanying guidance notes to measure the RETAKE OTs' fidelity to ESSVR components and factors affecting ESSVR implementation. To address these aims, this chapter reports the processes and results relating to identifying and ratifying core and desirable ESSVR intervention components, field-testing the checklist and guidance notes, and assessing the inter-rater reliability of the checklist. The discussion provides a reflection on the use of retrospective review of stroke survivor ESSVR records where the research and clinical implications of doing so are also highlighted. This chapter has been published in *Pilot and Feasibility Studies* and, therefore, some repetition from the background literature review chapter might be evident. See Figure 4-1 for a visual representation of how the findings of this study contribute to other studies within this thesis.

The citation for the published manuscript is below:

Powers, K., Clarke, S., Phillips, J., Holmes, J. A., Cripps, R., Craven, K., Farrin, A., das Nair, R., & Radford, K. A. (2022). Developing an implementation fidelity checklist for a vocational rehabilitation intervention. *Pilot and Feasibility Studies*, *8*(1). https://doi.org/10.1186/s40814-022-01194-x

Figure 4-1. The interrelationships between the findings of this study and the subsequent studies within this thesis.



Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; NHS, National Health Service; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

4.2. Abstract

Background: Despite growing numbers of studies reporting the efficacy of complex interventions and their implementation, many studies fail to report information on implementation fidelity or describe how fidelity measures used within the study were developed. This study aimed to develop a fidelity checklist for measuring implementation fidelity of an early, stroke-specialist vocational rehabilitation intervention (ESSVR) in the RETAKE trial.

Methods: To develop the fidelity measure, previous checklists were reviewed to inform assessment structure, core intervention components were extracted from intervention descriptions into a checklist, which was ratified by eight experts in fidelity measurement and complex interventions. Guidance notes were generated to assist checklist completion. To test the measure, two researchers independently applied the checklist to fifteen stroke survivor intervention case notes using retrospective observational case review. The scoring was assessed for interrater reliability.

Results: A fidelity checklist containing 21 core components and 6 desirable components across 4 stages of intervention delivery was developed with corresponding guidance notes. Interrater reliability of each checklist item ranged from moderate to perfect (Cohen's kappa 0.69-1).

Conclusions: The resulting checklist to assess implementation fidelity is fit for assessing delivery of vocational rehabilitation for stroke survivors using retrospective observational

case review. The checklist proved its utility as a measure of fidelity and may be used to inform the design of future implementation strategies.

4.3. Background

Poorly implemented interventions threaten participant and trial outcomes and undermine confidence in research findings. In intervention studies, it can be difficult to know whether interventions have been delivered as intended; that is, with fidelity (Bellg et al., 2004; Walton et al., 2019). However, despite the body of literature supporting the importance of fidelity, it is largely under-reported in studies of rehabilitation interventions (Hand et al., 2018; Lockett et al., 2018; Walton et al., 2017). Without information regarding the extent to which an intervention has been delivered with fidelity, it is difficult to know whether the treatment effect outcomes are masked by poor implementation of the intervention (Borrelli, 2011). Fidelity data are necessary to interpret intervention outcomes (Bellg et al., 2004). This is especially true of interventions with many interacting parts that are influenced by different contexts and factors, also called 'complex' interventions (Hart, 2009).

Complex interventions usually contain several 'core components' that are essential for the intervention to have an effect and to be considered as delivered with fidelity (Hasson, 2010b; Lipsey & Cordray, 2000). The higher the level of complexity and individual tailoring of the intervention and its components, the more difficult it may be to measure fidelity, (Hand et al., 2018; Hildebrand et al., 2012; Toglia et al., 2020), thus requiring a more sophisticated method of measurement to avoid drawing inappropriate conclusions about an intervention that might have been improperly implemented and making Type III errors (Dusenbury, 2003). Measuring fidelity provides insight into which components of an intervention are

essential for a positive participant outcome (Craig et al., 2008) by establishing what key components were or were not delivered in cases of improved outcomes (Dane & Schneider, 1998).

Fidelity measurement is underpinned by theoretical concepts that emanate from behaviour change theories (Bellg et al., 2004; Cane et al., 2012; Damschroder et al., 2009). Various frameworks have been developed to describe and define which aspects of intervention implementation should be considered and the methods to use when evaluating fidelity (Carroll et al., 2007; Damschroder et al., 2009; Hasson, 2010). One such framework is the Conceptual Framework for Implementation Fidelity (CFIF) (Carroll et al., 2007), which describes two key concepts to understanding implementation fidelity: 1) adherence (whether the recipient has received the intervention as intended) and 2) moderating factors (factors affecting faithful intervention implementation). Due to the comprehensiveness of this framework and its demonstrated usefulness in other complex intervention studies (Augustsson et al., 2015; Masterson-Algar et al., 2014), CFIF was used to define and describe fidelity in this study.

Some studies use quantitative data collection methods to measure elements of fidelity, such as fidelity checklists, that assess therapist adherence to core processes and determine which and core intervention components have been delivered (Lincoln et al., 2020; Walton et al., 2017). Others use qualitative data collection methods, such as interviews, capturing acceptability or engagement with the intervention experienced by participants (Toglia et al., 2020). These studies often do not include sufficient information regarding either the development of the fidelity measure used or the psychometric properties of the measure,

which invites scepticism (Rixon et al., 2016; Schoenwald et al., 2011; Walton et al., 2017; Walton et al., 2020). The lack of published studies detailing the development of fidelity measures emphasises the need for future research to make clear the processes used to assure good psychometric properties of the measure prior to its application.

There is a need for high-quality, psychometrically robust measures of fidelity, yet there is little agreement on how best to develop these measures (Walton et al., 2017; Walton et al., 2020). Recent guidance suggests that for a measure to be considered high quality, the psychometric (e.g., reliability and validity) and implementation properties (practicality) of the measure should be reported (Walton et al., 2020). Evaluation of a measure's psychometric properties can determine whether the scores consistently measure the intended constructs (Hand et al., 2018; Moncher & Prinz, 1991). Practicality of a fidelity measure, such as ease of use and time taken to complete, is also valuable for researchers to report as these are factors that other researchers and clinicians consider when choosing a measure (Hand et al., 2018; Smart, 2006).

Fidelity checklists are developed by using instructional information (i.e., intervention manuals), which is then distilled into a shortened list of intervention components and used to assess the presence of the components during delivery (Breitenstein et al., 2010; Walton et al., 2020). Checklists have the advantage of being simple and quick to administer by those without specialist training in the intervention itself, and in instances where study participants cannot be, or do not wish to be, recorded or interviewed (Walton et al., 2017). Assessment of fidelity through video or audio recordings of intervention delivery is currently considered the gold standard of fidelity assessment (Lorencatto et al., 2013), but is resource

intensive, especially in studies with many participants receiving interventions over an extended time period (Walton et al., 2020). Application of a fidelity checklist using retrospective review of intervention records might be a way to reduce resource use. Fidelity checklists have been generated in occupational therapy (Hand et al., 2018; Parvaneh et al., 2015), however, they are specific to the components of the various interventions they assess and inappropriate for use across studies of other interventions without adaptation (Craig et al., 2008; Hand et al., 2018).

Vocational Rehabilitation (VR) is an example of a complex intervention that helps someone with a health problem return to or remain in work (Waddell et al., 2008). VR involves helping people find work, helping those who are in work experiencing difficulties and supporting career progression in spite of illness or disability (Frank & Thurgood, 2006). VR is complex because it requires tailoring of the intervention to the individual receiving it, is sensitive to the behaviours of different stakeholders (e.g., patients, their therapists, their families, their employers) and can produce a variety of different outcomes (Craig et al., 2008). VR crosses organisational boundaries, involves interactions between multiple stakeholders, is highly individually tailored and requires behavioural change by the patient, their family and employer (Cancelliere et al., 2013; Loisel et al., 2005). Stroke is an example of a particularly complex condition because it often occurs with multiple comorbidities and results in numerous, unpredictable biopsychosocial impacts (Nelson et al., 2017). Delivering a particularly complex intervention (such as VR) in a complex patient group (such as stroke survivors) presents some challenges for intervention delivery and measurement of fidelity (such as tailoring and individualisation) to meet the specific needs of the recipients (Bragstad et al., 2019; Jones et al., 2016; Ntsiea et al., 2015a). A small number of studies

describe VR for stroke survivors (Baldwin & Brusco, 2011), but very few of these studies report whether VR was delivered with fidelity, which makes it difficult to draw firm conclusions about the effectiveness of VR after stroke (Walker et al., 2017) despite the existence of intervention non-specific fidelity measures (Hasson, 2010; Hoffmann et al., 2014).

This study describes the development and testing of an intervention fidelity checklist for an early, stroke specialist vocational rehabilitation intervention (ESSVR) to support stroke survivors to return to work after stroke in the REurn To work After stroKE (RETAKE) trial (Radford et al., 2020) (ISRCTN12464275). ESSVR combines conventional VR with case management (see Figure 4-2). It is delivered by a stroke-specialist occupational therapist (OT) trained to assess the impact of the stroke on the participant and their job; coordinate appropriate support from the UK National Health Service (NHS), employers and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where current work is not feasible. A more detailed description of the intervention can be found elsewhere (Grant, 2016). ESSVR is delivered in four stages (early recovery, graded return to work, job retention and discharge), each comprising several core and desirable components.

This study aimed to develop and test a checklist for measuring implementation fidelity of ESSVR delivery in RETAKE.

Objectives:

(1) To identify and extract core ESSVR intervention components and generate guidance notes to assess the fidelity of their delivery within the RETAKE trial.

(2) To ratify the checklist components and guidance notes against expert opinion, supporting the measure's content validity.

(3) To test the utility of the checklist for assessing fidelity of ESSVR delivery using retrospective observational review of stroke survivors' intervention records.

(4) To assess interrater reliability in fidelity checklist completion.

Figure 4-2

A brief description of ESSVR

Early Stroke Specialist Vocational Rehabilitation

- Aims to support stroke survivors to return to work, and keep them in work 12-months post-stroke
- Complex, individually-tailored manualised intervention that adopts a case coordination model (39, 40, 41, 54).
- Delivered to stroke survivors, their employers, and their families.
- Provides a re-accessible service for up to 12 months post stroke.
- Core components include:
    - Early intervention (within 12 weeks of stroke)
    - Assessing stroke impact on patient and their job role
    - Educating patients/families/employers about stroke and its impact on work
    - Strategies to lessen impact e.g., pacing to manage fatigue
    - Work preparation, i.e., establishing routines and activities to increase stamina, concentration and confidence; practicing work skills
    - Liaising with employers and other key stakeholders to plan and monitor a phased return to work.

4.4. Materials and Methods

Ethical approval for the RETAKE trial and the studies within the trial was obtained through the East Midlands – Nottingham 2 Research Ethics Committee (REC) (Ref: 18/EM/0019).

4.4.1. Development of the Fidelity Checklist

The development of the fidelity checklist and its associated guidance notes was informed by Walton et al. (Walton et al., 2020) and distilled into five steps: 1) review previous measures of fidelity; 2) analyse and develop a framework for the content of the intervention; 3) develop a fidelity checklist and associated guidance for checklist completion; 4) obtain feedback regarding content and wording; 5) pilot and refine the checklist.

The initial structure of the ESSVR fidelity checklist was based on a checklist developed for an earlier VR study (Holmes et al., 2020) for people with traumatic brain injury. The logic model and intervention descriptions (Dumas et al., 2001) provided the initial content for the development of the ESSVR fidelity checklist.

The fidelity assessment in RETAKE used observational retrospective review of stroke survivor ESSVR intervention records that included session content case report forms (CRFs), OT clinical notes, and correspondence between the OT, stroke survivor and other key stakeholders to assess intervention fidelity (see Table 4-1). ESSVR was delivered to community dwelling stroke survivors, their families, and their employers over a period of up to 12 months following randomisation.

Table 4-1

Detailed descriptions of the components of the participant ESSVR intervention records

Intervention record component	Description
Content CRFs	Details each intervention session. OTs assign 10-minute units to components of the intervention and other common OT practices.
OT clinical notes	OT notes from each point of contact with the stroke survivor and key stakeholders.
Supplementary material	Extra materials provided in the case file. Includes: 1. Evidence of correspondence (e.g., copies of emails and written communication to key stakeholders) 2. Educational information provided to key stakeholders.

Abbreviations: CRFs, case report forms; ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist

3.4.1.1. Version 1

Version 1 of the checklist used the same format as a fidelity checklist created to assess a similar VR intervention delivered to people with traumatic brain injury (Holmes et al., 2020) designed to be completed through observation of individual sessions. Both the VR intervention designed for people with traumatic brain injury and the VR intervention for stroke survivors require complex, highly individualised intervention that considers the patient's individual, family, and work contexts. The VR in TBI checklist was developed to be completed through direct observation of a therapy session whereby the assessor recorded the extent of delivery ('always', 'sometimes', 'seldom', or 'never' delivered) for each of the 18 components of the intervention in the session. The assessor was also prompted to record moderating factors impacting intervention delivery or receipt, such as participant responsiveness and political, economic, and organisational context (Grant, 2016).

The checklist used for VR following traumatic brain injury was adapted for use in this study by modifying existing components and adding additional components identified in the ESSVR logic model. The process to complete the checklist was adapted to use observation of stroke survivor intervention records to assess the delivery of intervention components across the entire intervention delivery period (up to 12 months). It required the fidelity assessors (KP, RC), who were research assistants with a background in psychology and no training in OT or VR, to determine the frequency with which a component was delivered by the RETAKE OT ('always', 'sometimes', 'seldom', or 'never' delivered) and included a space for the assessor to record moderating factors that may have facilitated or prevented faithful delivery or receipt of each component. There were no accompanying guidance notes to aid interpretation or completion.

3.4.1.2. Piloting of Version 1 and proposed changes

The research assistants (KP, RC) applied Version 1 of the fidelity checklist to 8 sets of participant intervention records collected from the ESSVR *feasibility study* (Grant, 2016). The intervention records were first read for familiarisation before data were extracted against the checklist components. Following piloting, changes were made to increase clarity and facilitate administration (see Table 4-2).

These proposed changes were discussed by members of the research team comprising an experienced stroke and OT researcher (KR), research OTs with experience of designing and implementing fidelity checklists (JH, JP), and research assistants with no clinical background who developed and implemented the fidelity checklist in this study (KP, RC, SC). Agreed changes were incorporated into a new version of the fidelity checklist (Version 2).

3.4.1.3. Piloting of Version 2 and production of guidance notes

The revised checklist was independently piloted against a further 10 sets of participant intervention records from the feasibility trial by two research assistants (KP, RC) who met to discuss discrepancies in administration and data extraction. Two clinical-academic OTs familiar with the intervention and responsible for training therapists in its delivery were consulted where there were discrepancies or questions regarding the intervention components. The ESSVR manual was also consulted for clarification. The piloting and consultation led to the development of Version 3 of the checklist. Guidance notes for checklist administration were developed with reference to the intervention training manual and with input from the RETAKE OT training team.

The guidance notes explain each component of the intervention in detail, providing definitions of key phases and concepts to assist the person administrating the checklist. The guidance notes also give examples of where to find the evidence to support each component.

3.4.1.4. Expert Panel

An expert panel was then formed to foster opinion from researchers with a clinical background and/or fidelity measurement expertise in relation to complex rehabilitation trials.

The expert panel consisted of eight researchers with both expertise in fidelity measurement and experience of measuring fidelity in complex rehabilitation trials. The purpose of the expert panel was to assist in (1) distinguishing between the 'core' and 'desirable' components of the intervention, (2) defining key words and phrases within the fidelity checklist and guidance notes, and (3) assessing the suitability of the fidelity checklist and accompanying guidance notes.

Version 3 of the fidelity checklist and Version 1 of the guidance notes were emailed to the expert panel members prior to the meeting. During the meeting, KP presented an anonymised participant intervention record from the feasibility study to the expert panel. The participant's case was used to illustrate the application of the fidelity checklist and promote discussion of the components.

The panel discussed the core and desirable components of the intervention, practical application of the fidelity checklist and the potential limitations of the methodology (e.g., method relies on OT record keeping), providing feedback and suggestions for amendments.

The feedback resulted in Version 4 of the fidelity checklist and Version 2 of the guidance notes.

3.4.1.5. Piloting of Versions 4 & 5 of the Fidelity Checklist and Version 2 of the Guidance Notes

Version 4 was independently piloted by two research assistants (KP, SC) on a further two cases from the RETAKE trial and discrepancies discussed. No changes were made to the fidelity checklist and only minor changes were made to the guidance notes where further clarification was needed.

A digitised version of the checklist was created in Microsoft Excel and piloted by a third researcher with no clinical background, with no prior involvement in the fidelity checklist development to test the functionality of the digitised checklist. No further changes were made.

3.4.1.6. Interrater reliability

Participant intervention records for 15 ESSVR recipients were selected at random to assess interrater reliability. Treating OTs were asked to redact identifiable information and upload the anonymised intervention records to a secure file transfer service. Two independent researchers (KP and JP), one with no background in OT or VR (KP), and one expert in VR and OT who was instrumental in the development of the intervention (JP), independently applied the fidelity checklist assisted by the guidance notes.

A Cohen's kappa statistic was calculated to assess interrater reliability. Based on guidelines for the interpretation of Kappa values, a value between 0 and 0.20 indicates no to slight agreement, 0.21 and 0.39 minimal agreement, 0.40 and 0.59 weak agreement, 0.60

and 0.79 moderate agreement, 0.80 and 0.90 strong agreement and 0.90 and above almost perfect agreement (McHugh, 2012).

4.5 Results

4.5.1. Development of fidelity checklist and guidance notes

Two materials were produced to aid in the assessment of fidelity in RETAKE: the fidelity checklist and its accompanying guidance notes (see Appendices 8.4 and 8.5). The fidelity checklist was structured into the four stages of the intervention as described in the OTs' intervention manual: Early Recovery, Graded Return to Work, Job Retention, and Discharge Process.

To implement the checklist, the fidelity assessor was asked to review each participant's intervention record. For each component, the assessor was asked whether there was sufficient evidence of the component's delivery, where the assessor could select 'YES', 'NO', or 'NOT DELIVERABLE' from a drop-down menu. The checklist provided space for the assessor to record details verbatim from the intervention record that would either evidence where the component had been delivered or provide evidence for why the component was not deliverable (moderating factors; e.g., where the OT did not have consent to contact an employer).

4.5.1.1. Piloting of Version 1 and proposed changes

Across Versions 1-3 of the fidelity checklist, changes were made to the structure and content to best capture the core components of the intervention, increase clarity, and facilitate the administration of the checklist. Version 1 listed 10 core components. Proposed changes related to the evaluation of component delivery where 'frequency' was replaced

with ‘no evidence’, ‘some evidence’, and ‘extensive evidence’, and a box created to extract the supporting evidence verbatim into the checklist.

For full description of changes made to each version of the checklist, see Table 3-2.

4.5.1.2. Piloting of Version 2 and production of guidance notes

During the piloting of Version 2, the OT training manual was consulted. This provided the biggest structural difference in the checklist. Consulting the training manual resulted in the classification of intervention components into the four phases (1. Early Recovery, 2. Graded Return to Work, 3. Job Retention, and 4. Discharge Process) to mirror the information provided to the RETAKE OTs. Additional components specific to work monitoring and discharge processes were extracted from the RETAKE OT training manual. These components were highlighted as being essential to intervention delivery but were not explicitly listed in the logic model.

4.5.1.3. Expert Panel

Version 3 of the checklist and Version 1 of the guidance notes were taken to the expert panel. The expert panel facilitated discussion regarding the core components and their status as ‘core’ or ‘desirable’ to the intervention delivery. Based on feedback from the expert panel, the components and other key concepts and phrases were more clearly defined in the guidance notes. Jargon was minimised to improve the clarity and accessibility of the guidance notes.

The expert panel agreed that in addition to evidencing each component verbatim from the intervention records, the assessors should record the source of the evidence (e.g., correspondence, therapy notes, etc.). The expert panel also agreed that the assessor should

record how long it takes to complete each fidelity assessment to evaluate the speed of checklist completion and compare to other methods of fidelity assessment.

4.5.1.4. Versions 4 and 5

Version 4 of the fidelity checklist and Version 2 of the guidance notes were produced which incorporated the recommendations from the expert panel. Following application of the checklist to two further sets of ESSVR participant intervention records, the fidelity checklist was digitised into a Microsoft Excel spreadsheet to increase its utility. The spreadsheet contained a drop-down menu for the assessor to select whether there was sufficient evidence of the component or if the component was not deliverable. The assessor was then directed to provide evidence verbatim from the intervention record where possible in the next box where the assessor was also asked to select the source (CRF, clinical case notes, correspondence, etc.) from another drop-down menu.

Scoring of the fidelity checklist was written into a calculation which was automatically populated via the drop-down menu selection of 'YES', 'NO', and 'NOT DELIVERABLE'. The total overall fidelity score was calculated based on the number of delivered components divided by the number of components that were deliverable. Components that were classified as 'desirable' were only included in the calculation where they were delivered and were thus weighted differently than those classified as 'core'. E.g.,

$$\left(\frac{n\ core\ components\ delivered + n\ desirable\ componets\ delivered}{N\ core\ components - n\ undelivereable\ core\ components + n\ desireable\ components\ delivered}\right) \times 100 =$$

% Fidelity

Table 4-2

Description of changes from previous versions

Fidelity Checklist Version Number	**Changes made from previous version**
Version 1	Amalgamated RETAKE logic model content and the FRESH fidelity checklist structure to create a physical checklist of the ESSVR intervention components.
Version 2	Assessor no longer asked about the frequency with which the OTs delivered the intervention. Assessor asked about the evidence of the extent to which each component of the intervention: 'no evidence', 'some evidence' and 'extensive evidence'. Requires evidence of component delivery to be extracted verbatim from participant's case file.
Version 3	Assessor no longer asked to evaluate the extent of the evidence of the component and instead asked to decide whether there is 'adequate' evidence of the component

	with dichotomous answers 'adequate evidence' and 'not adequate evidence'. Components added from RETAKE ESSVR training manual. Components separated into intervention stages (Early Recovery and Work Planning, Graded Return to Work, Job Retention and Discharge Process). Guidance notes developed for use alongside checklist.
Version 4	Every item on the checklist is answered with 'Yes', 'No' or 'Not Applicable' Components are categorised as either 'core' or 'desirable' Components delivered to 'participant, participant's family, and participant's employer' made separate and addressed individually.

	Includes box for assessor to record the amount of time taken to complete the checklist.
Version 5	Checklist changed from Word to Excel Spreadsheet containing formulae to automatically sum core and desirable components within and across intervention stages. Formula written to calculate 12-week cut-off date for point of first contact with OT (Core Component 1) Drop drown menus added for 'Evidence Source' for use when adding evidence from case file. Data then extracted into next cell. Drop down menus for YES/NO/NOT DELIVERABLE when completing checklist.

Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; FRESH, Facilitating Return to work through Early Specialist Health-based interventions; OT, occupational therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

4.5.2. Interrater reliability

Assessment of 15 participant intervention records was completed by two independent assessors. The stroke survivors whose records were used to assess interrater reliability included six females (40%) and ages ranged from 33 to 61 years old (mean: 48.3 years, SD: 7.7). Cohen's kappa ranged from 0.69 to 1 (See Table 4-3). Eleven items achieved 100% agreement, eight items achieved 90% agreement, and eight items achieved 80% agreement.

Table 4-3

Assessment of interrater reliability per checklist item

Stage	Item	Component Description	Core or Desirable	Cohen's Kappa	95% CIs
1. Early Recovery	1.1	OT intervenes within 12 weeks of stroke.	Core	1	1
	1.2	OT assesses the impact of the stroke on participant.	Core	[a]	
	1.3	OT assesses the impact of the stroke on participant's job.	Core	[a]	
	1.4	OT assesses the impact of the stroke on participant's family.	Desirable	0.79	0.56-0.89
	1.5	OT helps participant plan a return to work and prepares them to return to work.	Core	1	1
	1.6	OT communicates in writing with relevant stakeholders regarding work status.	Core	[a]	
	1.7	OT coordinates VR across relevant sectors.	Core	0.74	0.44-0.87
2.Graded Return to Work	2.1	OT provides education and advice to participant.	Core	1	1
	2.2	OT provides emotional support to participant.	Desirable	0.83	0.73-1.0
	2.3	OT provides education and advice to employer.	Core	0.82	0.61-1.0
	2.4	OT provides emotional support to employer.	Desirable	0.76	0.73-1.0
	2.5	OT provides education and advice to participant's family.	Desirable	0.79	0.69-1.0
	2.6	OT provides emotional support to participant's family.	Desirable	0.79	0.69-0.88
	2.7	OT negotiates a phased return to work.	Core	1	1
	2.8	OT mediates workplace adjustments.	Core	1	1
	2.9	OT provides mechanism for feedback based on work performance.	Core	0.79	0.66-0.89
	2.10	OT continuously monitors participant's return to work to ensure sustainability and job retention.	Core	1	1
3. Job Retention	3.1	OT identifies issues that arise within return-to-work process with relevant stakeholders.	Core	0.75	0.58-0.89
	3.2	OT addresses issues that arise within return-to-work process with all stakeholders.	Core	0.69	0.61-0.78
	3.3	OT explores alternative duties and/or job roles with participant where current work could not be sustained/ was not feasible.	Core	0.76	0.63-1.0
	3.4	OT practices gradual, appropriate disengagement from intervention with participant.	Core	1	1
	3.5	OT discusses gradual, appropriate disengagement from intervention with participant's employer.	Core	0.79	0.48-0.89
4. Discharge	4.1	OT and participant agree an appropriate time point for withdrawing from intervention.	Core	0.81	0.69-1.0
	4.2	OT discusses and communicates mechanism for re-accessing vocational service or provides information about access to further avenues of support to participant.	Core	0.87	0.62-1.0
	4.3	OT discusses and communicates mechanism for re-accessing vocational service or provides	Core	0.9	0.79-1.0

		information about access to further avenues of support to participant's employer.			
	4.4	OT discusses and communicates mechanism for re-accessing vocational service or provides information about access to further avenues of support to participant's family.	Desirable	0.77	0.55-0.89
	4.5	OT provides participant's GP and other relevant health care professionals with a copy of discharge letter.	Core	1	1

Abbreviations: GP, general practitioner; OT, occupational therapist

4.5.3. Time taken to complete

The time taken to complete the fidelity checklist ranged from 30 minutes to 100 minutes (average 62 minutes). The average time taken to complete per assessor was 63.5 minutes (KP) and 57 minutes (JP).

4.6 Discussion

An ESSVR-specific fidelity checklist with adequate interrater reliability, that is relatively quick to apply, and guidance notes to aid checklist completion were developed and piloted using observational retrospective review of ESSVR participant intervention records. The checklist is adaptable to the specific contexts of the stroke survivors and other stakeholders and captures factors affecting the delivery of each component, facilitating identification and categorisation of implementation considerations. A future study will evaluate and report the fidelity of ESSVR delivery and factors affecting delivery of individual components in RETAKE.

Application of the fidelity checklist to assess interrater reliability produced a Cohen's kappa score ranging from 0.69-1, which indicates moderate to perfect interrater reliability (M. L. McHugh, 2012). Previous studies of fidelity checklist development report difficulties in obtaining high levels of agreement (Walton et al., 2019). It is possible that this study achieved higher agreement through the information provided to the fidelity assessors through the guidance notes. It is also possible that this could be due to the involvement of the assessors with the ESSVR training team, which may have influenced interpretation of the data in the ESSVR participant intervention records. Further research should explore whether other assessors with differing backgrounds would obtain the same high level of agreement. This study assessed interrater reliability using 15 stroke survivors' intervention case notes,

which is a small sample, but the results lend valuable information regarding how to improve the guidance notes to aid further understanding and agreement.

Of the eleven items within the checklist that yielded 'moderate' agreement, six of the items were core components and five were desirable components. The desirable components that produced 'moderate' agreement related to the OT's delivery of an ESSVR component to the stroke survivor's family or the delivery of emotional support to the employer. In exploring this further, the researchers completing the checklist disagreed whether these components were deliverable or not as opposed to the presence of sufficient evidence. An example of where these components would not be deliverable is if a stroke survivor expressed, explicitly or implicitly, that they would prefer their family not be involved in their intervention. Future applications of the checklist should take this into account and guidance notes should be altered to provide further clarity. Of the six core items, three items asked the researchers to determine the delivery of a component to relevant 'stakeholders' or 'sectors'. It is possible the disagreement on these items was related to lack of sufficient clarity in the guidance notes around the range of specific relevant stakeholders this might refer to. The other three core components that produced 'moderate' agreement all involved OT communication with the participant's employer. The delivery of these components was impacted by factors outside of the OT's control (e.g., employer engagement with the OT), which may explain discrepancies in the raters' marking. Updates to the guidance notes to reflect this and support future application are warranted.

Consultation with the expert panel provided a way to evaluate and establish the checklist's content validity. Expert ratification of a measure's components and scoring is a common

way to evaluate content validity and confirm that the measure is assessing what it intends to assess (Safikhani et al., 2013; Zamanzadeh et al., 2015). Recommendations for what constitutes as a suitable expert panel to establish content validity suggest that the members should be professionals with experience in the subject matter or clinical/research experience in the field (Davis, 1992). This study's expert panel comprised eight researchers with expertise in fidelity measurement within studies of complex interventions. Two of the researchers also had extensive knowledge and clinical experience of occupational therapy, vocational rehabilitation and ESSVR itself. By adopting the recommendations of the expert panel and adapting the checklist and its guidance notes, content validity was established. This study did not use a measure to quantify content validity, but this should be considered in future research to strengthen the measure (Froman & Schmitt, 2003). Additionally, the expert panel did not include a representative from the trial's Patient and Public Involvement group which would have provided added benefit in understanding what intervention components were of greater importance to those receiving it.

The time taken to apply the checklist ranged from 30 minutes to 100 minutes. For context, a typical ESSVR session with a stroke survivor might be expected to last 30 to 60 minutes and a stroke survivor might expect have over a dozen sessions over the course of 12 months in some cases. The variation in time taken to complete the checklist was most likely due to the variation in the amount of information included within each ESSVR participant intervention record. Fidelity measurement research highlights practicality of the measure (i.e., quick and easy use) as helpful for conserving resource (Bowen et al., 2009) and reducing burden within a study (Glasgow et al., 2005; Walton et al., 2017c). The time to complete the measure in this study using observational retrospective case review provides a considerably

quicker method to assessing an entire period of intervention delivery when compared with studies using more direct observational methods (Harting et al., 2004; Walton et al., 2017).

The associated guidance notes facilitated the checklist's use and provided a way to support the application of the checklist without having to provide additional training for future assessors. In the earlier stages of the checklist development, the research assistants initially applying the checklist frequently met with the research OTs responsible for training the RETAKE OTs to discuss discrepancies in interpretation and adequate demonstrations of component delivery, which aided the development of the guidance notes. These were refined to thoroughly cultivate understanding and aid practicality, which might further explain the adequate level of agreement and interrater reliability between the raters (KP & JP). The thorough process used to create and refine the guidance notes facilitated ease of checklist administration, which is another important aspect of measure implementation that studies of fidelity measures often fail to report (Rixon et al., 2016; Walton et al., 2017). With clear guidance notes facilitating sufficient levels of agreement, even where the person applying the checklist does not have a clinical background or experience in the intervention delivery, valuable study resources (e.g., clinical staff capacity and costings) may be conserved and may reduce bias. However, the results of the interrater reliability assessment are limited by the lack of a sensitivity analysis to determine what factors might have further influenced interrater reliability.

The intention of this study was to develop a checklist that could be applied by a research assistant in a trial, thereby reducing the risk of bias. Arguably, if the checklist is robust and guidance notes clear and the OTs adequately document the intervention, then a non-clinician should be able to extract the data and apply the checklist, saving valuable clinical

and research study resources, particularly given the high costs and capacity issues associated with the use of clinical staff. This approach is in no way intended to devalue clinical experience or expertise in the delivery of this or any other complex intervention, but rather aims to provide an efficient way of measuring fidelity during a clinical trial. Experienced clinical mentors overseeing clinical implementation of the intervention (55) could be informed of deviations from process and address these in real time during the trial, further facilitating faithful delivery of the intervention.

There are some limitations to this method of assessing fidelity. Using observational retrospective review of ESSVR participant intervention records in this study meant that fidelity checklist completion was dependent on the detailed record keeping of the RETAKE OTs. This limited the conclusions to whether there was sufficient evidence of the component's delivery. In cases where there was not sufficient evidence of a component's delivery, we could not confidently conclude that it had not been delivered. Direct observation of intervention delivery either in-person or via audio/video recorded sessions, is an effective way of confidently determining whether or not an intervention component has been delivered (Lorencatto et al., 2013; Walton et al., 2020). However, while observation of intervention delivery is an established rigorous approach to assessing fidelity, it not always possible or feasible as participants might not always give consent for session recording (Walton et al., 2017) and this approach also requires considerable staff and time resource (Cochrane & Laux, 2008; Walton et al., 2017). Direct observation of intervention delivery might also cause the person delivering the intervention to behave differently to when they're not being observed (Breitenstein et al., 2010; Dumas et al., 2001; Eames et al., 2008).

To help draw more confident conclusions about component delivery using observational retrospective case review, future research might include a method to further assist or encourage therapists in detailed record keeping through an electronic database, for example. Future implementation studies might also use this approach of assessing fidelity to support faithful delivery of interventions whereby intervention records could be reviewed on an ongoing basis starting from the beginning of intervention delivery. This approach would enable researchers to identify intervention components that are not being consistently delivered and support those delivering the intervention to deliver these components in future. Future research may also look to expand upon this method and the checklist, making it more robust by defining parameters for the *amount* of evidence present and assigning levels of sufficiency beyond 'Yes' 'No', and 'Not Deliverable' with reference to the components. Lastly, future research should seek to involve clinicians in further development and testing of the checklist, where the rates of interrater reliability could then compared with those of non-clinicians.

This approach to measuring fidelity allowed us to observe the intervention delivery over long periods of time over an unprescribed number of sessions across multiple study centres with multiple therapists. Whilst the checklist components are specific to the ESSVR intervention, the process followed to develop and apply the checklist is replicable and generalisable to studies of complex interventions. This approach may inform the design of implementation strategies in future studies of complex interventions.

4.7 Conclusion

The checklist and guidance notes developed in this study are fit for assessing the delivery of ESSVR components in the RETAKE trial and their application will be essential in providing context for the interpretation of the results of the trial with regards to the effectiveness of the intervention. The process followed to create the fidelity checklist in this study will inform the design of future implementation strategies for complex rehabilitation interventions.

This study also considered the feasibility of using retrospective review of intervention records to assess fidelity, which may facilitate robust longitudinal fidelity assessment procedures in future complex intervention studies. Establishing robust methods of assessing fidelity in complex rehabilitation interventions, such as ESSVR, will help researchers more confidently draw conclusions about the effectiveness of the interventions they seek to evaluate.

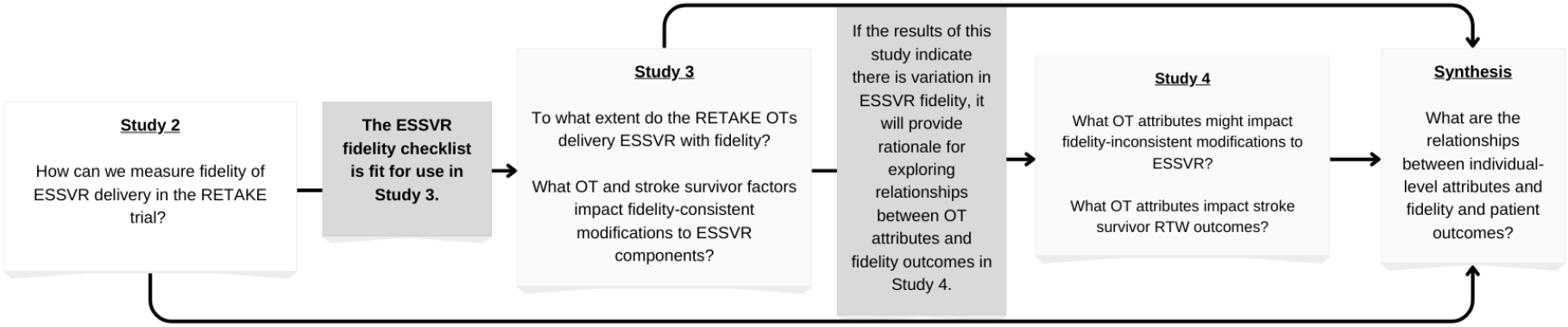
5. Chapter Five: Assessing fidelity to Early Stroke Specialist Vocational Rehabilitation

5.1. Preamble

The aim of Study Three is to determine the fidelity with which RETAKE OTs deliver ESSVR. To address these aims, this chapter reports the process of collecting stroke survivor ESSVR intervention records and using document analysis (a combination of content and thematic analysis) to populate the ESSVR fidelity checklist. Through this process, the overall fidelity to ESSVR delivery within and across OTs was determined as well as fidelity to individual ESSVR components. Document analysis also enabled me to assess the factors that influenced fidelity-consistent modifications to ESSVR. This chapter was submitted to *Pilot and Feasibility Studies* for consideration and, therefore, there may be some evident repetition from the background literature review. See Figure 5-1 for a visual representation of how this study was informed by and contributes to other studies within this thesis.

Figure 5-1

Visual representation of how Study Two informed Study Three and how the results of Study Three will inform Study Four.



Abbreviations: ESSVR, Early, Stroke Specialist Vocational Rehabilitation; NHS, National Health Service; OT, occupational therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

5.2. Abstract

Background: Existing studies of vocational rehabilitation for stroke survivors show promising results. However, they are limited by small numbers of participants and no, or limited, reports of whether the intervention was delivered as intended, i.e., with *fidelity.* Fidelity is crucial for contextualising efficacy outcomes because changes to delivery can threaten trial outcomes. Assessing fidelity-consistent and –inconsistent changes to intervention delivery provides essential information about the intervention's individual components. This study aimed to (i) determine fidelity to Early, Stroke-Specialist Vocational Rehabilitation (ESSVR), (ii) evaluate the extent to which each component was delivered with fidelity (or where there were "fidelity-inconsistent" modifications), and (iii) explore the factors leading to changes in ESSVR delivery to suit the context of the stroke survivor and delivery (or where there were "fidelity-consistent" modifications).

Methods: This study used mixed-methods document analysis comprising content and thematic analyses to analyse one stroke survivor's ESSVR record per treating Occupational Therapist (OT) within the RETurn to work After stroKE (RETAKE) trial. An ESSVR-specific fidelity checklist was used to triangulate data from the ESSVR records to determine overall fidelity to ESSVR, fidelity to each component of ESSVR (fidelity-inconsistent modifications) and the factors leading to changes made to ESSVR to suit the stroke survivor and context of delivery (fidelity-consistent modifications).

Results: ESSVR records were analysed for 39 stroke survivors and OTs. OT fidelity to ESSVR ranged from 31% to 100% (mean: 79%; SD: 19). Fidelity to individual ESSVR components ranged from 13% to 97% and deliverability of ESSVR components ranged from 10% to 100%. Components requiring RETAKE OTs to involve stakeholders such as employers and family

members were delivered with lower rates of fidelity than those centred on the stroke survivor.

Conclusions: ESSVR was a new intervention for RETAKE OTs and represented a notable shift from usual care practices. Overall, OTs delivered ESSVR with acceptable fidelity. However, some struggled with or resisted crossing service boundaries to engage employers or families, despite mentoring support. Additional training on engaging stroke survivors' employers may be necessary for OTs, along with further research to understand variation in OT behaviours and factors affecting traversing the work-health divide and employer engagement.

Trial registration: ISRCTN, ISRCTN12464275. Registered on 13 March 2018.

Keywords: Treatment fidelity, complex interventions, vocational rehabilitation, occupational therapy, stroke, randomised controlled trial, process evaluation, mixed-methods research, implementation

Key messages regarding feasibility:

1. What uncertainties existed regarding the feasibility?

- We were unsure whether Occupational Therapists (OTs) with little previous experience of delivering vocational rehabilitation would faithfully deliver Early, Stroke Specialist Vocational Rehabilitation (ESSVR) as intended, nor did we know what factors might create the need for fidelity-consistent modifications to suit the needs of the stroke survivor and the context of ESSVR delivery.

2. What are the key feasibility findings?

- Overall, OTs delivered ESSVR with fidelity. However, individual components of ESSVR were not delivered as consistently as others. Components centred on crossing service boundaries to engage stroke survivors' employers and families in ESSVR were not as consistently delivered as those centred on the stroke survivor. In some cases, the reasons were fidelity-consistent (for example self-employment or stroke impairment resulting in an ability to return to work) but in others modifications were fidelity inconsistent (e.g., no attempt made and rationale unclear). ESSVR components involving the gradual disengagement and discharge process also posed challenges to OTs' usual practice and were not consistently delivered.

3. What are the implications of the feasibility findings for the design of the main study?

- Further training to support OTs in engaging employers should be incorporated in the ESSVR training programme with ongoing support in clinical implementation. Additionally, further research to understand the barriers and enablers to OTs working across service boundaries should be carried out, especially with regards to engaging employers.

5.3. Background

Annually, 12.2 million people experience a new stroke, with 16% of strokes occurring in people aged 15-49 and 63% occurring in people aged below 70 (Owolabi et al., 2022). Despite the substantial proportion of people potentially in work at the time of their strokes, only 56% of stroke survivors return to work (RTW) within a year of their stroke on average internationally (Duong et al., 2019). Stroke survivors who do not RTW are at risk of poorer

quality of life and psychosocial outcomes than those who do RTW (Busch et al., 2009; Robison et al., 2009; Volz et al., 2018). Those who do RTW experience higher rates of perceived autonomy and meaningful participation and lower levels of depression and pain (Edwards et al., 2018; Volz et al., 2022; Westerlind et al., 2020). A recent update to the National Clinical Guideline for Stroke for the UK and Ireland underlines the need for stroke survivors to be offered vocational rehabilitation (VR) early in their rehabilitation (Intercollegiate Stroke Working Party, 2023). VR aims at supporting an employee and other key stakeholders (e.g., employers, colleagues, Human Resources teams) to facilitate a sustainable RTW or leave from it (Waddell et al., 2008).

Despite the need for VR (Intercollegiate Stroke Working Party, 2023), few studies have examined VR's effectiveness in supporting stroke survivors to RTW. A systematic review examining the effects of VR on stroke survivor RTW outcomes only identified six studies, all using a retrospective cohort design, with employment rates ranging from 12%-49% (Baldwin & Brusco, 2011). The authors highlighted the need for further high-quality efficacy studies, particularly randomised controlled trials (RCTs). Since Baldwin and Brusco's review in 2011 (Baldwin & Brusco, 2011), two RCTs of VR for stroke survivors have been conducted. Ntsiea and colleagues compared a 6-week-long workplace intervention delivered by occupational therapists (OTs) and physiotherapists (in addition to usual rehabilitation) to usual rehabilitation only, in 80 stroke survivors in Gauteng Provence South Africa (Ntsiea et al., 2015). The study was conducted in a single centre by two treating therapists. At six-months post-stroke, employment rates in the VR intervention arm were 60% (n=21) compared to 20% (n=7) of controls. To date, this is the largest RCT of post-stroke VR and whilst the results show promise for VR after stroke, more, larger, and UK-based RCTs are required to deliver such services locally.

Grant and colleagues (Grant, 2016; Grant et al., 2014; Radford et al., 2020) compared RTW outcomes of stroke survivors receiving early stroke-specific VR (n=23) to those receiving usual care only (n=23) in England at three, six- and twelve-months post-randomisation (Grant et al., 2014; Radford et al., 2020). VR was provided to intervention-arm participants over the course of up to twelve-months post-randomisation by a single OT in a single centre. At twelve months post-randomisation, eleven VR-arm participants (61%) were back at work compared with 6 usual care-arm participants (43%). This study involved a single centre and only one treating therapist. It concluded that while early, stroke-specific VR could influence RTW after stroke, a larger, UK-based trial was needed to demonstrate effectiveness.

Grant and colleagues' findings led to the development of the REturn To work After stroKE (RETAKE) trial (Radford et al., 2020), a large multi-centre RCT with embedded process and health economics evaluations delivered across sixteen sites in England and Wales, which provides the context for the current study. The RETAKE trial compares the effectiveness and cost-effectiveness of Early, Stroke-Specialist Vocational Rehabilitation (ESSVR) with usual-care stroke rehabilitation in getting stroke survivors back to work within 12 months of their stroke.

Whilst the employment rates of those receiving VR look promising in both aforementioned RCTs (Ntsiea et al., 2015; Radford et al., 2020), no concrete conclusions about the VR's effectiveness can be drawn due to the small numbers of participants and centres involved. Moving from single- to multi-centre RCTs require training of multiple therapists across multiple sites and, in doing so, there is a need to ensure the intervention is being delivered as intended, or with *fidelity*. The term 'fidelity' often comprises the concepts of *adherence* (faithful delivery of the intervention components), *competence* (acquisition of the skills required by those delivering the intervention), and/or *engagement* (key stakeholders'

interactions with the intervention in the way it was intended) (Walton et al., 2017; Walton, et al., 2020). For the purposes of this study, 'fidelity' refers to the adherence of therapists to intervention components. Measuring fidelity of an intervention's delivery within the context of an RCT provides valuable information about how an intervention works (Borrelli, 2011; Moore et al., 2015).

VR is a complex intervention. It is delivered through multiple interacting components, across different contexts (health and employment), requires specific skills and competencies by those delivering it and can produce a variety of outcomes for the key stakeholders receiving it (e.g., patients, their families, and their employers; Skivington et al., 2021; Von Thiele Schwarz et al., 2018). Typically, complex interventions are subject to changes (called modifications) in the intended delivery methods (Barrera et al., 2017; Wiltsey Stirman et al., 2015). They require a degree of adaptation, or *individualisation,* to meet the specific needs of the recipients and to facilitate the desired outcomes within the contexts they are delivered (Skivington et al., 2021; Wiltsey Stirman et al., 2017). Modifications can be fidelity-consistent, such as in individualisation, or fidelity-inconsistent, where intervention components are delivered in an unacceptable way or not delivered at all (Wiltsey Stirman et al., 2015).

Despite the potential threat that fidelity-inconsistent modifications pose to an intervention's implementation and overall success, there is very little research into the causal factors, their impact, and how to minimise their occurrence (Stirman et al., 2019; Von Thiele Schwarz et al., 2018). Understanding the modifications made and exploring the reasons and impact of these changes can help researchers unpick what, or how, adaptations to an intervention might increase the intervention's fit and effectiveness and, conversely, what modifications might hinder success (Baumann et al., 2015; Glasziou et al., 2010;

Walker et al., 2017; Wiltsey Stirman et al., 2015). Implementation fidelity frameworks help researchers to think objectively about causal factors in fidelity-inconsistent modifications. Many frameworks exist to characterise and identify which implementation-related characteristics of interventions should be considered and what methodologies and approaches to evaluation to adopt (Carroll et al., 2007; Damschroder et al., 2009; Hasson, 2010b; Masterson-Algar et al., 2014).

Through consideration of both therapists' faithful delivery of ESSVR components and the factors impacting component delivery, this study evaluates therapist fidelity to the ESSVR intervention delivered over the course of up to twelve months by specially trained OTs to support stroke survivors to return to, and stay in, work in the RETAKE trial.

This study aims to:

1. Determine fidelity to ESSVR process.

2. Evaluate the extent to which each ESSVR component was delivered with fidelity.

3. Explore factors leading to fidelity-consistent modifications in ESSVR.

5.4. Methods

5.4.1. Design

In the RETAKE trial (Radford et al., 2020), stroke survivors were randomised to receive up to twelve months of ESSVR from specially trained OTs (in addition to their usual care National Health Service [NHS] stroke rehabilitation) or usual care NHS stroke rehabilitation alone. The overall objective of ESSVR was to support sustainable RTW for community-dwelling stroke survivors following their stroke. The primary outcome in the RETAKE trial was self-reported RTW status (i.e., paid or unpaid work for at least two hours per week).

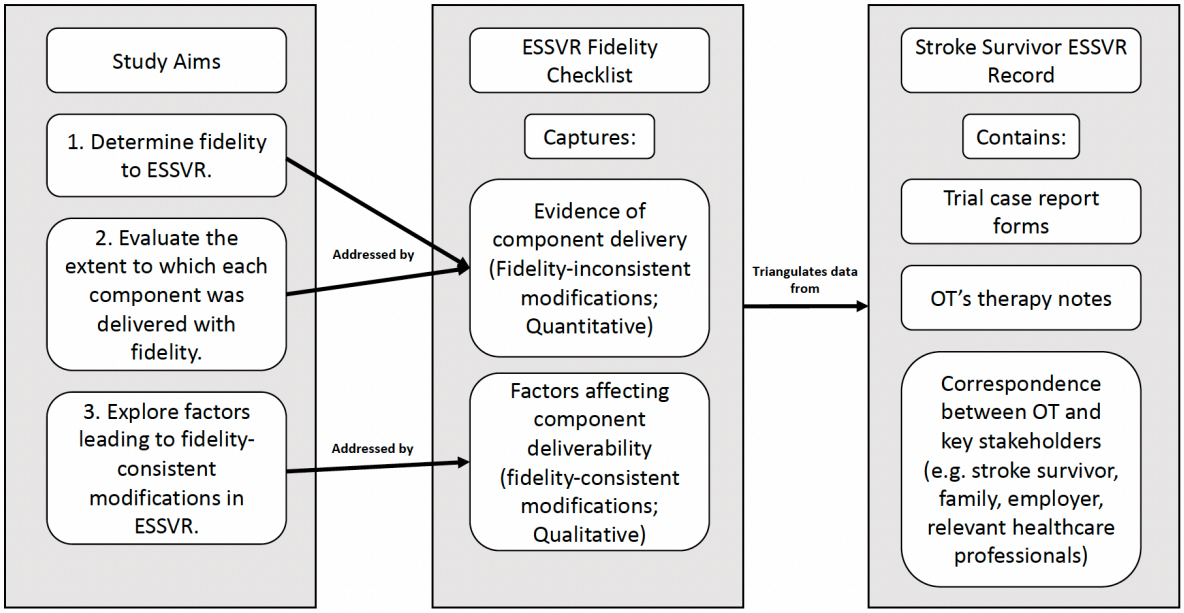
Fidelity was measured as part of an embedded, mixed-methods process evaluation (Radford et al., 2022). The Consolidated Framework for Implementation Fidelity (CFIF) is an implementation framework that proposes two key concepts to understand fidelity of intervention delivery: 1) adherence (whether the intervention has been delivered or received as intended) and 2) moderating factors (the factors that may impact the faithful delivery or receipt of the intervention). The CFIF has been used to comprehensively and effectively evaluate implementation fidelity in complex intervention studies (Augustsson et al., 2015; Masterson-Algar et al., 2014), and informed the creation of an ESSVR-specific fidelity checklist (Powers et al., 2022) used in this study.

The checklist, in the form of a Microsoft Excel file, comprises 27 ESSVR components (21 core components and 6 desirable components) across four intervention phases (early recovery, graded RTW, job retention, and discharge). Each checklist component has a corresponding field where the assessor selects an appropriate response from a drop-down menu to indicate the presence of each component (“Yes”, “No”, or “Not Deliverable”). The Microsoft Excel file contains a formula to assess the overall fidelity score based on the number of

components delivered divided by the number of components deliverable (Powers et al., 2022). Details of the development and testing of the ESSVR fidelity checklist used in this study, as well as the fidelity checklist itself, can be found elsewhere (Powers et al., 2022). See Figure 5-2 for an overview of this study's design, detailing how the ESSVR records and fidelity checklist address the aims of this study.

Figure 5-2

Design of Study Three



Abbreviations: ESSVR, Early, Stroke-Specialist Vocational Rehabilitation; OT, Occupational Therapist

5.4.2. Participants

The 39 OTs who were assessed for their fidelity to ESSVR were UK Health and Care Professions Council registered and typically had experience in stroke or neurological rehabilitation in community settings. Lack of community experience did not exclude OTs from involvement in RETAKE. OTs attended a two-day initial training session, and a further one-day refresher training session six months after commencing ESSVR delivery. Training encompassed training the RETAKE OTs in the intervention process and to deliver all ESSVR components (core and desirable) as well as introducing them to the RETAKE trial processes and associated paperwork. Training was supported by an ESSVR manual and monthly, one-hour group mentoring sessions led by an expert mentor with expertise in VR, stroke, and research. RETAKE OTs were encouraged to contact mentors between monthly sessions if they needed urgent or individual support. A description of training and mentoring can be found elsewhere (Craven et al., 2021).

RETAKE OTs included in the present study gave consent to have their data requested for fidelity assessment purposes.

Stroke survivor participants whose ESSVR records were collected and analysed in the present study were participants recruited to the RETAKE trial and randomised to receive ESSVR. Inclusion criteria were people aged 18 years or older, admitted to hospital with a new stroke, in work at the time of their stroke (paid or unpaid for at least two hours per week). Full eligibility criteria for the RETAKE trial are reported elsewhere (Radford et al., 2020). Two researchers (KP, JP) requested one randomly selected stroke survivor ESSVR record from each treating RETAKE OT (n = 39). RETAKE OTs were asked to send completed ESSVR records through a secure data transfer link. Once received, ESSVR records were redacted and analysed.

5.4.3. Description of ESSVR

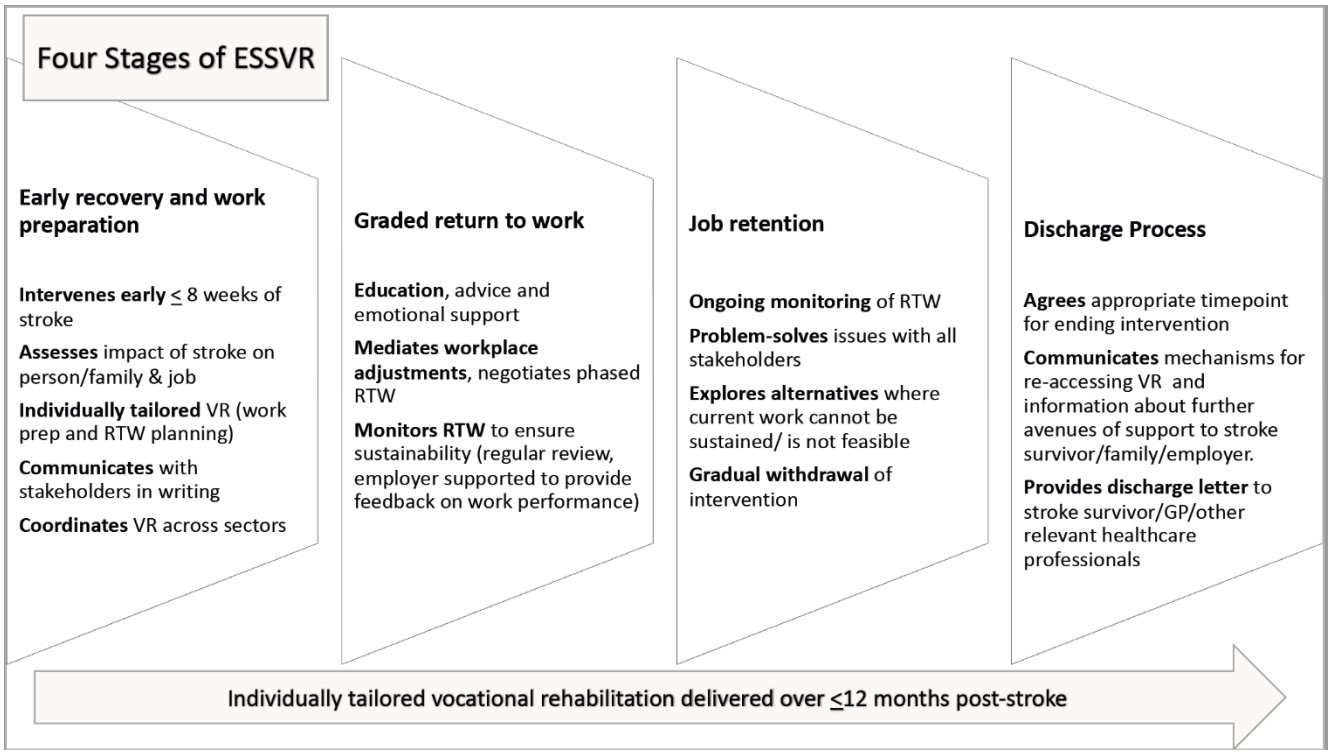
Informed by clinical (British Society of Rehabilitation Medicine, 2010, 2021; National Institute for Health and Care Excellence, 2013; Turner-Stokes, 2003) and our earlier studies (Grant, 2016; Grant et al., 2014; Phillips et al., 2010), ESSVR is a case coordination model of individually-tailored VR delivered in addition to usual NHS rehabilitation. It involves early intervention and ongoing support for community-dwelling stroke survivors for up to 12-months post-randomisation (Radford et al., 2020). The intervention, which is delivered in four stages (see Figure 5-3), commences with an assessment of the impact of the stroke on the stroke survivor, and their job, role and responsibilities (Stage One). This is followed by the development of a RTW plan, the use of strategies to lessen the impact of stroke, e.g., pacing to manage fatigue and prepare the stroke survivor for a RTW, e.g., activities to increase stamina, concentration and confidence and practice work skills, and education for the stroke survivors, their families, and employers. With an emphasis on cross-sector communication, the OT coordinates the rehabilitation across all sectors (e.g., the NHS, employers and other key service providers), liaising directly (where permitted) or indirectly (by letter) to work, and workplace adjustments (Stage Two). Stage Three involves monitoring the RTW to ensure sustainability, and consider work alternatives where RTW could not be attained (Grant et al., 2014; K A Radford et al., 2020). Stage Four comprises the supported discharge process in which the RETAKE OT communicates written information to the stroke survivor, their family, and their employer with information on how to re-access the RETAKE OT for further ESSVR intervention (if discharged before 12 months post-randomisation) or information regarding avenues for further support (if discharged at 12 months post-randomisation).

RETAKE OTs were originally trained that the supported discharge process was a part of Stage Three, with Stage Three as the final stage, but during the fidelity checklist development process (36), the expert panel consulted to ratify the fidelity checklist components agreed that this should be considered as a fourth, separate stage. This was related to ensuring consistency in checklist application and had no impact on the RETAKE OT's intended practice in delivering ESSVR.

Further descriptions of ESSVR (e.g., intervention logic model and TIDieR description) and its components can be found in the trial protocol (K A Radford et al., 2020), process evaluation protocol (Kathryn A Radford et al., 2022), and the ESSVR fidelity checklist development papers (Powers et al., 2022a).

Figure 5-3

The four stages of ESSVR



Abbreviations: ESSVR, Early, Stroke-Specialist Vocational Rehabilitation; GP, General Practitioner; RTW, Return-To-Work; VR, Vocational Rehabilitation

5.4.4. Data Sources

5.4.4.1. Stroke survivor ESSVR records

ESSVR records comprised RETAKE OT clinical notes detailing the content of individual sessions, trial- and ESSVR-specific case report forms, and copies of correspondence (emails and letters) with stroke survivors, their employers, and other key stakeholders. Qualitative data within the ESSVR records explained moderating factors related to those outlined in the CFIF (e.g., context, complexity and responsiveness). Collection of ESSVR records occurred between December 2019 and July 2022. A PhD scholar (KP) used the fidelity checklist to triangulate the qualitative and quantitative data to determine fidelity to ESSVR and its components (capturing fidelity-inconsistent modifications), and instances where ESSVR components were not deliverable, leading to fidelity-consistent modifications in ESSVR delivery.

5.4.5. Analysis

Stroke survivor ESSVR records were analysed using document analysis. Document analysis is an unobtrusive, analytic procedure of analysing and synthesising data in document form, including emails, letters, and notes (G. A. Bowen, 2009). Document analysis typically comprises elements of content and thematic analysis (Corbin & Strauss, 2015) and is an established and efficient mixed-methods approach (G. A. Bowen, 2009).

Content analysis was used to address the aims of evaluating the extent to which ESSVR was delivered overall and the degree to which each ESSVR component had been delivered. Content analysis is a systematic technique of categorising or coding data for the presence of specific, pre-defined themes or concepts and can allow researchers to code large volumes of

data with relative ease (Labuschagne, 2015; Stemler, 2001; U.S. General Accounting Office, 1996). In this study, a previously developed fidelity checklist and its associated guidance notes (Powers et al., 2022a) with demonstrated interrater-reliability were used to determine the evidence of ESSVR component delivery ("yes", "no", or "not deliverable"). The total fidelity assessment scores were calculated by dividing the number of components delivered by the number of deliverable components, multiplied by 100 to produce a percentage of fidelity (0-100%) (Powers et al., 2022a). 70% fidelity and above was considered 'adequate' fidelity as guided by a previous meta-analysis of the relationship between fidelity and improvement in outcomes in intervention studies (Durlak & DuPre, 2008).

Thematic analysis was used to explore the documented factors leading to fidelity-consistent and -inconsistent modifications in ESSVR. Thematic analysis is the practice of searching across a data set to identify and analyse repeated patterns, or themes (Braun & Clarke, 2006). Thematic analysis is considered an appropriate method when seeking to understand experiences and behaviours across a data set (Braun & Clarke, 2006, 2012), consistent with the study aims. The key steps within thematic analysis were; 1. Reading ESSVR records for familiarisation, 2. Extracting initial data regarding contextual factors leading to fidelity-consistent modification from the ESSVR records and into the fidelity checklist and creating initial codes, 3. Searching for themes among the contextual factors, 4. Reviewing and reflecting on the themes, 5. Naming and defining themes, 6. Reporting the themes (Braun & Clarke, 2012; Kiger & Varpio, 2020). These steps to conducting a thematic analysis are the most widely implemented in qualitative research (Braun & Clarke, 2012).

The content and thematic analyses are two different but complementary analysis methods. Each method of analysis provides us with a different way of analysing the data to provide us

with information related to the different aims of this study. Thus, the analyses were treated separately. However, the fidelity checklist (Powers et al., 2022b) was developed to help us triangulate the data and integrate these separate analyses in a way that allows for broad reflection within the results.

5.4.6. Ethics

Ethical approval was obtained through the East Midlands—Nottingham 2 Research Ethics Committee (REC) (Ref: 18/EM/0019).

5.5. Results

ESSVR intervention records were collected for 39 stroke survivors aged 33-70 (mean: 52; SD: 9.7) treated by 39 RETAKE OTs between March 2019 and July 2021. Due to constraints placed on the RETAKE trial due to the COVID-19 pandemic, we were not able to collect records at random. Instead, records were requested for the first stroke survivor each OT treated nine months after their initial training session. Where OTs did not have nine months experience of delivering the intervention, the intervention records for their last treated stroke survivor were requested.

Table 1 presents the demographic data of the RETAKE OTs included in this study (n=39). Demographic data of the stroke survivors whose ESSVR records were analysed in the present study are presented in Table 2.

Table 5-1

Demographics of the 39 OTs Delivering ESSVR

Attribute	n (% of sample)
Gender	
Woman	35 (90%)
Man	4 (10%)
Job Factors	
Clinical Role	
Clinical OT	31 (79%)
OT Team Leader	4 (10%)
Therapy Manager	2 (5%)
Independent OT	1 (3%)
Senior Research Assistant	1 (3%)
NHS Band[a]	
Band 6	24 (62%)
Band 7	15 (38%)
Experience	M (SD)
Years qualified as OT	17.3 (7.95)
Years experience of:	
Stroke rehabilitation	9.34 (7.17)
VR	3.55 (4)

Abbreviations: NHS, National Health Service; OT, Occupational Therapist; VR, Vocational Rehabilitation.

[a]The NHS pay band system allocates a point score to each role in the NHS, which determines the basic rate of salary for the role. Higher banding is associated with greater experience and higher pay associated with the role. Band 5 is typically entry-level for newly qualified OTs.

Table 5-2

Demographics of the 39 stroke survivors whose ESSVR records were analysed

Attribute	n (% of sample)
Gender	
Woman	13 (33%)
Man	26 (67%)
Age	
<55 years	21 (54%)
>55 years	18 (46%)
Employment Sector	
Public	11 (28%)
Private	21 (54%)
Self-Employed	7 (18%)

Note. Stroke survivor demographic data is limited due to the Leeds Clinical Trial Research Unit's data sharing restrictions at the time of writing this thesis.

5.5.1. Overall fidelity to ESSVR

Overall fidelity to ESSVR ranged from 31% to 100% across the 39 RETAKE OTs. The mean fidelity score was 79% (SD: 19%).

5.5.2. Fidelity to individual ESSVR components

Fidelity to individual components ranged from 13% to 97%. Eleven core components achieved high levels of fidelity (< 80%), which involved intervening within eight weeks of stroke onset (92% fidelity), assessment of the impact of the stroke on the stroke survivor (97% fidelity) and their job (97% fidelity), planning a phased RTW and preparing the stroke survivor to RTW (89% fidelity), providing education and advice to the stroke survivor (87% fidelity) and their employer (83% fidelity), monitoring the stroke survivors' RTW to ensure sustainability (92% fidelity), identifying (85% fidelity) and addressing (82% fidelity) issues arising in the RTW process, agreeing an appropriate time point to end ESSVR delivery with the stroke survivor (80% fidelity) and communicating in writing to relevant stakeholders (82% fidelity).Eight components (four core, four desirable) did not achieve acceptable (>70%) levels of fidelity. The core components that did not achieve acceptable fidelity involved the RETAKE OT's gradual and appropriate disengagement from the intervention with the stroke survivor's employer (41% fidelity), communicating how to re-access ESSVR or providing further avenues of support to the stroke survivor at the point of discharge (68% fidelity) and or their employer (33% fidelity), and providing the stroke survivor's GP with a copy of the discharge letter (48% fidelity).

The desirable components that did not achieve fidelity were all related to the stroke survivor's family. They included assessing the impact of the stroke on the family (62% fidelity), provision of relevant information (27% fidelity) and emotional support (36%

fidelity) to the family, and communicating how to re-access ESSVR or providing further avenues of support to the family (13% fidelity).

See Table 5-3 for the fidelity rates of each individual component of ESSVR.

Table 5-3

Rates of deliverability and factors leading to fidelity-consistent modification and rates of fidelity

Component	Number of instances where component was deliverable (%)	Factors leading to fidelity-consistent modification	Number of times component delivered with fidelity (%)
Stage One: Early Recovery			
Intervenes within 8 weeks of stroke	37 (95)	Error with randomisation system (n=2)	34 (92)
Assesses the impact of the stroke on the SS	39 (100)		38 (97)
Assesses the impact of the stroke on the SS's job	39 (100)		38 (97)
Helps the SS plan a RTW and prepares them to RTW	35 (90)	Stroke impairment impacted ability to consider RTW (n=4)	31 (89)
Communicates in writing with relevant stakeholders regarding work status	39 (100)		32 (82)
Coordinates VR-across relevant sectors	37 (95)	SS did not consent to contact employer (n=2) Stroke impairment impacted ability to consider RTW (n=1)	27 (73)
Assesses the impact of the stroke on the SS's family	37 (95)	No close family members (n=2)	23 (62)*
Stage Two: Graded RTW			
Provides education and advice to the SS	38 (97)	SS did not want information and withdrew (n=1)	33 (87)
Provides education and advice to the employer	23 (59)*	SS did not consent to contact employer (n=6) SS self-employed (n=6) SS withdrew before OT contacted employer (n=2) SS unemployed throughout ESSVR delivery (n=1) SS handed over to another RETAKE OT (n=1)	19 (83)
Negotiates a phased RTW	26 (67)*	Stroke impairment impacted ability to RTW (n=4) SS did not consent to contact employer (n=2) SS withdrew before component appropriate (n=2) SS disengaged before component appropriate (n=2)	19 (73)

		SS handed over to another RETAKE OT (n=1) Employer not receptive to OT's negotiations (n=1) SS decided not to RTW (n=1) SS unemployed throughout ESSVR delivery (n=1) Phased RTW already in place before involvement (n=1)	
Mediates workplace adjustments	24 (62)*	Stroke impairment impacted ability to RTW (n=5) SS decided not to RTW (n=2) SS did not consent to contact employer (n=2) SS withdrew before component appropriate (n=2) No workplace adjustments necessary (n=1) SS disengaged before component appropriate (n=1) SS unemployed throughout ESSVR delivery (n=1) SS handed over to another RETAKE OT (n=1)	18 (75)
Provides mechanism for feedback based on work performance	24 (62)*	Stroke impairment impacted ability to RTW (n=5) SS decided not to RTW (n=2) SS did not consent to contact employer (n=2) SS withdrew before component appropriate (n=2) SS disengaged before component appropriate (n=2) SS unemployed throughout ESSVR delivery (n=1) SS handed over to another RETAKE OT (n=1)	18 (75)
Continuously monitors the SS's RTW to ensure sustainability and job retention	24 (62)*	Stroke impairment impacted ability to RTW (n=6) SS disengaged before component appropriate (n=3) SS decided not to RTW (n=2) SS handed over to another RETAKE OT (n=2) SS withdrew before component appropriate (n=2)	22 (92)
Provides emotional support to the SS	24 (62)*	No evidence this was required (n=15)	19 (79)
Provides emotional support to the employer	4 (10)**	No evidence this was required (n=18) SS self-employed (n=6) SS did not consent to contact employer (n=5) Stroke impairment impacted ability to consider RTW (n=2) SS withdrew before component appropriate (n=2) SS unemployed throughout ESSVR delivery (n=1) SS handed over to another RETAKE OT (n=1)	3 (75)
Provides education and advice to the SS's family	22 (56)*	Family not involved in rehabilitation (n=13) No close family members (n=2) SS withdrew before component appropriate (n=1)	6 (27)**

		SS handed over to another RETAKE OT (n=1)	
Provides emotional support to the SS's family	14 (36)**	Family not involved in rehabilitation (n=13) No evidence this was needed (n=8) No close family members (n=2) SS withdrew before component appropriate (n=1) SS handed over to another RETAKE OT (n=1)	5 (36)**
Stage Three: Job Retention			
Identifies issues that arise within the RTW process with relevant stakeholders	27 (69)*	Stroke impairment impacted ability to RTW (n=5) SS withdrew before component appropriate (n=3) SS disengaged before component appropriate (n=2) SS did not consent to contact relevant stakeholders (n=1) SS handed over to another RETAKE OT (n=1)	23 (85)
Addresses the issues that arise within the RTW process with all stakeholders	27 (69)*	Stroke impairment impacted ability to RTW (n=5) SS withdrew before component appropriate (n=3) SS disengaged before component appropriate (n=2) SS handed over to another RETAKE OT (n=1) SS did not consent to contact employer (n=1)	22 (82)
Explores alternative duties and/or job roles for the SS where current work could not be sustained/ was not feasible	17 (44)**	SS returned to original work role (n=13) Stroke impairment impacted ability to RTW (n=2) SS withdrew before component appropriate (n=3) SS disengaged before component appropriate (n=1) SS handed over to another RETAKE OT (n=2) SS not discharged when notes collected (n=1)	13 (77)
Practices gradual, appropriate disengagement from the intervention with the SS	28 (72)	SS handed over to another RETAKE OT (n=5) SS withdrew before component appropriate (n=3) SS disengaged before component appropriate (n=2) SS not discharged when notes collected (n=1)	22 (79)
Practices gradual, appropriate disengagement from the intervention with the SS's employer	17 (44)**	SS self-employed (n=6) SS withdrew before component appropriate (n=3) SS did not consent to contact employer (n=3) SS handed over to another RETAKE OT (n=3) SS decided not to RTW (n=3) SS not discharged when notes collected (n=1) Stroke impairment impacted ability to RTW (n=1) SS unemployed throughout ESSVR delivery (n=1) SS made redundant during ESSVR delivery (n=1)	7 (41)**

Stage Four: Discharge Process			
Agrees an appropriate time point for withdrawing from the intervention with the SS	26 (67)*	SS handed over to another RETAKE OT (n=4) SS withdrew before component appropriate (n=3) SS disengaged before component appropriate (n=3) SS seen for 12 months (n=2) SS not discharged when notes collected (n=1)	21 (81)
Discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the SS	31 (80)	SS handed over to another RETAKE OT (n=4) SS withdrew before component appropriate (n=3) SS not discharged when notes collected (n=1)	21 (68)*
Discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the SS's employer	18 (47)**	SS self-employed (n=6) SS handed over to another RETAKE OT (n=4) SS decided not to RTW (n=3) SS withdrew before component appropriate (n=3) SS did not consent to contact employer (n=2) SS not discharged when notes collected (n=1) SS unemployed throughout ESSVR delivery (n=1) SS made redundant during ESSVR delivery (n=1)	6 (33)**
Provides the SS's GP and other relevant health care professionals with a copy of the Discharge Letter	31 (80)	SS handed over to another RETAKE OT (n=6) SS not discharged when notes collected (n=1) SS moved away from the UK (n=1)	15 (48)**
Discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the SS's family	16 (41)**	Family not involved in rehabilitation (n=13) SS withdrew before component appropriate (n=3) SS handed over to another RETAKE OT (n=3) No close family members (n=2) SS not discharged when notes collected (n=1) SS disengaged before component appropriate (n=1)	2 (13)**

Note: Shaded rows indicate desirable components

*<70%

**<50%

Abbreviations: GP, General Practitioner; OT, occupational therapist; RTW, return to work; SS, Stroke Survivor

5.5.3. Deliverability of ESSVR components

Individual components ranged from being deliverable in 10% to 100% of cases. Sixteen components (11 core, 5 desirable) of ESSVR were deliverable in fewer than 70% of cases, leading to fidelity-consistent changes to ESSVR delivery.

Core components that were deliverable (could have been delivered) but were not delivered in 70% of cases, related to the RTW process and the gradual disengagement and discharge processes. Desirable components that that could have been but were not delivered related to provision of emotional support and communication with the stroke survivor's family.

Six components (3 core, 3 desirable) were deliverable in fewer than 50% of cases. Core components included exploring alternative duties and/or job roles for the stroke survivor when their current work could not be sustained or was no longer feasible (43.6%); practicing gradual disengagement from (44%) and communicating how to re-access ESSVR or providing further avenues of support to the stroke survivor's employer (47%). Desirable components that could not be delivered in around 50% of cases, related to providing emotional support to the stroke survivor's family (36%) and employer (10%), as well as communicating how to re-access ESSVR and/or providing further avenues for support to the stroke survivor's family such as further support from local services or charities (41%).

See Table 5-4 for the factors leading to fidelity-consistent modifications within each ESSVR component.

Table 5-4

Factors leading to fidelity-consistent modifications

Factors leading to fidelity-consistent modifications	Number of components affected (%)	Number of stroke survivors affected (%)
Stroke survivor handed over to another RETAKE OT due to treating OT's departure before this component was appropriate	18 (67)	5 (13)
Stroke survivor withdrawal from study	17 (63)	3 (8)
Stroke survivor unable to consider RTW due to impacts of stroke	11 (41)	5 (13)
Stroke survivor did not give consent for RETAKE OT to contact employer	10 (37)	6 (15)
Stroke survivor disengaged from ESSVR	10 (37)	3 (8)
Stroke survivor not discharged at time of record collection	8 (30)	1 (3)
Stroke survivor not employed throughout ESSVR delivery	7 (26)	1 (3)
Stroke survivor decided not to RTW	6 (22.2)	3 (7.7)
Lack of family involvement in rehabilitation	4 (15)	15 (39)
Stroke survivor was self-employed	3 (11)	7 (18)
Emotional support was not required for: *Stroke survivor* *Stroke survivor's family* *Employer*	 1 (4) 1 (4) 1 (4)	 15 (39) 8 (21) 18 (46)
Stroke survivor already RTW before RETAKE OT's involvement	2 (7)	1 (3)
Stroke survivor made redundant during RTW process	2 (7)	1 (3)
Stroke survivor returned to their original job role (therefore exploration of work alternatives not necessary)	1 (4)	13 (33)
Stroke survivor moved out of the country	1 (4)	1 (3)
Stroke survivor seen for 12 months post-randomisation and could not re-access ESSVR	1 (4)	2 (5)

Abbreviations: OT, occupational therapist; RETAKE, RETurn to work After stroKE trial; RTW, return to work; SS, Stroke Survivor

5.6. Discussion

This study aimed to explore RETAKE OTs' fidelity-consistent and inconsistent modifications to ESSVR, and its individual components, and to identify what factors might influence fidelity-consistent modifications to increase the intervention's fit. Following the application of an intervention-specific fidelity checklist (Powers et al., 2022) to 39 stroke survivor ESSVR records, we found that, on average, RETAKE OTs delivered ESSVR with acceptable levels of fidelity overall. When ESSVR components were individually analysed, those components that required the RETAKE OT to involve other stakeholders (e.g., the stroke survivors' family, other healthcare providers, and employers) were delivered with lower rates of fidelity than those centred on the stroke survivor. We also found that stroke-, family- and work-related factors impacted the deliverability of individual ESSVR components, requiring RETAKE OTs to tailor and individualise ESSVR delivery (i.e., making fidelity-consistent modifications) to the stroke survivor and to the context in which they were delivering ESSVR.

The recently published National Clinical Guideline for Stroke for the UK and Ireland (Intercollegiate Stroke Working Party, 2023) emphasises the need for VR to coordinate action that crosses service boundaries and involves all relevant stakeholders (e.g., the stroke survivor, their family and employer). This is echoed within the components of ESSVR. However, the components involving relevant stakeholders, specifically stroke survivors' families and employers, were implemented least often due to poor fidelity (fidelity-inconsistent modifications) and low deliverability (fidelity-consistent modification). In La Torre and colleagues'(La Torre et al., 2022) overview of systematic reviews exploring the barriers and facilitators of RTW after stroke, five of the included systematic reviews emphasise the need for engaging the stroke survivor's employer in the RTW process

(Donker-Cools et al., 2016; Edwards et al., 2018; Frostad Liaset & Lorås, 2016; Jellema et al., 2016a; Jellema et al., 2016b). These reviews identify the employer as a motivating factor in RTW and acknowledge the need for VR providers to consider the stroke survivor's working environment to best support sustainable RTW (La Torre et al., 2022). Despite the demonstrated need for employer involvement evident in clinical guidelines and recent reviews (Dunn et al., 2022; Intercollegiate Stroke Working Party, 2023; La Torre et al., 2022), our results show a consistent lack of engagement with employers. The repeated non-delivery of these components is inconsistent with current guidelines and raises several considerations around the perceived or real challenges incurred in crossing service boundaries and engaging employers.

Many of the RETAKE OTs did not have experience of working with employers prior to their involvement in the RETAKE study. Whilst the RETAKE OTs were trained in how to involve employers in ESSVR delivery, the results from this study demonstrate that further training may be required to support OTs to engage employers. Furthermore, in the six instances where the stroke survivor did not give consent for the RETAKE OT to contact their employer, the reasons for the non-consent are not documented in the ESSVR records. A qualitative meta-synthesis conducted by Brannigan and colleagues (2017) suggests that stroke survivors may experience uncertainty about disclosing their stroke to employers due to the possibility of being perceived differently (Brannigan et al., 2017; Gilworth et al., 2009; Gustafsson & Turpin, 2012). It is unclear what factors are contributing to the stroke survivors' reticence for the RETAKE OTs to engage employers in this study. However, it could be that the stroke survivors are not being given enough information about how this engagement could be beneficial to them.

Dunn and colleagues' (Dunn et al., 2022) recent realist review of early intervention VR interventions, which also strongly advocates for employer engagement in VR provision, postulates that by involving the employer in early, regular communication, the VR recipient (e.g., stroke survivor) and the employer will be more engaged in the RTW process, leading to an increase in the patient's confidence in their ability to work (Dunn et al., 2022). Providing information to stroke survivors about their employment rights as a stroke survivor and employee and the benefits of engaging employers in future ESSVR training sessions might lead to increased stroke survivor motivation to involve employers.

It is also important to consider that seven of the stroke survivors whose ESSVR records were analysed in the present study were self-employed. In these instances, there was no 'employer' for the RETAKE OTs to engage with, therefore the direct employer engagement components become 'Not Deliverable' within the fidelity checklist. However, when delivering ESSVR to a self-employed stroke survivor, the RETAKE OTs were required to adapt ESSVR in a way that considered the stroke survivor as an employee attempting to RTW, but also as an employer with the power to make changes to the work environment, working patterns, and job roles and responsibilities to enhance sustainable RTW. This finding suggests that upskilling OTs to deliver ESSVR requires not only training in how to engage employers, but also requires more specific skills in supporting self-employed stroke survivors.

In addition to the National Clinical Guideline for Stroke for the UK and Ireland's (Intercollegiate Stroke Working Party, 2023) recommendations, research into involvement of stroke survivors' families in rehabilitation advocates for families to be considered during stroke rehabilitation and treatment (Creasy et al., 2015; Lutz et al., 2015, 2017). Failing to involve stroke survivors' families has been found to lead to greater potential for unmet

needs, such as lack of information about rehabilitation processes and residual stroke-related disabilities (Monaghan et al., 2005). Despite evidence supporting the importance of involving families in the rehabilitation process, research suggests that this is not consistently practiced (Creasy et al., 2013, 2015) and that rehabilitation health professionals are hesitant to involve families in the rehabilitation process for fear that this may negatively impact the therapeutic relationship between themselves and the stroke survivor (Frampton et al., 2008; Levack et al., 2015; Levack et al., 2011). Our results provide some further evidence that working with families posed an additional challenge to RETAKE OTs, both in the sense that the components were consistently not delivered (fidelity-inconsistent modification) nor deliverable (fidelity-consistent modification).

There are a few things to consider to account for the consistent failure to deliver components around engaging families in ESSVR in this study. As deduced from the ESSVR records, the stroke survivors whose records were analysed in this study mostly experienced mild strokes and were largely independent in their activities of daily living. This suggests that these stroke survivors might not have needed their individually tailored ESSVR to include the engagement of their families to produce desired RTW outcomes. The literature that postulates that families should be engaged in the stroke rehabilitation process focus on more functional outcomes (i.e., activities of daily living) (Frampton et al., 2008; Levack et al., 2015; Levack et al., 2011). Additionally, in some instances, the ESSVR documentation made it difficult to determine whether it was appropriate to involve family members in the ESSVR process. This is a limitation of document analysis. The consistent failure to engage families could also be indicative of RETAKE OT reticence to involve families in ESSVR, as suggested by previous literature (Frampton et al., 2008; Levack et al., 2015; Levack et al., 2011). Although the ESSVR components around family engagement were considered ‘desirable’ within the

fidelity checklist due to the unknown impact of involving family in VR processes, RETAKE OTs were trained to deliver them as if they were core components and evidence of their delivery, or detailed reason for their non-delivery, was expected to be present in the ESSVR records. Further exploration of the impact of family engagement on ESSVR, and VR processes more generally, is needed to fully grasp its necessity in the context of VR. Future studies might seek to explore the facilitators and barriers to family involvement in VR processes specifically with the aim of developing a strategy for encouraging further collaboration with families, if seen as beneficial.

The other components that were consistently not delivered were those within the discharge phase of ESSVR (Stage Four). Prior to their involvement in the trial, the RETAKE OTs largely were not regularly working with patients for prolonged periods of time, ending with a gradual disengagement and discharge process, within the remit of their usual care service. On average, RETAKE OTs did not consistently deliver the components of Stage Four, which all centre on communicating information about re-accessing ESSVR (where discharge happened before 12 months post-randomisation) as well as sources of where additional support might be sought (where discharge occurred at 12 months post-randomisation) with key stakeholders, namely families and employers. This might be a further demonstration of the above considerations with regards to working across the boundaries of their usual care service provision.

The final common factor that led to largely fidelity-consistent modification is where the severity of the impacts of the stroke on the stroke survivor prevented the stroke survivor from being able to RTW. Whilst stroke severity, as categorised by ‘mild’, ‘moderate’ or ‘severe’ was not captured from the stroke survivor data in this study, it was deduced from the notes and correspondence within the ESSVR records that most of the stroke survivors

whose records were analysed experienced a mild stroke as stated previously. However, even mild strokes can create impacts that render stroke survivors unable to RTW. La Torre and colleagues' overview of 24 systematic reviews (La Torre et al., 2022) found that individual abilities impacted by stroke were among the main barriers to making a successful RTW after stroke, especially for those who experience resulting speech (Wei et al., 2016) and cognitive impairments (Donker-Cools et al., 2016) which can still result from even stroke categorised as 'mild'. The barriers to RTW these impacts create are echoed in the results of this study where five stroke survivors were unable to consider RTW of any kind during the ESSVR delivery period due to the impacts of their strokes.

5.6.1. *Future Research*

Whilst the overall fidelity score averaged across the 39 OTs indicates that there was acceptable fidelity, the standard deviation indicates wide variation. Future research should turn its attention to what might be causing the variation in delivery. This study identified some stroke survivor factors that could have affected ESSVR component delivery, but implementation research also indicates that therapist factors (e.g., experience, attitudes and beliefs, etc.) might also impact therapist behaviour, fidelity and patient outcomes overall (Heinonen & Nissen-Lie, 2020; Wiltsey Stirman et al., 2015). Future research should therefore also explore the relationship between fidelity to ESSVR and stroke survivor RTW outcomes.

5.6.2. *Strengths & Limitations*

This study provides the implementation literature with a further exploration of factors impacting intervention delivery through fidelity-consistent and –inconsistent modifications. The strength of this study is in its use of rich source material (i.e., ESSVR records) that

facilitated document, content and thematic analyses to explore potential barriers and facilitators to delivery of ESSVR and its components.

The gold-standard method of assessing fidelity is through audio and video recordings of intervention sessions (Lorencatto et al., 2013) because they provide an objective account of what processes occurred within the session. However, recordings can be resource-intensive and impractical for studies of interventions taking place over long periods of time in different settings, such as ESSVR (Walton et al., 2020). Additionally, participants do not always consent to be video or audio recorded (Walton et al., 2017) and observation of intervention delivery sessions may change intervention provider behaviour (Breitenstein et al., 2010; Dumas et al., 2001; Eames et al., 2008). Retrospective analysis of stroke survivor ESSVR records allowed us to non-invasively understand what ESSVR components were delivered over the course of up to 12 months.

Whilst this method provided valuable longitudinal insight into ESSVR delivery, it was almost entirely dependent on the record keeping of the RETAKE OTs. The fidelity checklist could only be completed based on the evidence provided by the RETAKE OTs, and therefore we could only conclude that there was, or was not, *evidence* of a component's delivery. This was a consideration in cases which, upon analysis, were found to be incomplete. In some instances, there was RETAKE OT handover during the ESSVR process where documentation from one RETAKE OT stopped and presumably continued within another RETAKE OT's separately kept ESSVR record for the same participant. This limitation could be circumvented in future studies seeking to employ the same method by ensuring that intervention records, even those that are handed over to another treating professional, are filed in the same place and that only one file exist per participant or patient and that proper handover is documented to ensure continuity of care.

The findings of this study are limited because only one stroke survivor ESSVR record was assessed per RETAKE OT. The stroke survivor ESSVR records that were selected to assess fidelity were from a time point where the OTs would have had at least 9 months of experience delivering ESSVR (apart from cases where RETAKE OTs left before this time point, and their final case was selected for assessment). The timing of the fidelity assessment might reflect the RETAKE OTs' greatest ability to deliver ESSVR and may not be a true reflection of the quality of ESSVR delivery overall. Future studies should seek to collect stroke survivor ESSVR records from several time points to ascertain a clearer picture of overall quality.

In the present study, fidelity assessment was used as a tool that could be used to provide insight and context to efficacy results. Conducting a fidelity assessment, while still providing valuable, contextual knowledge, could have been made more valuable still if the process had been designed to facilitate ESSVR implementation. Assessing RETAKE OTs at an earlier time point, or across several time points, would have enabled the research team to adapt training and mentoring to address the components consistently not being delivered, facilitating further fidelity.

5.7. Conclusions

For the RETAKE OTs, ESSVR was a new process and one that asked them to operate in many different ways to their usual care roles within their existing services. Evaluating fidelity of ESSVR delivery showed that, on average, RETAKE OTs with mostly limited previous experience of VR were able to deliver ESSVR with acceptable rates of fidelity within the context of the RETAKE trial. There were, however, areas of intervention delivery that

RETAKE OTs could potentially be supported to deliver more faithfully and consistently, especially those that involve crossing services boundaries to engage employers. These findings raise considerations around the need to understand more about what barriers and facilitators OTs experience in crossing service boundaries and engaging key stakeholders. OTs may need to be provided with additional training and education about engaging stroke survivors' employers and adapting ESSVR for self-employed stroke survivors. The findings also indicate that further discussion is warranted regarding the necessity for engaging stroke survivors' families in the ESSVR process. Finally, assessing fidelity to ESSVR in this study demonstrated considerable variability amongst the RETAKE OTs and further research exploring potential factors related to fidelity and ultimately to stroke survivor RTW outcomes would be beneficial to further contextualising ESSVR efficacy outcomes.

6. Chapter Six: Individual-level attributes affecting fidelity and return-to-work outcomes.

6.1. Preamble

This chapter comprises Study Four, the final study within my PhD. The first aim of Study Four was to explore the relationships between OT attributes (knowledge, experience, engagement with mentoring, confidence, and attitudes and beliefs towards evidence-based practice) and fidelity of ESSVR delivery. To achieve this, OT attribute data were collected at the OTs' initial training sessions (knowledge, experience, confidence and attitudes and behaviors towards evidence-based practice). Engagement with mentoring was measured across each OT's involvement with the study. Fidelity assessment scores (reported in Chapter Five) were analysed against OT attribute data within a series of linear regression analyses.

The second aim of Study Four was to explore the relationships between OT attributes of attitudes and beliefs towards EBPs on fidelity and stroke survivor return-to-work outcome at 12 months. To achieve this, OT attribute data were collected as described above, with the addition of questionnaire data assessing OT attitudes, behaviours, and confidence towards using EBPs. Data were analysed using a series of linear and logistic regression analyses.

The relationship between OT attributes of knowledge, experience, and engagement with mentoring on fidelity and stroke survivor return-to-work outcome at 12 months has been published in the *International Journal of Environmental Research and Public Health* and, therefore, there may be some evident repetition from the background literature review.

The citation for the published manuscript is below:

Powers, K., Roshan das Nair, Phillips, J., Farrin, A., & Radford, K. A. (2023). Exploring the Association between Individual-Level Attributes and Fidelity to a Vocational Rehabilitation Intervention within a Randomised Controlled Trial. *International Journal of Environmental Research and Public Health, 20*(6), 4694–4694. https://doi.org/10.3390/ijerph20064694

Due to delays in obtaining ethical approval, data regarding OT confidence and attitudes and beliefs towards evidence-based practice was only available in a subset of OTs (n=19), which was analysed separately and is reported in this chapter. See Figure 6-1 for a visual representation of how this study was informed by the findings from other studies in this thesis.

6.2. Abstract

Understanding which attributes or characteristics of those delivering interventions affect intervention fidelity and patient outcomes is important for contextualising intervention effectiveness. It may also inform implementation of interventions in future research and clinical practice. This study aimed to explore the relationships between attributes of Occupational Therapists (OTs), their faithful delivery of an early, stroke-specialist vocational rehabilitation intervention (ESSVR), and stroke survivor return-to-work (RTW) outcomes. Thirty-nine OTs were surveyed about their experience and knowledge of stroke and vocational rehabilitation and were trained to deliver ESSVR. ESSVR was delivered across 16 sites in England and Wales between February 2018 and November 2021. OTs received monthly mentoring to support ESSVR delivery. The amount of mentoring each OT received was recorded in OT mentoring records. Fidelity was assessed using an intervention component checklist completed using retrospective case review of one randomly selected participant per OT. Linear and logistic regression analyses explored relationships between OT attributes, fidelity, and stroke survivor RTW outcome. Fidelity scores ranged from 30.8%-100% (Mean: 78.8%, SD: 19.2%). Only OT engagement in mentoring was significantly associated with fidelity (b = 0.29, 95% CI = 0.05-0.53, $p < 0.05$). Increased fidelity (OR = 1.06, 95% CI = 1.01-1.1, p = 0.01) and increasing years of stroke rehabilitation experience (OR = 1.17, 95% CI = 1.02-1.35] was significantly associated with positive stroke survivor RTW outcomes. A subset analysis of 19 OTs found that self-reported theoretical knowledge of VR (b = 19.2, 95% CI = 3.25 – 35.15, $p < 0.05$) and OT confidence in their ability to ask a patient about their needs, values, and treatment preferences (b = 0.93, 95% CI = 0.14 – 1.73, $p < 0.05$) were significant individual predictors of the fidelity assessment score, but this did not remain significant in the multivariate model. In the subset analysis, only OT engagement in

mentoring was significantly associated with positive stroke survivor outcomes (OR = 1.07, 95% CI = 1-1.5, $p < 0.05$). Findings of this study suggest that mentoring OTs may increase fidelity of delivery of ESSVR, which may also be associated with positive stroke survivor return to work outcomes. The results also suggest that OTs with more stroke rehabilitation experience may be more effective at supporting stroke survivors to RTW. Upskilling OTs to deliver complex interventions, like ESSVR, in clinical trials may require mentoring support in addition to training to ensure fidelity.

6.3. Background

Results of intervention studies typically only report whether an intervention is shown to attain target outcomes, but attention is not often afforded to more nuanced considerations around intervention implementation (O'Shea et al., 2016; Slaughter et al., 2015; Walton et al., 2017). Understanding the implementation of an intervention can provide helpful information about why or how an intervention did or did not attain the targeted outcomes (Lockett et al., 2018; McGee et al., 2018; Nilsen, 2020). This is especially true of 'complex' interventions which comprise numerous components, require certain expertise, skills and behaviours of those delivering and receiving them, and target multiple groups and settings (e.g., patients, their therapists, their families, and their employers; Craig et al., 2008; Skivington et al., 2021). A complex intervention often requires its components to be modified to fit the needs of those delivering or receiving the intervention (Craig et al., 2008; Skivington et al., 2021). In these instances, it is important to consider 'fidelity', or the extent to which an intervention has been delivered (Bellg et al., 2004; Borrelli et al., 2005). Fidelity assessment can be useful not just as an implementation technique to monitor and support healthcare professionals delivering an intervention over the course of the study period (Forsberg et al., 2015; Sijercic et al., 2020; Thijssen et al., 2017), but also to help researchers contextualise the results of a study. Despite the importance of measuring fidelity, systematic reviews have shown that fidelity assessments are rarely conducted (Dalgetty et al., 2019; O'Halloran et al., 2014; Waltman et al., 2017), or in cases where assessment has occurred, reported (Copeland et al., 2015; Spencer & Wheeler, 2016). Higher levels of fidelity in studies of complex behaviour change interventions are linked to better patient outcomes (Farmer et al., 2017; Marques et al., 2019; McHugo et al., 1999; Strunk et al., 2010), which suggests it is important for researchers to understand what

factors promote fidelity. Achieving fidelity in some complex intervention studies can be difficult and studies within implementation research have therefore highlighted the importance for thorough investigation into factors which may influence fidelity outcomes (Carroll et al., 2007; Damschroder et al., 2009; Hasson, 2010). Due to the number of stakeholders involved in the delivery and receipt of complex interventions, the influence of individual-level attributes on fidelity outcomes is of particular interest (Sijercic et al., 2020; Wiltsey Stirman et al., 2015).

Individual-level attributes are personal characteristics that can be stable, i.e., thought to stay the same over time (e.g., education, openness to change, critical thinking; (Flint-Taylor et al., 2014) or unstable, which are subject to change over time (practice, engagement, illness; (Arnkelsson & Smith, 2000). Studies of the factors affecting the implementation of evidence-based practice (EBP) have shown that attributes of both healthcare professionals and patients may contribute to poor fidelity outcomes, or implementation failure (Grol & Wensing, 2004; Hart & Bagiella, 2012; Solberg, 2000). Research regarding which therapist attributes (e.g., gender, years of experience, level of education, etc.) impact fidelity outcomes is inconsistent and inconclusive (Campbell et al., 2013; Carpenter et al., 2012; Sijercic et al., 2020). For example, while years since qualifying as a therapist has not demonstrated clear directionality (Campbell et al., 2013; Carpenter et al., 2012; Sijercic et al., 2020), experience in skills related to an intervention has been shown to improve fidelity rates (James et al., 2001). Therapist positive attitudes and beliefs towards EPBs (McHugh & Barlow, 2010; Wiltsey Stirman et al., 2015), greater competency (Branson et al., 2018; Campos-Melady et al., 2017), and greater self-efficacy (Colquhoun et al., 2017; Eccles et al., 2005) have consistently been found to considerably and positively affect either fidelity or patient outcome across patient groups, intervention type and setting (Heinonen & Nissen-

Lie, 2020; Johns et al., 2019; Wampold et al., 2017). Most studies exploring the impact of therapist attributes on fidelity outcomes are embedded in studies of interventions delivered by psychotherapists (as detailed in systematic reviews (Heinonen & Nissen-Lie, 2020; Johns et al., 2019). Research within complex intervention studies delivered by other professions outside of psychotherapy is lacking and inconclusive.

Vocational Rehabilitation (VR) is an intervention that supports people in returning to or remaining in work (Waddell et al., 2008). Many long-term neurological conditions, including stroke, can affect a person's ability to stay in or return to work. VR interventions are considered complex, because they contain many interacting parts that are influenced by many different contexts (e.g. patients, their therapists, their families, and their employers) and factors (Hart, 2009). The delivery of VR requires the intervention to be tailored to the person receiving it, being sensitive to the changing behaviours of the different stakeholders or those delivering, receiving, and affected by the intervention. It crosses organisational boundaries and can produce a variety of outcomes (Hart & Bagiella, 2012). Occupational therapists are healthcare professionals who support people's activities of daily living and are therefore well-situated to deliver VR. VR interventions have been studied in stroke survivor populations (Grant, 2016; Ntsiea et al., 2015), but there is no reported measurement of implementation considerations, such as fidelity or the individual-level attributes, that might be affecting implementation or outcomes. Without information regarding the context around intervention delivery, confident conclusions regarding study results and intervention effectiveness are not possible, and the likelihood of patients receiving potentially life-changing intervention is diminished.

This study sought to explore the relationships between OT attributes, implementation fidelity, and stroke survivor return to work outcomes and was conducted using data

collected from the RETurn to work After stroKE (RETAKE) trial (ISRCTN: 12464275); a large multi-centre randomised controlled trial (RCT) of a complex, VR intervention to support stroke survivors to return to and stay in work following their stroke.

6.4. Materials and Methods

We used a correlational design drawing on qualitative and quantitative data from RETAKE OTs and stroke survivors in the RETAKE trial intervention group to explore the relationships between OT attributes, implementation fidelity, and stroke survivor RTW outcome at 12-month post-randomisation in the RETAKE trial (Trial Registration: ISRCTN, ISRCTN12464275. Registered on 13th March 2018). Ethical approval for the RETAKE trial and the studies within the trial was obtained through the East Midlands – Nottingham 2 Research Ethics Committee (REC) (Ref: 18/EM/0019).

6.4.1. Participants

We recruited at least two OTs from each of RETAKE's 16 study sites across England and Wales to be trained to deliver the intervention. Aside from being a qualified OT, there were no other inclusion/exclusion criteria for OT recruitment, but previous experience of stroke and VR in community settings was desirable.

Stroke survivors who were recruited to the RETAKE study (Radford et al., 2020), and whose data were included in this study, were required to be:

- Aged 18 or older
- Admitted to hospital with a new stroke prior to recruitment
- Working at the time of their stroke (paid or unpaid, for at least two hours per week)
- Have capacity to provide informed consent for participation

- Sufficient English language proficiency to participate in the study

Stroke survivors who did not intend to return to work were excluded.

6.4.2. Early Stroke Specialist Vocational Rehabilitation

Early stroke specialist vocational rehabilitation (ESSVR) combines conventional VR with case management. It is delivered by a stroke specialist OT who is trained to assess the impact of the stroke on the stroke survivor and their job; coordinate appropriate support from the National Health Service (NHS), employers and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where current work is not feasible or cannot be maintained (Grant et al., 2014). ESSVR is delivered to community-dwelling stroke survivors in four stages (early recovery, graded return to work, job retention, and discharge), each comprising several core and desirable components. More information regarding the RETAKE trial and ESSVR can be found in the trial protocol (Kathryn A. Radford et al., 2020).

6.4.3. Training for Occupational Therapists

OTs were invited to attend a two-day, manualised, face-to-face training session facilitated by expert trainers and mentors in VR. The aim of the session was to acquaint the OTs with the components of the intervention and the research process. Following their initial training, the OTs were also encouraged to attend monthly, hour-long mentoring sessions to receive ongoing mentoring support from an OT with expertise in VR. The aim of mentoring was to support the OTs to deliver the intervention with fidelity and to foster peer support through discussion of the OTs' active ESSVR cases and sharing best practice. OTs were encouraged to contact their mentor outside of group mentoring if further support was needed. OTs attended a one-day, in-person, refresher training session six months after their initial training session.

6.4.4. Measures of OT Attributes

6.4.4.1. Previous Experience and Knowledge

We designed a form to capture information about the OTs' education levels, and years of experience in OT, stroke rehabilitation and VR. The form also asked whether OTs had recent experience of health research (yes or no) and theoretical knowledge of VR (yes or no).

6.4.4.2. Competency

OTs' competency to deliver the intervention was assessed at three different time points: immediately following the two-day initial ESSVR training session, following the refresher training session held six months after training, and twelve months after the initial training session. At the initial and six-month competency assessments, the OTs were given a vignette (that illustrated a case study) and the OT was asked to create a treatment plan. To assess competency at the third time point, stroke survivor ESSVR records documenting the trial intervention for one randomly selected participant who had completed the intervention, per trained OT was requested.

Competency was assessed by the central training team comprising two OTs with expertise in the ESSVR intervention and OT research. OT responses were marked against a rubric assessing their knowledge, clinical reasoning, and written communication. These scores were used to categorise competency as 'needs support', 'competent', and 'highly competent'. Assessments were independently double-marked and any discrepancies that affected classification were discussed and agreed between the two raters.

6.4.4.3. Evidence-Based Practice Attitude Scale – 36 (EBPAS-36)

The Evidence-Based Practice Attitude Scale-36 (EBPAS-36) English Version (Rye et al., 2017) was used to assess OTs' attitudes towards using evidence-based interventions in practice in mental health practitioners and social workers (Rye et al., 2017, 2019). The EBPAS-36

contains 36 questions that cover 12 subscales (each subscale with three questions each) and assess the professional's likelihood to integrate an evidence-based intervention into practice based on the 1) requirement to do so, 2) intuitive appeal of adopting the evidence-based intervention, 3) openness to new practices, 4) perceived divergence of the usual practice from research-based or academically developed interventions, 5) limitations of evidence-based intervention and their inability to address client/patient needs, 6) the evidence-based intervention's fit with the values and needs of the client/patient and the clinician, 7) negative perceptions of monitoring, 8) balance between perceptions of clinical skills and science, 9) time and administrative burden of learning and evidence-based intervention, 10) job security related to using and learning evidence-based interventions, 11) perceived organisational support for adopting evidence-based practice, and 12) positive perceptions of receiving feedback (Rye et al 2017, 2019). Clinicians are asked to respond to statements using a five-point Likert-scale to indicate their level of agreement (0 meaning 'not at all' to 4 meaning 'to a very great extent'. To prevent response bias, five of the subscales (divergence, limitations, monitoring, balance, and burden) are framed negatively and reverse-scored when calculating the total score. The total score is also generated by summing the individual item scores and indicates the clinician's overall attitude towards evidence-based practice. Higher scores indicate more positive global attitude to integrating evidence-based interventions into practice (Rye et al, 2017).

6.4.4.4. Evidence-Based Practice Confidence Scale (EPIC)

The Evidence-Based Practice Confidence Scale (EPIC; Salbach & Jaglal, 2011) is an 11-item questionnaire that assesses the clinician's self-efficacy of various activities related to integrating evidence-based practice into clinical practice. For each item, clinicians are asked

to rate their level of confidence to complete each activity on a scale of 0% (indicating no confidence) to 100% (indicating complete confidence) in intervals of 10%. The EPIC has strong validity and reliability (Salbach et al., 2012) and has been validated for use in OTs (Clyde et al., 2016).

6.4.4.5. Engagement with Mentoring

The amount of contact each OT had with their mentor, inside and outside of their mentoring group, was recorded in minutes. Mentoring was summarised over two time periods, the amount of mentoring each OT received before their selected fidelity case began and stroke survivor and the amount of mentoring received during their selected fidelity case.

6.4.5. Fidelity Assessment

The fidelity assessment used retrospective review of stroke survivor intervention records that included session content case report forms (CRFs), OT clinical notes, and correspondence between the OT, stroke survivors and other key stakeholders to assess intervention fidelity (see Table 6-1). Stroke survivor intervention records that were collected for competency assessment were also used for the fidelity assessment (see above). Once the stroke survivor intervention records were obtained, researchers (KP, JP) used an ESSVR-specific fidelity checklist and its associated guidance notes to assess component delivery. Total fidelity assessment score was calculated based on the number of components delivered divided by the total number of components that were deliverable and multiplied by 100 to provide a percentage of fidelity (0-100%). More information regarding the development and psychometric properties of the ESSVR fidelity checklist can be found elsewhere (Powers et al., 2022a).

Table 6-1

Brief descriptions of the components of the stroke survivor intervention records.

Intervention record component	Description
Content CRFs	OTs indicate which components of the intervention and other common OT practices were delivered in a session.
Therapist clinical notes	OT notes from each instance of contact with the stroke survivor or other key stakeholders.
Supplementary material	Extra materials provided in the case file. Includes: 1. Evidence of correspondence (e.g., copies of emails and written communication to key stakeholders) 2. Educational information provided to key stakeholders.

Abbreviations: CRFs, case report forms; OT, occupational therapist

6.4.6. Return to Work Outcome

Stroke survivor RTW outcome was assessed 12 months post-randomisation. Stroke survivors were asked whether they had returned to work (yes or no). The definition of RTW in this study was “return to paid or unpaid work, for at least two hours per week”. This could include returning to the previous role or working in a new role.

6.4.7. Statistical Methods

A series of univariate linear regression analyses were performed to identify any potential predictors. Statistically significant results were adjusted for potential confounding factors. In

cases where more than one variable was found to predict fidelity score, a multivariate linear regression analysis was conducted.

6.5. Results

Due to delays in obtaining ethical approval for the use of the EBPAS-36 (Rye et al., 2017) and the EPIC (Salbach & Jaglal, 2011), a main analysis exploring the impact of OT attributes on fidelity and stroke survivor RTW outcomes is reported followed by an analysis of the subset of OTs for whom EBPAS-36 and EPIC data are available for.

6.5.1. Main Analysis

6.5.1.1. Description of Occupational Therapists

Data on therapist-level attributes were collected between February 2018 and November 2020. A total of 46 OTs across 16 sites were recruited and trained to deliver ESSVR. Of these, 39 OTs sent the stroke survivor intervention records as requested (one stroke survivor per OT, n=39). Non-response was due to illness (n=2) and no recruitment of ESSVR participants (n=3). For demographic characteristics of the OTs see Table 2.

Table 6-2

Attributes of the 39 OTs in Main Analysis Delivering ESSVR.

Attribute	**n (% of sample)**
Gender	
Female	35 (90%)
Male	4 (10%)
Job Factors	
Clinical Role[a]	
OT	31 (79%)
OT Team Leader	4 (10%)
Therapy Manager	2 (5%)
Independent OT	1 (3%)
Senior Research Assistant	1 (3%)
NHS Band[b]	
Band 6	24 (62%)
Band 7	15 (38%)
Experience	M (SD)
Years qualified as OT	17.3 (7.95)
Years of experience in:	
Stroke rehabilitation	9.34 (7.17)
VR	3.55 (4)
Recent research experience	
Yes	7 (18%)
No	32 (82%)
Knowledge	
Theoretical knowledge of VR	
Yes	22 (56%)
No	17 (44%)
Initial Competency Assessment	
Needs support	
Competent	9 (23%)
Highly competent	28 (72%)
	2 (5%)
Engagement with Mentoring	**Mean (Standard Deviation)**
Total minutes of mentoring received	378.74 (286.38)
Average minutes of mentoring per month	37.77 (25.02)

Abbreviations: NHS, National Health Service; OT, Occupational Therapist; VR, Vocational Rehabilitation. [a]Job titles of "OT", "OT Team Leader", and "Therapy Manager" represent increasing responsibility within the NHS. The one "Independent OT" was working in private

practice and was linked to an NHS site for study purposes. The “Senior Research Assistant” was a qualified, practicing OT, but had a clinical research role within their institution. [b]The NHS band system allocates a point score to each role in the NHS, which determines the basic rate of salary for the role. The higher the band, the more pay and experience associated with the role. The typical entry-level band for OTs is Band 5.

6.5.1.2. Fidelity Scores

Fidelity assessment scores ranged from 30.8% to 100%, with an average score of 78.8% (SD: 19.2%).

6.5.1.3. OT Attributes

6.5.1.3.1. Relationship between OT attributes and fidelity assessment score

Data regarding experience, post-training competence, engagement with mentoring, and fidelity assessment were collected and analysed for all 39 OTs. Of the nine OT attributes analysed through a series of simple linear regression calculations, only the average amount of mentoring received per month was a significant predictor of fidelity assessment score ($F(1, 37) = 6.21$, $p < 0.05$, with an R^2 of 0.12). OTs' predicted fidelity assessment score was equal to 67.86 + 0.29% (minutes of mentoring). Fidelity assessment score increased by 0.29% for each minute of mentoring received per month. This effect remained significant when adjusted for potential confounding variables (experience, knowledge, and total previous amounts of mentoring received).

See Table 3 for the individual relationships between OT attributes and fidelity assessment score.

Table 6-3

Relationship between OT attributes and fidelity assessment score for 39 OTs

Attributes	*β*	95% Confidence Interval		*p*
		Lower	*Upper*	
Experience				
Years qualified as OT	0.28	-0.52	1.07	0.49
Years of stroke rehabilitation experience	0.41	-0.48	1.28	0.36
Years of VR experience	-0.29	-1.89	1.31	0.72
Knowledge				
Level of education	1.61	-9.34	12.55	0.77
Theoretical knowledge of VR	6.95	-5.55	19.45	0.27
Recent research experience	11.14	-4.86	27.14	0.17
Initial Competence	6.44	-7.00	19.89	0.34
Engagement				
Amount of mentoring received pre-fidelity case (minutes)	0.01	-0.01	0.03	0.43
Average monthly amount of mentoring received (minutes)	0.29	0.05	0.53	0.02*

Abbreviations: OT, Occupational Therapist; VR, Vocational Rehabilitation. **p<0.05*

6.5.1.3.2. Relationships between OT attributes and stroke survivor RTW outcomes

Univariate logistic regression was conducted to explore and identify attributes that might be associated with the likelihood that stroke survivors would RTW following ESSVR delivery. Increase in years of stroke rehabilitation experience (OR=1.16, 95% CI [1.02, 1.32]), increase in average minutes of mentoring received monthly (OR=1.03, 95% CI [1.0, 1,07]), and fidelity assessment score (OR=1.06, 95% CI [1.01, 1.1]) were found to be independently associated with increased likelihood of a stroke survivor's RTW (See Table 4). The attributes shown to be independently associated with increased likelihood of RTW were included in a multivariate logistic analysis.

Table 6-4

Relationship between OT attributes and stroke survivor RTW outcomes at 12 months post-randomisation explored by univariate logistic regression.

Attributes	Odds Ratio	95% Confidence Interval		*p*
		Lower	*Upper*	
Experience				
Years qualified	1.1	1.0	1.2	0.05
Years of stroke rehabilitation experience	1.16	1.02	1.32	0.02*
Years of VR experience	1.19	0.98	1.45	0.08
Knowledge				
Level of education	1.58	0.51	4.92	0.43
Theoretical knowledge of VR	0.82	0.22	3.0	0.76
Recent research experience	0.59	0.1	3.49	0.56
Initial Competence	1.71	0.91	33.35	0.06
Engagement				
Amount of mentoring received pre-fidelity case (minutes)	1.0	1.0	1.0	0.16
Average monthly amount of mentoring received (minutes)	1.03	1.0	1.07	0.04*
Fidelity				
Fidelity assessment score (%)	1.06	1.01	1.1	0.01*

Abbreviations: OT, Occupational Therapist; VR, Vocational Rehabilitation. *$p<0.05$

A multivariate logistic regression analysis was performed to further explore the relationship between OT stroke rehabilitation experience and fidelity of ESSVR delivery on the likelihood of stroke survivors returning to work (RTW) following ESSVR. The logistic regression model was statistically significant [X^2 (2, N = 39) = 14.07, p = 0.001]. The model explained 30.3% (Cox & Snell R^2) of the variance in RTW outcome. Increasing years of stroke rehabilitation experience (OR=1.17, 95% CI [1.02, 1.35]) and increasing fidelity assessment score (OR=1.06, 95% CI [1.01, 1.1]) was associated with an increase in the likelihood of returning to work (See Table 5).

Table 6-5

Relationship between OT attributes and stroke survivor RTW outcomes at 12 months post-randomisation through univariate logistic regression.

Attributes	**Odds Ratio**	**95% Confidence Interval**		***p***
		Lower	***Upper***	
Experience				
Years of stroke rehabilitation experience	1.17	1.02	1.35	0.03*
Fidelity				
Fidelity assessment score (%)	1.06	1.01	1.1	0.02*

*p<0.05.

6.5.2. Analysis of Subset of OTs

6.5.2.1. Description of Occupational Therapists

Data on therapist-level attributes for OTs included in the subset analysis were collected between September 2019 and November 2020. A total of 19 OTs for whom EBPAS-36 and EPIC data and complete stroke survivor intervention records were available. For demographic characteristics of the OTs see Table 6.

Table 6-2

Attributes of the 19 OTs included in the subset analysis

Attribute	n (% of sample)	
Gender		
Female	15 (79%)	
Male	4 (21%)	
Job Factors		
Clinical Role		
Clinical OT	15 (79%)	
OT Team Leader	2 (11%)	
Independent OT	1 (5%)	
Senior Research Assistant	1 (5%)	
NHS Band Level		
Band 6	13 (68%)	
Band 7	6 (32%)	
Experience	n (% of sample)	M (SD)
Years qualified as OT		17.53 (8.9)
Years of experience in:		
Stroke rehabilitation		7.97 (8.18)
Vocational Rehabilitation		2.8 (3.75)
Recent research experience		
Yes	1 (5%)	
No	18 (95%)	
Knowledge	n (% of sample)	
Theoretical knowledge of VR		
Yes	11 (58%)	
No	8 (42%)	
Initial Competency		
Needs support	3 (16%)	
Competent	15 (79%)	
Highly competent	1 (5%)	
Engagement with Mentoring		
Total minutes of mentoring received		229.37 (211.46)
Average minutes of mentoring per month during selected case		36.08 (24.86)

Abbreviations: NHS, National Health Service; OT, Occupational Therapist; VR, Vocational Rehabilitation. [a]Job titles of "OT", "OT Team Leader", and "Therapy Manager" represent increasing responsibility within the NHS. The one "Independent OT" was working in private practice and was linked to an NHS site for study purposes. The "Senior Research Assistant" was a qualified, practicing OT, but had a clinical research role within their institution. [b]The

NHS band system allocates a point score to each role in the NHS, which determines the basic rate of salary for the role. The higher the band, the more pay and experience associated with the role. The typical entry-level band for OTs is Band 5.

6.5.2.2. Fidelity Scores

Fidelity assessment scores in the subset ranged from 42% to 100%, with an average score of 80.2% (SD: 18.4%).

6.5.2.3. OT Attributes

Data regarding experience, post-training competence, engagement with mentoring, attitudes behaviours and confidence towards EBPs, and fidelity assessment scores were collected and analysed for 19 OTs.

6.5.2.3.1. Relationship between OT attributes and fidelity assessment score

Of the 15 OT attributes analysed through univariate analysis, two were found to be significantly associated with an increased fidelity assessment score. OT self-reported theoretical knowledge of VR (β = 19.2, 95% CI = 3.25 – 35.15, $p < 0.05$) and OT confidence in their ability to ask a patient about their needs, values, and treatment preferences (β = 0.93, 95% CI = 0.14 – 1.73, $p < 0.05$) were both significant predictors of the fidelity assessment score.

A multiple linear regression was calculated to predict fidelity assessment score based on self-reported theoretical knowledge of VR and OT confidence in their ability to ask a patient about their needs, values, and treatment preferences. A significant regression equation was found ($F(2, 16) = 5.89$, $p < 0.05$) with an R^2 of 0.35. OTs' predicted fidelity assessment score is equal to 7.2 + 15.15 (Knowledge) + 0.73 (Confidence), where knowledge is coded as 0 = No and 1 = Yes, and confidence is measured on a scale of 0% (no confidence) - 100% (complete confidence). OTs with self-reported theoretical knowledge of VR scored 15.15% higher than those without VR knowledge and the score increased 0.73% for each

percentage of confidence reported. However, neither OT confidence (β = 0.73, 95% CI = -0.03 – 1.48, p = 0.06) nor self-reported theoretical knowledge of VR (β = 15.15, 95% CI = -0.16 – 30.47, p = 0.05) were significant predictors of fidelity assessment score (See Table 6-7).

Table 6-7

Relationship between OT attributes and fidelity assessment score for a subset of 19 OTs

Attributes	***β***	**95% Confidence Interval**		***p***
		Lower	***Upper***	
Experience				
Years qualified	0.09	-0.97	1.14	0.86
Years of stroke rehabilitation experience	0.09	-1.07	1.25	0.87
Years of VR experience	-0.38	-2.91	2.15	0.75
Knowledge				
Level of education	-7.07	-24.83	10.68	0.41
Theoretical knowledge of VR	19.2	3.25	35.15	0.02*
Recent research experience	20.04	-20.09	60.17	0.31
Post-Training Competence	4.89	-15.67	25.45	0.62
Engagement				
Amount of mentoring received pre-fidelity case (minutes)	0.01	-0.04	0.05	0.82
Average monthly amount of mentoring received (minutes)	0.06	-0.32	0.44	0.75
EBPAS-36				
Overall EBPAS Score	7.07	-23.82	37.95	0.64
EPIC				
'Ability to identify a gap in their knowledge related to a patient's situation'	0.36	-0.37	1.09	0.31
'Ability to determine if evidence from the research literature applies to their patient's situation'	0.39	-0.08	0.85	0.95
'Ability to ask their patient about their needs, values and treatment preferences'	0.93	0.14	1.73	0.02*
'Ability to decide on an appropriate course of action based on integrating the research evidence, clinical judgement and patient preferences'	0.62	-0.02	1.25	0.06
'Ability to continually evaluate the effect of their course of action on the patient's outcomes'	0.54	-0.35	1.42	0.22

Abbreviations: EBPAS, Evidence Based Practice Attitudes Scale; OT, Occupational Therapist; VR, Vocational Rehabilitation. **p<0.05*

6.5.2.3.2. Relationships between OT attributes and stroke survivor RTW outcomes

Univariate logistic regression was conducted to explore and identify attributes that might be associated with the likelihood that stroke survivors would RTW following ESSVR delivery. Increases in the amount of mentoring per month during the case selected for fidelity assessment (OR=1.07, 95% CI [1, 1.5]) was found to be associated with an increased likelihood of a stroke survivor's RTW (See Table 8). ASs only one attribute was found to be predictive of stroke survivor RTW outcome, multivariate logistic regression was not required.

Table 6-8.

Relationship between OT attributes and stroke survivor RTW for a subset of 19 OTs

Attributes	**Odds Ratio**	**95% Confidence Interval**		***p***
		Lower	***Upper***	
Experience				
Years qualified	1.07	0.95	1.21	0.25
Years of stroke rehabilitation experience	1.33	0.96	1.84	0.08
Years of VR experience	1.44	0.87	2.4	0.16
Knowledge				
Level of education	0.7	0.11	4.44	0.7
Theoretical knowledge of VR	1.6	0.23	11.27	0.64
Recent research experience	0	0		1.0
Post-Training Competence	5.25E + 9	0		1.0
Engagement				
Amount of mentoring received pre-fidelity case (minutes)	1.01	1	1.02	0.13
Average monthly amount of mentoring received (minutes)	1.07	1	1.15	0.04*
EBPAS-36				
Overall EBPAS Score	0.19	0.01	5.18	0.32
EPIC				
'Ability to identify a gap in their knowledge related to a patient's situation'	1.02	0.95	1.11	0.56
'Ability to determine if evidence from the research literature applies to their patient's situation'	1.01	0.96	1.06	0.78
'Ability to ask their patient about their needs, values and treatment preferences'	1.1	0.98	1.23	0.09
'Ability to decide on an appropriate course of action based on integrating the research evidence, clinical judgement and patient preferences'	0.97	0.9	1.06	0.57
'Ability to continually evaluate the effect of their course of action on the patient's outcomes'	1.1	0.97	1.26	0.13
Fidelity				
Fidelity assessment score (%)	1.04	0.98	1.1	0.18

Abbreviations: EBPAS, Evidence Based Practice Attitudes Scale; OT, Occupational Therapist; VR, Vocational Rehabilitation. *$*p<0.05$*

6.6. Discussion

Little evidence exists regarding what therapist attributes might impact fidelity and patient outcomes in complex rehabilitation interventions outside of the psychotherapy literature. The main analysis within this study found that only greater amounts of mentoring received per month during the stroke survivor case selected for fidelity assessment was associated with higher rates of fidelity to ESSVR delivery, and that more stroke rehabilitation experience and higher fidelity rates were associated with a greater likelihood of stroke survivor return-to-work at 12 months post-randomisation. In the subset analysis of 19 OTs, it was suggested that OT self-efficacy with EBPs might influence fidelity outcomes and that greater amounts of mentoring per month during the stroke survivor case was associated with a greater likelihood of stroke survivor return-to-work at 12 months post-randomisation.

Despite the importance of assessing fidelity in clinical trials, it is a construct often overlooked in occupational therapy studies. The OTs in the present study were able to deliver ESSVR with 78.8% fidelity on average, which is high when compared to other studies with similar evaluations (Hardeman et al., 2008; Lorencatto et al., 2013). These findings suggest that ESSVR was delivered with acceptable (70% or higher) rates of fidelity and that the wider RETAKE trial might not be impacted by issues of poor fidelity.

Engagement with mentoring has been shown to be predictive of fidelity in interventions delivered by OTs in other studies (Dopp et al., 2015). The complexity and individual tailoring required of ESSVR, in combination with the observation that the average amount of engagement per month, not the total amount of mentoring previously received was predictive of fidelity assessment score, might suggest that while mentoring does not necessarily develop OTs into vocational rehabilitation experts in ESSVR, ongoing

engagement with mentoring might support the OTs to deliver complex interventions like ESSVR with fidelity in a trial context. This might be due to way mentoring was structured in RETAKE, i.e. to create opportunities for further knowledge acquisition and peer support as well as supervision from an expert mentor (Craven et al., 2021a; Santacroce et al., 2004). These results, taken with the results of Döpp and colleagues' (Dopp et al., 2015) study, suggest that mentoring might be an effective implementation strategy for OTs delivering complex interventions. The finding that total amount of mentoring received was not associated with fidelity is surprising, and future research should consider what further experience or training would be required to facilitate OTs becoming 'experts' in ESSVR delivery. Regardless, future studies of complex interventions should consider the inclusion of mentoring and encourage the therapists to engage with it to support fidelity of intervention delivery.

Higher rates of fidelity have long been associated with more positive patient treatment outcomes (Carroll et al., 2007a; Durlak & DuPre, 2008). The results of the present study reinforce such findings. What is surprising is that the OTs' previous experience of 'stroke rehabilitation' was related to return-to-work outcome, but not their previous experience of 'vocational rehabilitation'. OTs with more years of experience in stroke rehabilitation may be able to better understand the contextual factors that prevent someone from returning to work after their stroke which, in turn, might lead the OT to individually tailor ESSVR in a way that effectively supports the stroke survivor to return to work. Further research is required to understand this relationship. Mentoring may have helped OTs with a wide range of VR experience to deliver ESSVR with fidelity. This suggests that consistent, timely mentoring support may be more important in the implementation of VR than previous experience of delivering it.

In our study, initial competence to deliver ESSVR was hypothesized to be a factor with the potential to influence fidelity outcomes, because it has previously been demonstrated as a predictor of implementation fidelity in other studies (Beck et al., 2021; Wiltsey Stirman et al., 2015). Contrary to previous research, therapist competence was not indicative of fidelity in this study. However, this discrepancy could be because the time between the OTs' initial competency assessment and the case sampled for fidelity assessment varied greatly, with most OTs having at least six months of experience before starting the intervention with the stroke survivor selected for fidelity assessment. Most OTs (n=34; 87%) had also attended their refresher training session. In the time elapsed between their initial training and their selected fidelity assessment case, the OTs initial competency and understanding of the intervention would likely have increased. Future studies might investigate this further by measuring attributes at additional time points and exploring the changes in attributes over time that might occur due to involvement in clinical research and engagement with intervention training.

This study was exploratory in nature and had a very small sample of OTs. Data on some attributes were only available for 19 OTs. The findings should be interpreted in this light. However, occupational therapy and VR research attempting to explore the relationships between therapist attributes, fidelity and treatment outcomes outside of psychotherapy is scarce and while psychotherapy is also a complex intervention, it is different from VR and not typically delivered by occupational therapists. Therefore, we cannot assume that research findings from psychotherapy studies will necessarily translate/transfer to VR and or OT-delivered interventions.

This study included large numbers of potential predictor variables and limited numbers of OTs and stroke survivors. This is especially true of the analysis of the subset of 19 OTs,

where 15 individual univariate linear regressions were calculated. Statistically, one would be expected to find one significant result by chance in a set of 20 predictor variables (Quinn & Keough, 2002), which implies that the two significant predictor variables (knowledge of VR and OT self-efficacy) within the subset analysis may have been significant by chance. Because of the small sample size, we were also unable to explore in depth the interactions between the predictor variables themselves. The small sample of OTs in this study mostly included women (which is representative of the national picture of the profession, with 91% of OTs being women (*HCPC Diversity Data Report 2021: Occupational Therapists*, n.d.) with little self-reported recent research experience. However, it is difficult to generalise the results of the study to a larger population of OTs who might have more extensive research experience.

To assess fidelity in this study, OTs were asked for a specified stroke survivors' intervention records to which a fidelity checklist (Powers et al., 2022) was applied. Fidelity checklist completion was dependent on the record keeping of the OTs and completeness of the intervention records, which limits fidelity conclusions to 'evidence of' the delivery of components. OTs were trained to maintain their intervention records in a way that was easily accessible for the research team, however it is possible that OTs might not have recorded evidence of component delivery. Additionally, this study sampled one stroke survivor's intervention records per OT, which begs the consideration that the cases sampled might not be a true reflection of the OTs' actual overall fidelity. Future studies might look to examine several stroke survivors per OT and explore the changes in fidelity assessment score over time and the factors associated with those changes.

This study did not explore the impact of stroke survivor attributes on return-to-work outcome. There is a plethora of systematic reviews examining predictors of return-to-work

after stroke which have identified attributes related to highly likelihood of returning to work after a stroke, such as milder stroke severity (Ashley et al., 2019), being male (J D Edwards et al., 2018), and having independence in activities of daily living (J D Edwards et al., 2018). What is lacking from these systematic reviews, and from studies of return to work after stroke more generally, is greater consideration of the impact of work-related attributes (such as the adaptability of the stroke survivor's role or the relationships with employers), which should be considered in future studies. The present study also did not consider the impact of organisational factors, which would have provided further context for the environment in which the OTs were delivering the intervention. For example, pressure for service development and organisational motivation to address the needs of a changing healthcare climate are factors that are associated with greater therapist fidelity rates (Henggeler et al., 2008). Additionally, resource availability (i.e., adequate staffing, capacity, and service financial resources) might negatively impact fidelity and should be considered in future studies.

We suggest that providing support from expert mentors to OTs is a key implementation strategy for ensuring the faithful delivery of ESSVR and similar interventions. Future research should seek to further explore the mechanisms of action within mentoring to understand what underlying mechanisms of the mentoring might be facilitating delivery with fidelity (e.g., peer support, discussion of cases, etc.). Future studies should seek to include higher numbers of therapists and stroke survivors to achieve the statistical power needed to explore the relationships between attributes, fidelity, and patient outcomes more effectively (D. Cox & Grus, 2019; Perepletchikova et al., 2007; Southam-Gerow et al., 2021).

6.7. Conclusions

Taken together, the findings of this study suggest that upskilling OTs to deliver complex interventions, like ESSVR, in clinical trials may require mentoring support in addition to training, to ensure fidelity. Furthermore, providing mentoring to ensure intervention fidelity may positively influence individual participant outcomes in return-to-work after stroke.

7. Chapter Seven: Discussion

7.1 Introduction

In Chapters Three, Four, Five, and Six, I describe four interrelated studies. Study One (Chapter Three) describes a systematic review which investigated the impact of therapist attributes on patient outcomes in studies of complex intervention outside of the psychotherapy literature. The therapist attributes measured, their impact on patient outcomes and the methods used to measure the attributes and outcomes were described with reference to the existing psychotherapy literature. Study Two (Chapter Four) describes the development and piloting of a fidelity checklist to assess OT adherence to the ESSVR intervention. This fidelity checklist was used to conduct Study Three (Chapter Five), where I explored the extent to which ESSVR was delivered with fidelity and identified factors that created fidelity-consistent changes in ESSVR delivery. In Study Four (Chapter Six), I explored the impact of OT attributes on fidelity-inconsistent changes in ESSVR delivery as well as the impact of OT attributes on stroke survivor return-to-work outcomes at 12 months post-stroke. The individual chapters within this thesis consider the implications, strengths, limitations, and methodological considerations of the individual studies. This final discussion chapter synthesises the results of these four studies and relates them to the existing literature and theory.

This chapter provides an overall discussion of these studies, summarising their key findings and synthesising the results of the research to describe the impact of individual-level attributes on fidelity and return-to-work outcomes. The overall findings and key recommendations are presented (7.2.), the strengths, limitations and methodological

considerations of the thesis identified (7.3) and the impact of the COVID-19 pandemic reflected on (7.4). The chapter closes with its overall conclusions (7.5).

7.2 Overall Findings and Key Recommendations

This research aimed to explore what individual-level attributes might impact implementation fidelity and participant outcomes in studies of complex rehabilitation interventions, specifically within the context of an early, stroke-specialist vocational rehabilitation intervention (ESSVR) for stroke survivors. Four interrelated studies were conducted to meet these aims. The main findings of these studies are as follows:

7.2.1. The literature about what therapist attributes impact patient outcomes is sparce but does provide some starting points.

Study One in this thesis conducted a systematic review of literature examining the connection between therapist attributes and patient outcomes. While there is substantial research in psychotherapy literature investigating the impact of therapist attributes on patient outcomes, this study revealed a scarcity of similar research outside of psychotherapy. The included studies within the systematic review, mostly studies within physiotherapy, suggest that therapist behaviours that supported patient autonomy and self-management elicited more positive patient functional outcomes (e.g. reduced ratings of pain and disability). The review was further limited by the small numbers of participants (both therapists and patients) in the studies.

Despite the small number of studies included in the review, the findings suggested some therapist attributes that may impact patient outcomes, but through potentially complex interrelationships. I used the COM-B model within the Behaviour Change Wheel (Michie et al., 2011) as a lens to help unpick the complex relationships between therapist attributes and patient outcomes in the included studies. I observed that physiotherapist autonomy-supportive behaviours were suggested to be associated with patients' increased adherence to home-based exercise programmes. In thinking about this finding through the lens of the COM-B, therapist autonomy-supportive behaviours may have engaged in complex interplay between the patients' capabilities, opportunities, and motivations to engage in home-based rehabilitation, which may have ultimately resulted in better clinical outcomes such as decreased pain or increased mobility.

Deci and Ryan's (1985) Self-Determination Theory (SDT) helps us further understand why therapists' autonomy supportive behaviours might produce better patient outcomes. SDT provides a way of articulating what factors impact a person's motivations to perform a particular set of behaviours. Within SDT, a person's motivation is largely impacted by autonomy (perceived control of our own behaviour), competence (mastery of or skill in the targeted behaviour) and relatedness (sense of attachment to others). If a therapist can support these three constructs with their patient, for example through autonomy supportive behaviours, they will help the patient become more intrinsically motivated (driven by satisfaction and interest as opposed to extrinsic reward or obligation; Deci and Ryan, 1985). Intrinsic motivation then helps people move towards integration of the desired behaviour.

In relating SDT back to the findings of the systematic review conducted in Study One, therapists engaging in autonomy supportive behaviours, including collaborative individualised goal setting, may have been fostering greater intrinsic motivation within their patients. This intrinsic motivation may have then helped patients to adhere to their rehabilitation programmes. There is a plethora of research that suggests that while patient adherence to their physiotherapy programme is a key predictor of treatment outcome (e.g. reduction in pain and increase in function), 50% to 70% of patients are not adequately adherent to their exercise programmes (Beinart et al., 2013; Peek et al., 2016).

While the studies included in Study One's systematic review are helpful for starting to understand what therapist attributes might impact patient outcomes outside of the psychotherapy literature, it also highlights the lack of consistency across studies. Some

attributes were more consistently measured in the included studies (e.g., therapist autonomy supportive behaviours), but there is little consensus about how best to measure these attributes. Additionally, only one study (Chipchase et al., 2016) measured a therapist attribute that fell within the Opportunity (e.g., resources and environment) component of the COM-B, which was not associated with any changes in patient outcomes. Attributes relating to COM-B 'Opportunity' (e.g. resources and environment) could include environmental factors such as therapist workload or working hours.

Study One's systematic review was conducted to help inform the selection of therapist attributes to measure, and the tools to measure them with, within the context of RETAKE. With the included studies largely made up of physiotherapy studies, it was difficult to apply the findings to the context of the attributes of the OTs within the RETAKE trial. The lack of studies within OT, which also comprises highly complex interventions, is puzzling (Creek, 2009; Creek et al., 2005). However, the findings highlighted the need to create an ESSVR-specific fidelity checklist and assessment method that also had the ability to help us explore the factors and attributes of both the RETAKE OTs and stroke survivors that might be impacting ESSVR delivery.

The lack of research on how therapist attributes affect patient outcomes beyond the field of psychotherapy makes it challenging to identify important attributes in complex rehabilitation studies and determine the best measurement methods. Future research to explore the complex interrelationships between therapist attributes and patient outcomes is warranted to better contextualise the effectiveness of interventions.

7.2.2. Assessing 'fidelity' can help to capture the factors impacting intervention delivery and should be assessed separately to 'competency'.

Study Two centred on creating and testing an ESSVR-specific fidelity checklist. This resulted in a 27-item fidelity checklist comprising both core (n=21) and desirable (n=6) components of the ESSVR intervention and accompanying guidance notes for how to complete the checklist. The checklist was ratified by an expert panel and applied to a set of 15 stroke survivor ESSVR intervention records by two researchers independently. The researchers achieved acceptable agreement, which was possibly facilitated by the comprehensive guidance notes. Retrospective review of ESSVR records was considered to be an effective method for assessing fidelity and a suitable alternative to the gold standard of observation using video or audio recorded intervention sessions.

Despite emphasis on the importance of measuring, reporting, and supporting fidelity outcomes in intervention studies (Walton et al., 2017), there is little consensus of how best to do this. Developing psychometrically sound measures of fidelity can provide insight into variation within an intervention's delivery. If fidelity-inconsistent modification of the intervention is established during the fidelity assessment, researchers and clinicians can explore explanations for this and implement remedial strategies in real time so that the trial outcomes are not impacted. These remedial strategies might include extra mentoring support at a therapist-level and increased peer knowledge sharing, a resource library or refresher training sessions at a trial-level. Through this exploration, we can then start to understand how to best support the people delivering and receiving these interventions and better ensure the successful delivery of complex rehabilitation intervention studies. In this

PhD, I chose to explore this variation in ESSVR delivery by statistically examining the relationships between OT attributes and fidelity assessment score.

While guidance on how to develop robust, intervention-specific measures of fidelity exists (e.g., Powers et al., 2022; Walton et al., 2020), when and how often to measure fidelity is less clear. ESSVR fidelity assessment, as conducted in Study Three, was conducted at a time point when the RETAKE OTs were expected to be the most experienced and faithful in their delivery. There are therefore three main considerations when interpreting these findings: 1. the results of the assessment may have overestimated overall fidelity to ESSVR, 2. The RETAKE fidelity and competency measurements were assessing two different constructs, and 3. There was no opportunity to provide helpful feedback to RETAKE OTs about their performance as a result of the fidelity assessment.

Fidelity and competence are concepts that are often conflated but require separate consideration. The ESSVR training process used case vignettes to assess RETAKE OTs' competence in ESSVR at regular time points (following initial training, refresher training) with the purpose of ensuring that RETAKE OTs had the knowledge, skills and competency required to deliver ESSVR. The competency assessment was able to highlight OTs in need of additional support to deliver ESSVR. OTs were given some feedback on their competency assessment and additional support with delivery was provided by the expert mentors. Unlike the results of Waller and Turner's (2016) systematic review (described in 2.9.3.), which suggest that therapist competency predicted fidelity, Study 4 did not show an association between competency ratings and fidelity assessment scores (Powers et al., 2023). These results suggest that more competent OTs did not necessarily deliver ESSVR

more faithfully and, importantly, that adherence to ESSVR (as measured by the fidelity checklist) and competence in ESSVR are different constructs and should be measured and interpreted differently. That adherence and competence are different constructs of fidelity is congruous with the existing fidelity literature (Walton et al., 2018). However, it also suggests that further reporting of the ESSVR competency assessment process in RETAKE (Phillips et al., *In prep*) would be helpful for trialists designing their training and mentoring programmes.

While Study Four demonstrated that competency and adherence are different constructs, it might have been useful to feedback the results of the fidelity assessments to the RETAKE OTs as a further implementation strategy. Within the RETAKE trial, RETAKE OTs were required to attend monthly mentoring sessions. Mentoring was designed with the purpose of supporting RETAKE OTs' fidelity to ESSVR as well as other trial processes (e.g., enhancing recruitment, reducing contamination, completing CRFs). Study Four demonstrated that mentoring was associated with higher rates of fidelity, but perhaps fidelity to ESSVR could have been supported further. If the RETAKE OTs had been assessed for their fidelity to ESSVR at different time points throughout their involvement in RETAKE, for example, after their first participant, this might have provided an early insight into which components RETAKE OTs struggled to consistently deliver. For example, Study Three of this thesis found that crossing service boundaries to engage employers presented a challenge for RETAKE OTs for a myriad of potential reasons. Knowing this sooner might have afforded the ESSVR training and mentoring team valuable insight as well as an opportunity to 'course correct' through further training for RETAKE OTs. Future studies of complex interventions should engage in early and continuous fidelity assessment to provide insight into therapist training needs and further support fidelity.

7.2.3. RETAKE OTs delivered ESSVR with fidelity overall, but some ESSVR components need further investigation.

Study Three evaluated the extent to which ESSVR and its individual components were delivered with fidelity and explored the factors that led to fidelity-consistent modifications to ESSVR delivery. The fidelity checklist was applied to 39 stroke survivor ESSVR records. Completed fidelity assessments suggested that OTs delivered ESSVR with 78.2% fidelity on average, which is consistent with what is considered in the implementation literature to be 'good' fidelity (Durlak & DuPre, 2008). The results suggested that despite ESSVR being a new intervention to the RETAKE OTs, they delivered ESSVR with acceptable fidelity overall. However, there was also noticeable variability in fidelity scores warranting further investigation. Rates of fidelity to individual components of ESSVR varied greatly, with four core and four desirable components failing to achieve acceptable rates of fidelity. Components that achieved higher rates of fidelity were those that were related to the REATKE OTs' usual care practices (e.g., assessment).

The four core components that did not achieve acceptable rates of fidelity were all concerned with the discharge process. Three of these components required the RETAKE OT to liaise with other key stakeholders (i.e., the stroke survivor's employer and GP). It is important to note that most RETAKE OTs were only able to routinely provide support to patients in their usual care caseloads for between six and twelve weeks. In contrast, ESSVR is delivered over 12 months. Practicing gradual disengagement from the ESSVR process with the stroke survivor might have been difficult due to lack of training in and experience of doing so after such a comparatively long period of intervention delivery. The analysis in Study Three was also limited by the record keeping of the RETAKE OT. It is possible that the

RETAKE OTs did communicate to and liaise with key stakeholders as is required in the discharge process, but that they did not accurately record having done so. Further research is required to understand the barriers to effectively delivering and recording the components of the discharge process.

All four desirable components that did not achieve acceptable rates of fidelity were related to involving the stroke survivor's family in the ESSVR process including: 1) assessing the impact of the stroke on the stroke survivor's family (62.2% fidelity), 2) providing emotional support to the stroke survivor's family (27.3% fidelity), 3) providing education and advice to the stroke survivor's family (27.3% fidelity), and 4) discussing and communicating the mechanism for re-accessing ESSVR *or* proving information about access to further avenues of support (12.5% fidelity).

In Study Two, the development of the ESSVR-specific fidelity checklist, I consulted an expert panel made up of researchers and clinicians with experience of complex intervention evaluation, clinical OT experience, and/or vocational rehabilitation experience (Powers et al., 2022). One of the specific objectives of this consultation was to ascertain what components of ESSVR might be 'core', or essential to ESSVR, and what might be 'desirable', or components that would still ideally be delivered, but were not thought to be pivotal to the success of the intervention. The outcome of the consultation with the expert panel was that any components that involved the stroke survivor's family should be 'desirable' as well as those that pertain to psychological support (Powers et al., 2022).

In Study Three, in only two stroke survivors' cases were there a lack of appropriate family members to liaise with. However, 33% (n=13) of stroke survivors whose ESSVR records were analysed did not want to involve their family in ESSVR. Not only do the NICE Guidelines for Stroke Rehabilitation in Adults (2013) advocate for involving the family in the assessment of the impact of the stroke, which is a component of ESSVR, as noted above, they go on to say that rehabilitation goals should be set collaboratively with the stroke survivor and their family or carer, and that families should be given adequate information about stroke and support (another ESSVR component), where *appropriate*. What is unclear within the NICE Guidelines (2013) is what specific situations constitute 'appropriateness' to involve stroke survivors' families. Much of the NICE Guidelines for Stroke Rehabilitation in Adults (2013) pertains to early stroke rehabilitation, which is aimed at restoring function and learning to adjust to the impacts of stroke. However, ESSVR, by definition, is an intervention delivered *early* in the stroke survivor's rehabilitation (i.e., within the first eight weeks of the onset of a new stroke). Assessing the impact of the stroke on the stroke survivor's family should therefore still be 'appropriate' at this time in the stroke survivor's rehabilitation.

There is also evidence from the VR literature that family factors might influence RTW for people with disabilities. Psychosocial factors, and specifically involvement of families in the RTW process have been shown to facilitate RTW in literature reviews (Wang et al., 2014), and qualitative meta-syntheses (Brannigan et al., 2017; Schwarz et al., 2018). Additionally, there is evidence to suggest that clinicians might feel a reticence to work with families of patients due to the desire to keep treatment goals patient-oriented (Levack et al., 2011; Levack et al., 2015). Further exploration of the factors impacting the engagement of family

members and RETAKE OT views of whether this is important to the RTW process is necessary.

7.2.4. Mentoring may have facilitated better fidelity outcomes, but further research is needed to understand how.

Study Four explored the relationships between therapist attributes and both implementation fidelity and stroke survivor return-to-work (RTW) outcomes in 39 OT and stroke survivor pairs. With regards to what OT attributes were associated with implementation fidelity, only increased amounts of mentoring received during their time working with the stroke survivor whose ESSVR records were assessed was associated with higher fidelity score. When exploring what OT attributes are associated with positive RTW outcomes, higher OT fidelity scores and more experience (in years) of providing stroke rehabilitation were associated with an increased likelihood of RTW. These findings suggest that therapists delivering complex rehabilitation interventions in research should be given the opportunity and be encouraged, if not mandated, to engage with mentoring to support fidelity of intervention delivery. OTs with more stroke rehabilitation experience may be better able to support stroke survivors to RTW than those with less experience. Finally, the results indicated that when ESSVR is delivered faithfully, it may be effective in supporting stroke survivors to make a positive RTW. This study was limited by the small numbers of participants and the number of attributes explored, which limited the ability to further explore the relationships between the attributes themselves.

To secure robust fidelity and, in the context of research, trial outcomes, researchers must take special care to ensure that clinicians delivering interventions are properly prepared to do so through comprehensive training and support programmes. In the context of complex interventions, therapist skill-building and maintenance may require changes in knowledge,

attitudes, and confidence, which can theoretically be achieved initially through training (Skivington et al., 2020; Damschroder et al., 2009). Although guidance does exist around best practices for clinicians involved in research (NIHR, 2015), there is little guidance regarding what strategies might best facilitate initial upskilling and ongoing maintenance of skills. The results of a scoping review conducted by Doyle and colleagues (2019) suggested that mentoring provided to OTs, defined as 'a relationship in which a mentor facilitates the personal and professional growth and development of another practitioner' (Occupational Therapy Board of Australia, 2014, p.1), resulted in increased knowledge acquisition and translation. While this review provides useful insight into what strategies facilitate upskilling, it did not provide conclusions related to the role of mentoring in complex rehabilitation studies carried out by OTs.

The Facilitating Return to work through Early Specialist Health (FRESH) feasibility study involved training and mentoring OTs to deliver an Early Specialist Traumatic brain injury Vocational Rehabilitation intervention (ESTVR) to people who had experience a traumatic brain injury (Holmes et al., 2021). The training and mentoring programme within FRESH comprised training sessions, provision of the ESTVR intervention manual, and monthly group mentoring sessions to ensure OT fidelity to ESTVR. This model of training and mentoring was adapted for use in RETAKE to upskill OTs and ensure fidelity to ESSVR (Radford et al., 2020). In her doctoral thesis investigating fidelity to ESTVR, Holmes (Holmes, 2017) qualitatively explored barriers and facilitators to fidelity through interviews with the study's OTs. The OTs in Holmes' thesis reflected that the mentoring programme was essential in supporting them to maintain fidelity to ESTVR. The OTs highlighted that the mentoring had specifically helped them to make fidelity-consistent modifications when adapting the intervention to meet the needs of the participants.

Craven and colleagues (2021) conducted semi-structured interviews with the RETAKE expert mentors and OTs to explore the mentors' roles in facilitating fidelity to and delivery of ESSVR. The results suggested that mentoring improved the OTs' understanding of and confidence to deliver ESSVR. The interviewees also reported that mentoring had improved OT and mentor perception of OT fidelity to ESSVR, however the study lacked quantitative data to evidence these perceptions.

Holmes' findings and the findings of Craven and colleagues (2021) are echoed in the results of Study Four within this thesis, which demonstrated the need for engagement in mentoring through quantitative means. The results of Study 4 are also in accordance with Doyle et al., (2019) scoping review suggesting that mentoring aids knowledge acquisition in OTs. Study Four also highlights that not only was mentoring essential for facilitating fidelity to ESSVR, but that fidelity to ESSVR increased the likelihood of the stroke survivor's successful RTW. This finding further supports the growing literature that has found higher levels of fidelity to be associated with better patient outcomes in studies of complex behaviour change interventions (e.g., Marques et al., 2019; Farmer et al., 2017; Strunk et al, 2010; McHugo et al., 1999).

In reflecting the findings of Study 4 (and those of Holmes, 2017, and Craven et al., 2021) back to NPT (May et al., 2009; May & Finch 2009), mentoring may have facilitated the OTs' coherence. In NPT, coherence the construct associated with sense-making' comprises four components relating to understanding how the intervention differs from usual-care practices (differentiation), the shared understanding of the aims of the intervention (communal specification), understanding individual roles and responsibilities (individual specification) and the understanding of the benefit and importance of the intervention (May et al.,2015; Craven et al., 2021). NPT proposes that coherence, along with the other

components of NPT) is essential for integrating a new set of practices, as ESSVR was to the RETAKE OTs, into usual practice.

The results of this thesis indicate that mentoring was a key implementation strategy for facilitating faithful ESSVR delivery. What remains unknown is what components of mentoring are essential to its success. This might be explored through realist evaluation, a theory-based approach used to unpick why complex interventions work (Pawson & Tilley, 1997). Realist evaluation approaches follow a line of enquiry to answer questions about what components work, for whom and in what circumstances or contexts (Pawson & Tilley, 1997; Salter & Kothari, 2014). The process unearths an intervention's underlying mechanisms that, when enacted in the appropriate context, generate a pattern of outcomes (Hewitt, Sims & Harris, 2012; Salter & Kothari, 2014). By using a realist evaluation approach, we may be able to distil the mentoring provided in RETAKE down to components that we can use in future studies of complex rehabilitation interventions and to make clinical recommendations.

7.2.5. Fidelity to ESSVR and experience of stroke rehabilitation may have facilitated positive RTW outcomes.

In Study Four, I explored the variation in occupational therapists' ESSVR delivery in the context of a definitive, multi-centre RCT where I was able to observe an association between regular engagement with mentoring and increased fidelity scores and, furthermore, an association between increased fidelity scores and stroke survivor RTW outcomes. This not only suggests that ESSVR, when delivered with fidelity, might support stroke survivor RTW, but emphasises the importance of mentoring as an implementation strategy to support fidelity. It was also observed that greater OT stroke rehabilitation

experience was associated with increased likelihood of stroke survivor RTW, which implies that clinicians with greater specialist skill or knowledge of a patient group might be able to support better patient outcomes.

The finding that fidelity to ESSVR was associated with greater likelihood of RTW is one supported by the implementation literature (e.g., Farmer et al., 2017; McHugo et al., 1999; Strunk et al., 2010). However, the finding that stroke survivors treated by RETAKE OTs with more years of experience in stroke rehabilitation were more likely to return-to-work contributes to the inconsistent literature about the influence of clinical experience on patient outcomes (Heinonen and Nissen-Lie 2020; Johns et al., 2019). Earlier studies of therapist experience found modest links between increased experience and better patient outcomes (Bickman, 1999; Stein & Lambert, 1995). However, more recent studies of the impact of therapist experience on patient outcome have largely found no association between experience and patient outcome (Budge et al., 2013; Minami et al., 2009) or a decline in patient outcome as therapist experience increases (Goldberg et al., 2016). In Johns and colleagues' (2019) systematic review of therapist effects, which included 21 studies published between 2012-2017, the impact of therapist experience on patient outcomes is only examined in one study (Goldberg et al., 2016). Goldberg and colleagues conducted a longitudinal analysis of therapists' patients' outcomes measured using the Outcome Questionnaire-45, which is used to measure psychotherapy progress (Lambert, 2004) and therapist experience was expressed as both years of experience and number of cases over time. However, perhaps surprisingly, increase in therapist experience (years of *or* number of cases) was associated with a statistically significant, albeit small, reduction in patient outcome (Years: $X^2(2) = 14.56$, $p < .001$; Cases: $X^2(2) = 23.20$, $p < .001$). When reflecting on the findings within their discussion, Goldberg and colleagues (2016) raised that

their findings were limited by the fact that they measured only the quantity of the therapists' experience in years and cases and not the *quality* of experience. The authors posit that the specific type of experience of the therapists may be important.

The results of Study Four in this thesis did not find a relationship between RETAKE OTs' years of experience as an OT and patient outcome, which is in accordance with the more recent psychotherapy literature. However, Study Four did find that increases in RETAKE OTs' experience of stroke rehabilitation was associated with an increased likelihood to RTW. This finding indicates that experience with a particular patient group, and the specialist knowledge gained from this experience, might be what is facilitating RTW outcomes. This chimes with the reflections from Goldberg et al.'s (2016) study regarding the importance of specifying the type of experience a therapist may have. Future studies within psychotherapy should examine the impact of therapist experience of different patient or client groups and its impact on patient outcomes. It could be that OTs with more experience of stroke rehabilitation are more aware of the barriers facing stroke survivors attempting to return to work and, therefore, better able to support them to do so. Further research into the differences between OTs with different levels of clinical experience is warranted.

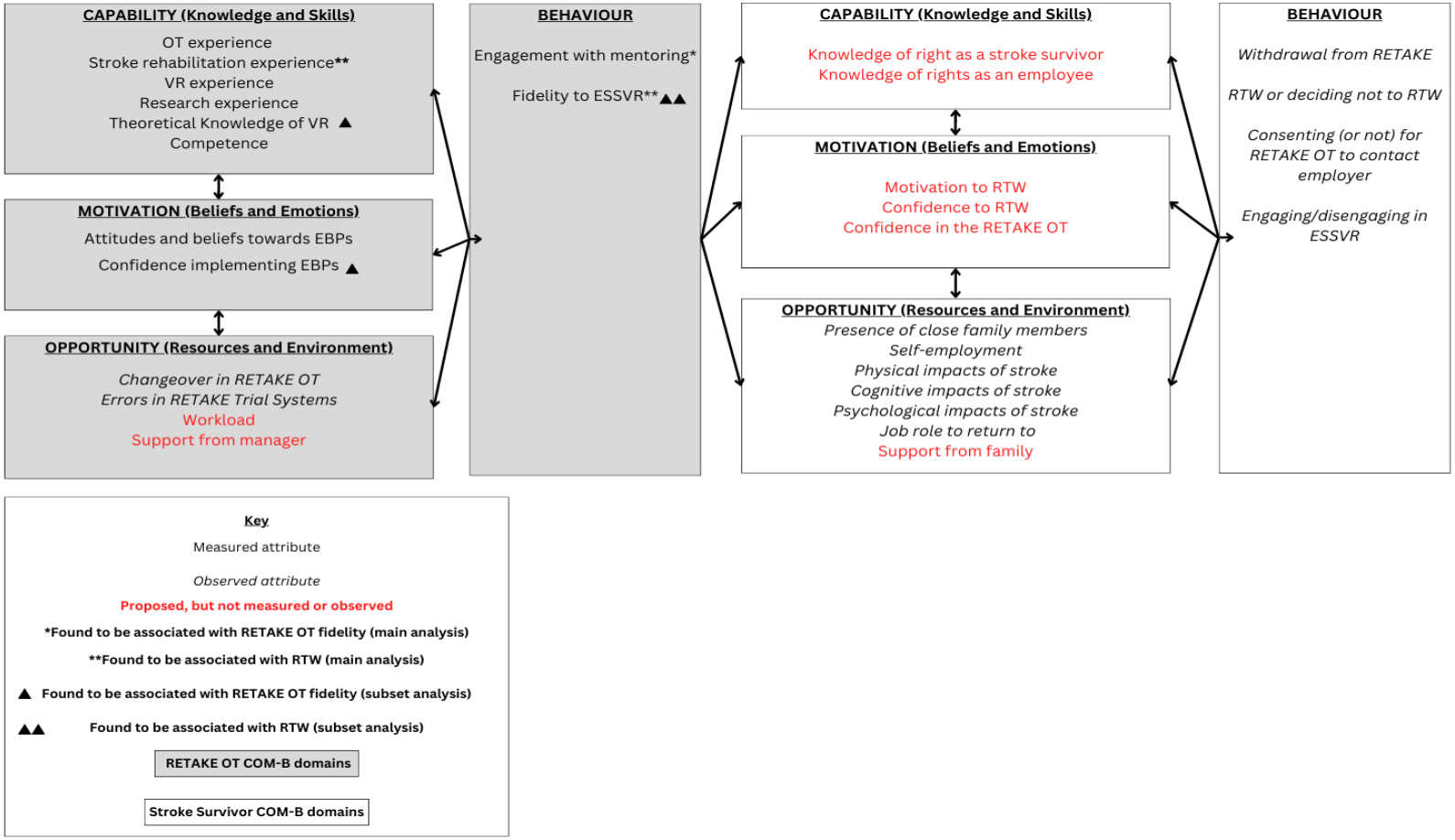
7.2.6. It is important to consider other factors and attributes that may have impacted intervention deliver and receipt.

Reflecting the results of Studies Three and Four (Powers et al., 2023) against the COM-B model, as was done in Study 1, provides some helpful directions for future research (Figure 7-1). The reflection reiterates the potential relationships between the RETAKE OTs'

attributes, fidelity to ESSVR, and stroke survivor RTW outcomes, but also highlights some key OT and stroke survivor attributes that were not measured.

Figure 7-1

Findings from Studies Three and Four mapped onto the COM-B Model



Abbreviations: COM-B, Capability-Opportunity-Motivation-Behaviour model of behaviour change; EBP, evidence-based practice; ESSVR, Early, Stroke Specialist Vocational Rehabilitation; OT, Occupational Therapist; RETAKE, RETurn to work After stroKE; RTW, return-to-work.

RETAKE OT attributes that were measured fell into the Capability (e.g. knowledge and skills), Motivation (e.g. beliefs and emotions) and Behaviour constructs of the COM-B (Michie et al., 2011), but attributes that fell into the Opportunity (e.g., resources and environment) construct were only observed. Study Three allowed us to observe that service-level environmental stressors, such as OT changeover and errors in trial systems, impacted the way ESSVR was delivered and received. For example, in the instance where the trial system failed, the RETAKE OT was not alerted to the randomisation of a stroke survivor to ESSVR, and the stroke survivor did not start ESSVR within eight weeks of their stroke. Another important consideration, which was not directly measured or captured by the fidelity checklist, is workload or support from the RETAKE OT's manager. 'Burnout', which is described as emotional and/or physical exhaustion, is associated with heavy workloads in OTs (Gupta et al., 2012; Poulsen et al., 2014). Work-related stress researchers have found that when employees experience lower levels of burnout, they are more engaged and motivated in their work (Schaufeli & Bakker, 2004). It is therefore reasonable to hypothesise that RETAKE OTs' workloads may have contributed to the fidelity of ESSVR delivery, and that future research is needed to understand the impact of these environmental factors on fidelity and patient outcomes.

The focus of this thesis was largely on the impact of therapist attributes that impacted patient outcomes, mapping the results of Studies Three and Four against the COM-B further demonstrates the importance of considering the attributes of the stroke survivors. RTW was the only stroke survivor outcome measured against RETAKE OT attributes, but attributes related to Opportunity, such as the presence of close family members and the biopsychosocial impacts of the stroke on the stroke survivor, were observed to impact Motivation, Capability, and Behaviour. For example, lasting impacts of stroke (e.g., cognitive

and physical difficulties) could leave a stroke survivor feeling unable to return to work, which is reiterated in systematic reviews examining predictors of RTW after stroke (Ashley et al., 2019; Edwards et al., 2018).

To understand more about how ESSVR might have impacted stroke survivors, future studies might look to measure changes in stroke survivors' Capabilities, specifically knowledge of employment law and what they are legally entitled to as a stroke survivor and an employee, and their Motivations, specifically their motivation to RTW and their confidence to do so. Together, these stroke survivor attributes might have impacted stroke survivor behaviours, such as disengaging from ESSVR, which may have ultimately impacted RTW. What was also not examined in this thesis was the role of the therapeutic alliance, or the therapeutic relationship between a patient and therapist, in influencing patient outcomes. Therapeutic alliance has consistently been found to be a key driver of positive patient outcomes in the psychotherapy literature (Ardito & Rabellino, 2011; Baier et al., 2020) and may help to explain the impact of therapist attributes on patient outcomes outside the psychotherapy literature. Future research should therefore measure both therapist attributes *and* patient attributes and outcomes in tandem to gain better understanding of how complex interventions produce their outcomes.

7.3. Strengths, Limitations and Methodological Considerations

The individual-level factors of stroke survivors and the RETAKE OTs delivering ESSVR were the only individual-level factors considered within this body of research. ESSVR was delivered by the RETAKE OTs to both stroke survivors and their employers, thus there is a need to further explore the impact of employer attributes on stroke survivor RTW in future.

The lack of consideration for employer attributes is therefore a limitation of the approach in this body of research and should be explored in a future study.

The conclusions drawn by this thesis are also limited by the fact that this research was conducted within an RCT. Despite RCTs being the gold standard for assessing the efficacy RCTs for complex interventions, a key limitation of RCTs of complex interventions is that the efforts made by trialists to support implementation of the intervention context can become the determinant of the trial's outcome (Minary et al., 2019; Wang et al., 2006). The results of the studies within this PhD suggest that mentoring, which was *designed* to facilitate fidelity to ESSVR within the context of the trial, *does* support fidelity to ESSVR and that fidelity to ESSVR is associated with increased likelihood of successful RTW. Unless a service is resourced enough to provide opportunity for mentoring, it could be that the increased likelihood of RTW after ESSVR delivery is not translatable to clinical practice. Future research should include observational studies within service regularly delivering complex interventions (e.g., occupational therapy).

A further limitation of the research within this thesis is the use of stroke survivor RTW outcome as one of the main outcomes in Study Four (Chapter Six). Dunn and colleagues (2021) explored of the outcomes produced by Early Intervention Vocational Rehabilitation (EIVR), which is VR delivered to people with a newly acquired neurological condition commencing within two to four weeks of the condition's onset, through realist review. The results of the review suggest that VR intervention can influence patient self-efficacy regarding work ability, psychological adjustment and ability of both patient and employer to engage with reasonable workplace adjustments (Dunn et al., 2021), which may then facilitate positive RTW outcomes. Taken with the findings of the studies within this PhD, complex VR interventions, such as ESSVR, may be creating meaningful, work-supportive

behaviour change in the patient and their employer, but using a binary and distal outcome such as RTW at 12 months does not allow us to capture the nuances underlying the impact of VR (Hilton et al., 2017). Instead, trialists should measure patient outcomes that fall within all components of the COM-B model to better understand the interrelated impacts of an intervention and how they translate to producing the desired outcomes.

Finally, the use of stroke survivor RTW at 12 months post-randomisation also did not allow us to consider the impact of wider environmental factors that created significant barriers to RTW, such as the severe acute respiratory syndrome virus pandemic (SARS-CoV-2, henceforth referred to as COVID-19).

7.4 Impact of the COVID-19 Pandemic

In March 2020, COVID-19 reached pandemic status. Like much of the world, the UK was greatly affected by COVID-19. In efforts to contain the spread of the virus, the World Health Organization (WHO) recommended social distancing and stay-at-home measures were put into place (WHO, 2020). Legally enforced, nationwide lockdowns were in effect from 26th March 2020 to 23rd June 2020 (1st lockdown), 5th November to 2nd December 2020 (2nd lockdown) and 6th January 2021 to 8th March 2021 (3rd lockdown). The COVID-19 pandemic created additional difficulties within the NHS which had implications for the RETAKE study and, by extension, my PhD research.

In attempts to prevent overwhelming the NHS during the COVID-19 pandemic, elective hospital appointments were reduced, and hospitals were urged to discharge patients as quickly as was safely possible (Douiri et al., 2021). Immediately, the number of people presenting in hospital with stroke (especially those experiencing mild strokes; Douiri et al.,

2021) as overall hospital emergency admissions fell by 29% (Appleby, 2020). The presence of risk factors, such as having experienced a stroke, increases a person's risk of catching COVID-19, the severity of the infection and even mortality (Guzik et al., 2020; Nannoni et al., 2021). The impact of COVID-19 was also felt throughout community rehabilitation services where HCPs were regularly redeployed to frontline services to support the COVID-19 response (NHS England, 2020). HCPs who were classed as vulnerable (e.g. those who were pregnant or had pre-existing conditions) were required to work from home where possible. Where service provision continued in the community, it was subject to changes based on emerging guidance from the WHO and the NHS. This led to many services adapting to delivering intervention remotely and no longer offering face-to-face intervention. The timeliness and intensity of rehabilitation have been shown to improve stroke survivor's functional outcomes (Kwakkel et al., 1997; Langhorn et al., 1993). Therefore, it is likely that stroke survivors were greatly impacted by the limited-service provision on over the course of the COVID-19 pandemic.

During the COVID-19 pandemic, many stroke survivors and other medically vulnerable people were advised to shield, even in times where lockdowns were lifted (WHO, 2020). To support employers and their employees, the UK government introduced the Coronavirus Job Retention Scheme which spanned a period of 18 months (1st March 2020 to 30th September 2021) and provided grants which enabled employers to furlough their employees at up to 80% their usual wages (Francis-Devine et al., 2022). The Coronavirus Job Retention Scheme had implications for many. For some, the scheme served to ensure job and financial security whereas for others, it created a sense of uncertainty and put businesses at risk.

At the time of the COVID-19 lockdown and stay-at-home measures, the RETAKE study was in the midst of stroke survivor recruitment and ESSVR delivery. Whilst the OTs in the RETAKE study were encouraged to carry on delivering ESSVR, some OTs were moved from their services to assist the NHS frontline. Service restrictions were put in place which prevented some OTs from conducting home visits with patients. Most OTs moved to remote working and were able to conduct ESSVR over the phone or through videoconferencing software. To aid the RETAKE OTs in delivering ESSVR remotely, the ESSVR training team developed a one-day workshop in order to understand the OTs' previous experience of remote VR delivery and to provide further telerehabilitation training. The training was held in October 2021 and was attended by 11 of the 19 active RETAKE OTs. The training programme included instructions on preparing stroke survivors to receive telerehabilitation, how to deliver it and how to assess risk, safeguarding and privacy considerations. It also signposted OTs to resources to support telerehabilitation sessions. The RETAKE OTs' previous experience of and confidence in delivering telerehabilitation varied greatly, but many OTs had started to use their Trusts' videoconferencing software to contact service users and RETAKE ESSVR participants.

The embedded process evaluation within RETAKE used a longitudinal case study design to explore stroke survivors' experiences of receiving RTW support qualitatively and quantitatively (Trusson et al., in Preparation). The case study series compared the support received by stroke survivors in the ESSVR plus usual care arm of RETAKE and stroke survivors in the usual care only arm over the course of the 12 months they were enrolled on the study. The results of the study revealed that COVID-19 created barriers to accessing community services, such as OT, and had job-related implications. For most stroke survivors

in the study, the COVID-19 pandemic and nationwide lockdowns provided an opportunity for stroke survivors to work from home, which enabled them to manage their fatigue and give more attention to their rehabilitation. For others, COVID-19 created an insurmountable barrier to returning to work, especially in cases where stroke survivors were not allowed or able to work from home. The implication of these barriers created by COVID-19 is that there are more individual (e.g., willingness or ability to engage with remotely delivered intervention) and job-related (e.g. having a manual job that cannot be carried out remotely) factors that may be impacting both the delivery of ESSVR and the stroke survivors' ability to RTW. These considerations should be taken into account when interpreting the results of Study Three, which explores the impact of therapist attributes on fidelity and RTW outcomes as some of the stroke survivors within that analysis will have been affected by COVID-19 and the related furlough scheme.

Therapeutic alliance, the working relationship between a service user or patient and their HCP, is a construct that has been shown in the complex rehabilitation literature to facilitate better patient outcomes, such as adherence to exercise programmes (e.g. Chan & Hagger, 2012; Jackson et al., 2012). Therefore, this was a construct I was hoping to explore as a potential predictor of stroke survivor RTW outcome. My PhD research initially included a component where therapeutic alliance would be assessed through direct observation of ESSVR sessions between the stroke survivors and their OTs and the completion of the Working Alliance Inventory (Observer Version; Titchenor & Hill, 1989). However, these observations were not completed due to the restrictions put in place in NHS community services, which saw many of the RETAKE OTs' teams moving to reduced service provision and home visits restricted.

A systematic review of the impact of remote delivery of psychological interventions on patient outcomes found that there was low impact on therapeutic alliance as long as certain caveats were put in place (e.g. the offer of a practice session to acquaint the patient with the technology, setting expectations together with the patient with regards to session structure and logistics, specific etiquette around videoconferencing, etc.; Lopez et al., 2019). One of the limitations of this study was that it did not consider the range of technological skills and communication abilities of the patients or therapists involved. When reflecting on the results of the review and their implications for ESSVR delivery, it is important to recognise that stroke commonly impacts communication and cognition (Stroke Association, 2021), adding another layer of complexity when considering the use of remote technology for ESSVR delivery. Exploring the impact of remotely delivered ESSVR on therapeutic alliance and its relationships to fidelity and stroke survivor RTW outcomes, would have provided valuable insight into the unique barriers and facilitators stroke survivors face in accessing and engaging with telerehabilitation and should be considered for future research.

7.5 Overall Conclusions

The results of the studies within this PhD suggest that expert mentoring facilitated OT fidelity to ESSVR, which, in combination with greater OT stroke rehabilitation experience, led to a higher likelihood of a successful return to work after stroke. Therefore, therapists with greater condition-specific experience might be able to better understand the challenges faced in the rehabilitation process and more easily appropriately adapt an intervention to meet those needs, thus ensuring a better patient outcome. Challenges faced in VR regarding the involvement of families, monitoring the stroke survivor's RTW, and practicing gradual disengagement warrant further exploration. Engaging in expert

mentoring might also facilitate therapists to deliver and intervention with fidelity, leading to better patient outcomes and more robust efficacy outcomes in the context of large, randomised controlled trials. Future studies of complex rehabilitation interventions should seek to recruit experienced therapists and provide expert mentoring to facilitate intervention implementation and support trial outcomes.

References

Aarons, G. A., Hurlburt, M., & Horwitz, S. M. (2011). Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(1), 4–23.

Aarons, G., McGuier, E., Green, A., Perrott, J., & Bradway, R. (2012). Adaptation happens: A qualitative case study of implementation of The Incredible Years evidence-based parent training programme in a residential substance abuse treatment programme. *Journal of Children's Services*, *7*. https://doi.org/10.1108/17466661211286463

Abdul Latif, L., Daud Amadera, J. E., Pimentel, D., Pimentel, T., & Fregni, F. (2011). Sample Size Calculation in Physical Medicine and Rehabilitation: A Systematic Review of Reporting, Characteristics, and Results in Randomized Controlled Trials. *Archives of Physical Medicine and Rehabilitation*, *92*(2), 306–315. https://doi.org/https://doi.org/10.1016/j.apmr.2010.10.003

Ackerman, S. J., & Hilsenroth, M. J. (2003). A review of therapist characteristics and techniques positively impacting the therapeutic alliance. *Clinical Psychology Review*, *23*(1), 1–33. https://doi.org/10.1016/S0272-7358(02)00146-0

Appleby, J. (2020). What is happening to non-covid deaths? *BMJ*, m1607. https://doi.org/10.1136/bmj.m1607

Aragaki, D., Saby, A., Zappaterra, M., & Escorpizo, R. (2021). Occupational Medicine and Vocational Rehabilitation. *Elsevier EBooks*, 89-99.e2. https://doi.org/10.1016/b978-0-323-62539-5.00006-0

Ardito, R. B., & Rabellino, D. (2011). Therapeutic Alliance and Outcome of Psychotherapy: Historical Excursus, Measurements, and Prospects for Research. *Frontiers in*

Psychology, *2*(270). https://doi.org/10.3389/fpsyg.2011.00270

Arnkelsson, G. B., & Smith, W. P. (2000). The impact of stable and unstable attributes on ability assessment in social comparison. *Personality and Social Psychology Bulletin*, *26*(8), 936–947. https://doi.org/10.1177/01461672002610004

Arwert, H. J., Schults, M., Meesters, J. J. L., Wolterbeek, R., Boiten, J., & Vliet Vlieland, T. (2017). Return to Work 2-5 Years After Stroke: A Cross Sectional Study in a Hospital-Based Population. *Journal of Occupational Rehabilitation*, *27*(2), 239–246. https://doi.org/10.1007/S10926-016-9651-4

Asgary-Eden, V., & Lee, C. M. (2011). Implementing an Evidence-Based Parenting Program in Community Agencies: What Helps and What Gets in the Way? *Administration and Policy in Mental Health and Mental Health Services Research*, *39*(6), 478–488. https://doi.org/10.1007/s10488-011-0371-y

Ashley, K. D., Lee, L. T., & Heaton, K. (2019). Return to Work Among Stroke Survivors. *Workplace Health & Safety*, *67*(2), 87–94. https://doi.org/10.1177/2165079918812483

Atkins, L., Francis, J., Islam, R., O'Connor, D., Patey, A., Ivers, N., Foy, R., Duncan, E. M., Colquhoun, H., Grimshaw, J. M., Lawton, R., & Michie, S. (2017). A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science*, *12*(1), 1–18. https://doi.org/10.1186/s13012-017-0605-9

Augustsson, H., von Thiele Schwarz, U., Stenfors-Hayes, T., & Hasson, H. (2015). Investigating Variations in Implementation Fidelity of an Organizational-Level Occupational Health Intervention. *International Journal of Behavioral Medicine*, *22*(3), 345–355. https://doi.org/10.1007/s12529-014-9420-8

Bachmann Peter; Bachmann, Stefan, C. O. (2018). Recommendations for Improving

Adherence to Home-Based Exercise: A Systematic Review TT - Empfehlungen zur Verbesserung der Adhärenz zu Heimübungsprogrammen: Eine Übersichtsarbeit. *Physikalische Medizin, Rehabilitationsmedizin, Kurortmedizin*, *28*(01), 20–31. https://doi.org/10.1055/s-0043-120527

Baier, A. L., Kline, A. C., & Feeny, N. C. (2020). Therapeutic alliance as a mediator of change: A systematic review and evaluation of research. *Clinical Psychology Review, 82,* Article 101921. https://doi.org/10.1016/j.cpr.2020.101921

Baker, S. M., Marshak, H. H., Rice, G. T., & Zimmerman, G. J. (2001). Patient participation in physical therapy goal setting. *Physical therapy*, *81*(5), 1118-1126.

Baldwin, C., & Brusco, N. K. (2011). The effect of vocational rehabilitation on return-to-work rates post stroke: a systematic review. *Topics in Stroke Rehabilitation*, *18*(5), 562–572.

Baldwin, S. A., & Imel, Z. E. (2013). Therapist effects: Findings and methods. *Bergin and Garfield's Handbook of Psychotherapy and Behavior Change*, *6*, 258–297.

Barrera, M., Berkel, C., & Castro, F. G. (2017). Directions for the Advancement of Culturally Adapted Preventive Interventions: Local Adaptations, Engagement, and Sustainability. *Prevention Science : The Official Journal of the Society for Prevention Research*, *18*(6), 640–648. https://doi.org/10.1007/S11121-016-0705-9

Bassett, S. (2012). Measuring Patient Adherence to Physiotherapy. *Journal of Novel Physiotherapies*, *02*(07). https://doi.org/10.4172/2165-7025.1000e124

Baumann, A. A., Powell, B. J., Kohl, P. L., Tabak, R. G., Penalba, V., Proctor, E. K., Domenech-Rodriguez, M. M., & Cabassa, L. J. (2015). Cultural Adaptation and Implementation of Evidence-Based Parent-Training: A Systematic Review and Critique of Guiding Evidence. *Children and Youth Services Review*, *53*, 113–120. https://doi.org/10.1016/J.CHILDYOUTH.2015.03.025

Beck, A. K., Baker, A. L., Carter, G., Robinson, L., McCarter, K., Wratten, C., Bauer, J., Wolfenden, L., & Britton, B. (2021). Is fidelity to a complex behaviour change intervention associated with patient outcomes? Exploring the relationship between dietitian adherence and competence and the nutritional status of intervention patients in a successful stepped-wedge randomised clinical trial of eating as treatment (EAT). *Implementation Science*, *16*(1), 1–10. https://doi.org/10.1186/S13012-021-01118-Y/TABLES/3

Beinart, N. A., Goodchild, C. E., Weinman, J. A., Ayis, S., & Godfrey, E. L. (2013). Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: a systematic review. *The Spine Journal*, *13*(12), 1940–1950. https://doi.org/10.1016/j.spinee.2013.08.027

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., & Czajkowski, S. (2004). Enhancing Treatment Fidelity in Health Behavior Change Studies: Best Practices and Recommendations From the NIH Behavior Change Consortium. *Health Psychology*, *23*(5), 443–451. https://doi.org/10.1037/0278-6133.23.5.443

Ben-Yishay, Y., Silver, S. M., Piasetsky, E., & Rattok, J. (1987). Relationship between employability and vocational outcome after intensive holistic cognitive rehabilitation. *Journal of Head Trauma Rehabilitation*, *2*(1), 35–48. https://doi.org/10.1097/00001199-198703000-00007

Benny, E., & Evans, C. (2020). Ontario Musculoskeletal Physiotherapists' Attitudes toward and Beliefs about Managing Chronic Low Back Pain. *Physiotherapy Canada*, *72*(4), 355–363. https://doi.org/ 10.3138/ptc-2019-0026

Beutler, L. E., Machado, P. P. P., & Neufeldt, S. A. (1994). Therapist variables. In *Handbook of*

psychotherapy and behavior change, 4th ed. (pp. 229–269). John Wiley & Sons.

Bhattacharyya, O., Reeves, S., & Zwarenstein, M. (2009). What Is Implementation Research? *Research on Social Work Practice*, *19*(5), 491–502. https://doi.org/10.1177/1049731509335528

Bickman, L. (1999). Practice makes perfect and other myths about mental health services. *American Psychologist, 54*(11), 965–978. https://doi.org/10.1037/h0088206

Blackburn, I. M., James, I. A., Milne, D. L., Baker, C., Standart, S., Garland, A., & Reichelt, F. K. (2001). The revised cognitive therapy scale (CTS-R): Psychometric properties. *Behavioural and Cognitive Psychotherapy*, *29*(4), 431–446. https://doi.org/10.1017/S1352465801004040

Blakely, C. H., Mayer, J. P., Gottschalk, R. G., Schmitt, N., Davidson, W. S., Roitman, D. B., & Emshoff, J. G. (1987). The fidelity-adaptation debate: Implications for the implementation of public sector social programs. *American Journal of Community Psychology*, *15*(3), 253–268. https://doi.org/10.1007/bf00922697

Bonner, B., Pillai, R., Sarma, P. S., Lipska, K. J., Pandian, J., & Sylaja, P. N. (2015). Factors predictive of return to work after stroke in patients with mild−moderate disability in India. *European Journal of Neurology*, *23*(3), 548–553. https://doi.org/10.1111/ene.12887

Borrelli, B. (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry*, *71*(SUPPL. 1). https://doi.org/10.1111/j.1752-7325.2011.00233.x

Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A. J., Czajkowski, S., Breger, R., DeFrancesco, C., Levesque, C., Sharp, D. L., Ogedegbe, G., Resnick, B., & Orwig, D. (2005b). A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health

behavior research. *Journal of Consulting and Clinical Psychology*, *73*(5), 852–860. https://doi.org/10.1037/0022-006x.73.5.852

Boswell, J. F., Kraus, D. R., Constantino, M. J., Matteo Bugatti, & Castonguay, L. G. (2017). The implications of therapist effects for routine practice, policy, and training. *American Psychological Association EBooks*, 309–323. https://doi.org/10.1037/0000034-017

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C. P., Squiers, L., Fabrizio, C., & Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, *36*(5), 452–457. https://doi.org/10.1016/j.amepre.2009.02.002

Bowen, G. A. (2009). Document analysis as a qualitative research method. *Qualitative Research Journal*, *9*(2), 27–40. https://doi.org/10.3316/QRJ0902027/FULL/XML

Bragstad, L. K., Bronken, B. A., Sveen, U., Hjelle, E. G., Kitzmüller, G., Martinsen, R., Kvigne, K. J., Mangset, M., & Kirkevold, M. (2019). Implementation fidelity in a complex intervention promoting psychosocial well-being following stroke: an explanatory sequential mixed methods study. *BMC Medical Research Methodology*, *19*(1). https://doi.org/10.1186/s12874-019-0694-z

Brannigan, C., Galvin, R., Walsh, M. E., Loughnane, C., Morrissey, E. J., Macey, C., Delargy, M., & Horgan, N. F. (2017). Barriers and facilitators associated with return to work after stroke: a qualitative meta-synthesis. *Disability and Rehabilitation*, *39*(3), 211–222. https://doi.org/10.3109/09638288.2016.1141242

Branson, A., Myles, P., Mahdi, M., & Shafran, R. (2018). The Relationship between Competence and Patient Outcome with Low-Intensity Cognitive Behavioural Interventions. *Behavioural and Cognitive Psychotherapy*, *46*(1), 101–114. https://doi.org/10.1017/S1352465817000522

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706QP063OA

Braun, V., & Clarke, V. (2012). Thematic analysis. *APA Handbook of Research Methods in Psychology, Vol 2: Research Designs: Quantitative, Qualitative, Neuropsychological, and Biological.*, 57–71. https://doi.org/10.1037/13620-004

Breitenstein, S. M., Gross, D., Garvey, C. A., Hill, C., Fogg, L., & Resnick, B. (2010). Implementation fidelity in community-based interventions. *Research in Nursing & Health*, *33*(2), n/a-n/a. https://doi.org/10.1002/nur.20373

British Society of Rehabilitation Medicine. (2010). *Vocational Assessment and Rehabilitation for People with Long-term Conditions: Recommendations for Best Practice*.

British Society of Rehabilitation Medicine. (2021). *2021 BSRM Standards for specialist rehabilitation for community dwelling adults - update of 2002 standards*.

Brod, M., Stewart, A. L., Sands, L., & Walton, P. (1999). Conceptualization and Measurement of Quality of Life in Dementia: The Dementia Quality of Life Instrument (DQoL). *The Gerontologist*, *39*(1), 25–36. https://doi.org/10.1093/geront/39.1.25

Budge, S. L., Owen, J. J., Kopta, S. M., Minami, T., Hanson, M. R., & Hirsch, G. (2013). Differences among trainees in client outcomes associated with the phase model of change. *Psychotherapy, 50*(2), 150–157. https://doi.org/10.1037/a0029565

Buining, E. M., Kooijman, M. K., Swinkels, I. C. S., Pisters, M. F., & Veenhof, C. (2015). Exploring physiotherapists' personality traits that may influence treatment outcome in patients with chronic diseases: a cohort study. *BMC Health Services Research*, *15*, 558. https://doi.org/https://dx.doi.org/10.1186/s12913-015-1225-1

Burton, C. R., Horne, M., Woodward-Nutt, K., Bowen, A., & Tyrrell, P. (2014). What is rehabilitation potential? Development of a theoretical model through the accounts of

healthcare professionals working in stroke rehabilitation services. *Disability and Rehabilitation*, *37*(21), 1955–1960. https://doi.org/10.3109/09638288.2014.991454

Busch, M. A., Coshall, C., Heuschmann, P. U., McKevitt, C., & Wolfe, C. D. A. (2009). Sociodemographic differences in return to work after stroke: the South London Stroke Register (SLSR). *Journal of Neurology, Neurosurgery & Psychiatry*, *80*(8), 888–893. https://doi.org/10.1136/jnnp.2008.163295

Campbell, B. K., Buti, A., Fussell, H. E., Srikanth, P., McCarty, D., & Guydish, J. R. (2013a). Therapist predictors of treatment delivery fidelity in a community-based trial of 12-step facilitation. *The American Journal of Drug and Alcohol Abuse*, *39*(5), 304–311. https://doi.org/https://dx.doi.org/10.3109/00952990.2013.799175

Campos-Melady, M., Smith, J. E., Meyers, R. J., Godley, S. H., & Godley, M. D. (2017). The effect of therapists' adherence and competence in delivering the adolescent community reinforcement approach on client outcomes. *Psychology of Addictive Behaviors*, *31*(1), 117–129. https://doi.org/10.1037/adb0000216

Cancelliere, C., Cassidy, J. D., & Colantonio, A. (2013). Specific disorder-linked determinants: traumatic brain injury. In *Handbook of work disability* (pp. 303–314). Springer.

Cancelliere, C., Donovan, J., Stochkendahl, M. J., Biscardi, M., Ammendolia, C., Myburgh, C., & Cassidy, J. D. (2016). Factors affecting return to work after injury or illness: Best evidence synthesis of systematic reviews. *Chiropractic and Manual Therapies*, *24*(1). https://doi.org/10.1186/s12998-016-0113-z

Cane, J., O'Connor, D., & Michie, S. (2012a). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*, *7*(1), 1–17. https://doi.org/10.1186/1748-5908-7-37/TABLES/3

Cane, J., O'Connor, D., & Michie, S. (2012b). Validation of the theoretical domains

framework for use in behaviour change and implementation research. *Implementation Science*, *7*(1), 37. https://doi.org/10.1186/1748-5908-7-37

Carpenter, K. M., Cheng, W. Y., Smith, J. L., Brooks, A. C., Amrhein, P. C., Wain, R. M., & Nunes, E. V. (2012). "Old dogs" and new skills: How clinician characteristics relate to motivational interviewing skills before, during, and after training. *Journal of Consulting and Clinical Psychology*, *80*(4), 560.

Carroll, C., & Booth, A. (2015). Quality assessment of qualitative evidence for systematic review and synthesis: is it meaningful, and if so, how should it be performed? *Research Synthesis Methods*, *6*(2), 149–154.

Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., & Balain, S. (2007a). A conceptual framework for implementation fidelity. *Implementation Science*, *2*(1), 1–9. https://doi.org/10.1186/1748-5908-2-40

Castellini, G., Gianola, S., Bonovas, S., & Moja, L. (2016). Improving Power and Sample Size Calculation in Rehabilitation Trial Reports: A Methodological Assessment. *Archives of Physical Medicine and Rehabilitation*, *97*(7), 1195–1201. https://doi.org/https://doi.org/10.1016/j.apmr.2016.02.013

Chambers, D. A., Glasgow, R. E., & Stange, K. C. (2013). The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implementation Science*, *8*(1). https://doi.org/10.1186/1748-5908-8-117

Chan, D. K., & Hagger, M. S. (2012). Self-determined forms of motivation predict sport injury prevention and rehabilitation intentions. *Journal of Science and Medicine in Sport, 15*(5), 398–406. https://doi.org/10.1016/j.jsams.2012.03.016

Chan, D. K., Lonsdale, C., Ho, P. Y., Yung, P. S., & Chan, K. M. (2009). Patient Motivation and Adherence to Postsurgery Rehabilitation Exercise Recommendations: The Influence of

Physiotherapists' Autonomy-Supportive Behaviors. *Archives of Physical Medicine and Rehabilitation*, *90*(12), 1977–1982. https://doi.org/10.1016/j.apmr.2009.05.024

Chen, H.T. (2015). *Practical program evaluation : theory-driven evaluation and the integrated evaluation perspective*. Sage Publications.

Chen, H.-T. (2015). *Practical program evaluation : theory-driven evaluation and the integrated evaluation perspective*. Sage Publications PP - Thousand Oaks, Ca.

Chen, H. (1990). Issues in constructing program theory. *New Directions for Program Evaluation*, *1990*(47), 7–18. https://doi.org/10.1002/EV.1551

Chipchase, L. S., Cavaleri, R., & Jull, G. (2016). Can a professional development workshop with follow-up alter practitioner behaviour and outcomes for neck pain patients? A randomised controlled trial. *Manual Therapy*, *25*, 87–93. https://doi.org/https://dx.doi.org/10.1016/j.math.2016.06.010

Chorpita, B. F., & Daleiden, E. L. (2014). Structuring the Collaboration of Science and Service in Pursuit of a Shared Vision. *Journal of Clinical Child and Adolescent Psychology*, *43*(2), 323–338. https://doi.org/10.1080/15374416.2013.828297

Clyde, J. H., Brooks, D., Cameron, J. I., & Salbach, N. M. (2016). Validation of the Evidence-Based Practice Confidence (EPIC) Scale With Occupational Therapists. *American Journal of Occupational Therapy*, *70*(2), 7002280010p1. https://doi.org/10.5014/ajot.2016.017061

Cochrane, W. S., & Laux, J. M. (2008). A survey investigating school psychologists' measurement of treatment integrity in school-based interventions and their beliefs about its importance. *Psychology in the Schools*, *45*(6), 499–507. https://doi.org/10.1002/pits.20319

Colquhoun, H L, M. E., L., Duncan, E. A., Fiander, M., Champagne, C., & Grimshaw, J. M.

(2017). A systematic review of interventions to increase the use of standardized outcome measures by rehabilitation professionals. *Clinical Rehabilitation*, *31*(3), 299–309. https://doi.org/https://dx.doi.org/10.1177/0269215516644309

Colquhoun, Heather L., Carroll, K., Eva, K. W., Grimshaw, J. M., Ivers, N., Michie, S., Sales, A., & Brehaut, J. C. (2017). Advancing the literature on designing audit and feedback interventions: Identifying theory-informed hypotheses. *Implementation Science*, *12*(1), 1–10. https://doi.org/10.1186/s13012-017-0646-0

Common mental health problems: identification and pathways to care Clinical guideline. (2011). www.nice.org.uk/guidance/cg123

Constantino, M. J., Boswell, J. F., & Coyne, A. E. (2021). Patient, Therapist, and Relational Factors. In M. Barkham, W. Lutz, & L. G. Castonguay (Eds.), *Bergin and Garfield's Handbook of Psychotherapy and Behavior Change* (50th Anniv, pp. 225–262). John Wiley & Sons, Inc.

Constantino, M. J., Marnell, M. E., Haile, A. J., Kanther-Sista, S. N., Wolman, K., Zappert, L., & Arnow, B. A. (2008). Integrative cognitive therapy for depression: A randomized pilot comparison. *Psychotherapy: Theory, Research, Practice, Training*, *45*(2), 122–134. https://doi.org/10.1037/0033-3204.45.2.122

Copeland, L., McNamara, R., Kelson, M., & Simpson, S. (2015). Mechanisms of change within motivational interviewing in relation to health behaviors outcomes: A systematic review. *Patient Education and Counseling*, *98*(4), 401–411. https://doi.org/10.1016/j.pec.2014.11.022

Corbin, J., & Strauss, A. (2015). *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory* (4th ed.). Sage.

Costa, P. T., & McCrae, R. R. (2008). The revised NEO personality inventory (NEO-PI-R). *The*

SAGE Handbook of Personality Theory and Assessment: Volume 2 - Personality Measurement and Testing, 179–198. https://doi.org/10.4135/9781849200479.N9

Cox, D. R., & Grus, C. L. (2019). From continuing education to continuing competence. *Professional Psychology: Research and Practice*, *50*(2), 113–119. https://doi.org/10.1037/pro0000232

Cox, J. R., Martinez, R. G., & Southam-Gerow, M. A. (2019). Treatment integrity in psychotherapy research and implications for the delivery of quality mental health services. *Journal of Consulting and Clinical Psychology*, *87*(3), 221–233. https://doi.org/10.1037/ccp0000370

Coyne, A. E., Constantino, M. J., Gomez Penedo, J. M., Gnall, K. E., Ravitz, P., & McBride, C. (2018). Relation of patient and therapist interpersonal impact messages to outcome in interpersonal therapy for depression. *Journal of Psychotherapy Integration*, *28*(4), 475–488. https://doi.org/10.1037/int0000125

Craig, C. L., Marshall, A. L., Sjöström, M., Bauman, A. E., Booth, M. L., Ainsworth, B. E., Pratt, M., Ekelund, U., Yngve, A., Sallis, J. F., & Oja, P. (2003). International physical activity questionnaire: 12-Country reliability and validity. *Medicine and Science in Sports and Exercise*, *35*(8), 1381–1395. https://doi.org/10.1249/01.MSS.0000078924.61453.FB

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*, *337*(7676), a1655. https://doi.org/10.1136/bmj.a1655

Craven, K., Holmes, J., Powers, K., Clarke, S., Cripps, R. L., Lindley, R., Phillips, J., Tyerman, R., McKevitt, C., Clarke, D., & Radford, K. (2021). Embedding mentoring to support trial processes and implementation fidelity in a randomised controlled trial of vocational rehabilitation for stroke survivors. *BMC Medical Research Methodology*, *21*(1), 203.

https://doi.org/10.1186/S12874-021-01382-Y

Creasy, K. R., Lutz, B. J., Young, M. E., Ford, A., & Martz, C. (2013). The Impact of Interactions with Providers on Stroke Caregivers' Needs. *Rehabilitation Nursing*, *38*(2), 88–98. https://doi.org/10.1002/RNJ.69

Creasy, K. R., Lutz, B. J., Young, M. E., & Stacciarini, J. M. R. (2015). Clinical Implications of Family-Centered Care in Stroke Rehabilitation. *Rehabilitation Nursing : The Official Journal of the Association of Rehabilitation Nurses*, *40*(6), 349. https://doi.org/10.1002/RNJ.188

Creek, J. (2009). Occupational Therapy Defined as a Complex Intervention: A 5-Year Review. *British Journal of Occupational Therapy*, *72*(3), 105–115. https://doi.org/10.1177/030802260907200304

Creek, J., Ilott, I., Cook, S., & Munday, C. (2005). Valuing Occupational Therapy as a Complex Intervention. *British Journal of Occupational Therapy*, *68*(6), 281–284. https://doi.org/10.1177/030802260506800607

Creswell, J. W., & Clark, V. L. P. (2017). *Designing and Conducting Mixed Methods Research*. SAGE Publications. https://books.google.co.uk/books?id=eTwmDwAAQBAJ

Crits-Christoph, P., Baranackie, K., Kurcias, J., Beck, A., Carroll, K., Perry, K., Luborsky, L., McLellan, A., Woody, G., Thompson, L., Gallagher, D., & Zitrin, C. (1991). Meta-Analysis of Therapist Effects in Psychotherapy Outcome Studies. *Psychotherapy Research*, *1*(2), 81–91. https://doi.org/10.1080/10503309112331335511

Dalgetty, R., Miller, C. B., & Dombrowski, S. U. (2019). Examining the theory-effectiveness hypothesis: A systematic review of systematic reviews. *British Journal of Health Psychology*, *24*(2), 334–356. https://doi.org/10.1111/bjhp.12356

Daly, M., & Delaney, L. (2013). The scarring effect of unemployment throughout adulthood

on psychological distress at age 50: Estimates controlling for early adulthood distress and childhood psychological factors. *Social Science and Medicine*, *80*, 19–23. https://doi.org/10.1016/j.socscimed.2012.12.008

Damschroder, L., Aron, D., Keith, R., Kirsh, S., Alexander, J., & Lowery, J. (2009). Fostering Implementation of Health Services Research Findings into Practice: A Consolidated Framework for Advancing Implementation Science. *Implementation Science, 4*(50). https://doi.org/10.1186/1748-5908-4-50

Dane, A. V., & Schneider, B. H. (1998). Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clinical Psychology Review*, *18*(1), 23–45. https://doi.org/10.1016/s0272-7358(97)00043-3

Davidoff, F., Dixon-Woods, M., Leviton, L., & Michie, S. (2015). Demystifying theory and its use in improvement. *BMJ Quality & Safety*, *24*(3), 228–238. https://doi.org/10.1136/BMJQS-2014-003627

Davis, L. L. (1992). Instrument review: Getting the most from a panel of experts. *Applied Nursing Research*, *5*(4), 194–197. https://doi.org/10.1016/S0897-1897(05)80008-4

De Maddalena, H., Pfrang, H., Schohe, R., & Zenner, H. P. (1991). [Speech intelligibility and psychosocial adaptation in various voice rehabilitation methods following laryngectomy]. *Laryngo- Rhino- Otologie*, *70*(10), 562–567. https://doi.org/10.1055/S-2007-998098

De Maddalena, Harry, & Zenner, H. P. (1996). Evaluation of speech intelligibility after prosthetic voice restoration by a standardized telephone test. *Surgery and Prosthetic Voice Restoration after Total and Subtotal Laryngectomy. Elsevier, Amsterdam*, 183–187.

De Neve, J. E., & Oswald, A. J. (2012). Estimating the influence of life satisfaction and

positive affect on later income using sibling fixed effects. *Proceedings of the National Academy of Sciences of the United States of America*, *109*(49), 19953–19958. https://doi.org/10.1073/pnas.1211437109

Deci, E. L., & Ryan, R. M. (1985). The general causality orientations scale: Self-determination in personality. *Journal of Research in Personality*, *19*(2), 109-134.

Delgadillo, J., Branson, A., Kellett, S., Myles-Hooton, P., Hardy, G. E., & Shafran, R. (2020). Therapist personality traits as predictors of psychological treatment outcomes. *Psychotherapy Research*, *30*(7), 857–870. https://doi.org/10.1080/10503307.2020.1731927

Delgadillo, J., Rubel, J., & Barkham, M. (2020). Towards personalized allocation of patients to therapists. *Journal of Consulting and Clinical Psychology*, *88*(9), 799–808. https://doi.org/10.1037/ccp0000507

Denissen, J. J. A., Geenen, R., van Aken, M. A. G., Gosling, S. D., & Potter, J. (2008). Development and Validation of a Dutch Translation of the Big Five Inventory (BFI). *Journal of Personality Assessment*, *90*(2), 152–157. https://doi.org/10.1080/00223890701845229

Deyo, R. A., Battie, M., Beurskens, A. J., Bombardier, C., Croft, P., Koes, B., Malmivaara, A., Roland, M., Von Korff, M., & Waddell, G. (1998). Outcome measures for low back pain research. A proposal for standardized use. *Spine*, *23*(18), 2003–2013. https://doi.org/10.1097/00007632-199809150-00018

Donker-Cools, B. H. P. M., Wind, H., & Frings-Dresen, M. H. W. (2016). Prognostic factors of return to work after traumatic or non-traumatic acquired brain injury. *Disability and Rehabilitation*, *38*(8), 733–741. https://doi.org/10.3109/09638288.2015.1061608

Döpp, C. M. E., Graff, M. J. L., Teerenstra, S., Olde Rikkert, M. G. M., Nijhuis-van der Sanden,

M. W. G., & Vernooij-Dassen, M. J. F. J. (2015). Effectiveness of a training package for implementing a community-based occupational therapy program in dementia: a cluster randomized controlled trial. *Clinical Rehabilitation*, *29*(10), 974–986. https://doi.org/10.1177/0269215514564699

Douiri, A., Muruet, W., Bhalla, A., James, M., Paley, L., Stanley, K., Rudd, A. G., Wolfe, C. D. A., Bray, B. D., & SSNAP Collaboration (2021). Stroke Care in the United Kingdom During the COVID-19 Pandemic. *Stroke*, *52*(6), 2125–2133. https://doi.org/10.1161/STROKEAHA.120.032253

Doyle, N. W., Gafni Lachter, L., & Jacobs, K. (2019). Scoping review of mentoring research in the occupational therapy literature, 2002–2018. *Australian Occupational Therapy Journal*. https://doi.org/10.1111/1440-1630.12579

Dumas, J. E., Lynch, A. M., Laughlin, J. E., Smith, E. P., & Prinz, R. J. (2001). Promoting intervention fidelity: Conceptual issues, methods, and preliminary results from the EARLY ALLIANCE prevention trial. *American Journal of Preventive Medicine*, *20*(1 SUPPL.), 38–47. https://doi.org/10.1016/S0749-3797(00)00272-5

Duncan, P. W., Zorowitz, R., Bates, B., Choi, J. Y., Glasberg, J. J., Graham, G. D., Katz, R. C., Lamberty, K., & Reker, D. (2005). Management of adult stroke rehabilitation care: a clinical practice guideline. *Stroke*, *36*(9), e100–e143.

Dunn, D. S., & Brody, C. (2008). Defining the good life following acquired physical disability. *Rehabilitation Psychology*, *53*(4), 413–425. https://doi.org/10.1037/a0013749

Dunn, J. A., Hackney, J. J., Martin, R. A., Tietjens, D., Young, T., Bourke, J. A., Snell, D. L., Nunnerley, J. L., Hall, A., & Derrett, S. (2021). Development of a Programme Theory for Early Intervention Vocational Rehabilitation: A Realist Literature Review. *Journal of occupational rehabilitation*, *31*(4), 730–743. https://doi.org/10.1007/s10926-021-

10000-z

Duong, P., Sauvé-Schenk, K., Egan, M. Y., Meyer, M. J., & Morrison, T. (2019). Operational Definitions and Estimates of Return to Work Poststroke: A Systematic Review and Meta-Analysis. *Archives of Physical Medicine and Rehabilitation*, *100*(6), 1140–1152. https://doi.org/10.1016/J.APMR.2018.09.121

Durlak, J. A. (2015). Studying Program Implementation Is Not Easy but It Is Essential. *Prevention Science*, *16*(8), 1123–1127. https://doi.org/10.1007/s11121-015-0606-3

Durlak, J. A., & DuPre, E. P. (2008). Implementation Matters: A Review of Research on the Influence of Implementation on Program Outcomes and the Factors Affecting Implementation. *American Journal of Community Psychology*, *41*(3-4), 327–350. https://doi.org/10.1007/s10464-008-9165-0

Dusenbury, L. (2003). A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Education Research*, *18*(2), 237–256. https://doi.org/10.1093/her/18.2.237

Eames, C., Daley, D., Hutchings, J., Hughes, J. C., Jones, K., Martin, P., & Bywater, T. (2008). The leader observation tool: A process skills treatment fidelity measure for the Incredible Years parenting programme. *Child: Care, Health and Development*, *34*(3), 391–400. https://doi.org/10.1111/j.1365-2214.2008.00828.x

Eccles, M., Grimshaw, J., Walker, A., Johnston, M., & Pitts, N. (2005). Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. *Journal of Clinical Epidemiology*, *58*(2), 107–112. https://doi.org/https://doi.org/10.1016/j.jclinepi.2004.09.002

Edwards, J. D., Kapoor, A., Linkewich, E., & Swartz, R. H. (2017). Return to work after young stroke: A systematic review. *International Journal of Stroke*, *13*(3), 243–256.

https://doi.org/10.1177/1747493017743059

Egan, M., Daly, M., & Delaney, L. (2016). Adolescent psychological distress, unemployment, and the Great Recession: Evidence from the National Longitudinal Study of Youth 1997. *Social Science and Medicine*, *156*, 98–105. https://doi.org/10.1016/j.socscimed.2016.03.013

Eraifej, J., Clark, W., France, B., Desando, S., & Moore, D. (2017). Effectiveness of upper limb functional electrical stimulation after stroke for the improvement of activities of daily living and motor function: a systematic review and meta-analysis. *Systematic Reviews*, *6*(1). https://doi.org/10.1186/s13643-017-0435-5

Essery, R., Geraghty, A. W. A., Kirby, S., & Yardley, L. (2016). Predictors of adherence to home-based physical therapies: a systematic review. *Disability and Rehabilitation*, *39*(6), 519–534. https://doi.org/10.3109/09638288.2016.1153160

Fadyl, Joanna K, & McPherson, K. M. (2010). Understanding decisions about work after spinal cord injury. *Journal of Occupational Rehabilitation*, *20*(1), 69–80. https://doi.org/10.1007/s10926-009-9204-1

Fadyl, J. K., & McPherson, K. M. (2009). Approaches to Vocational Rehabilitation After Traumatic Brain Injury. *Journal of Head Trauma Rehabilitation*, *24*(3), 195–212. https://doi.org/10.1097/htr.0b013e3181a0d458

Farmer, C. C., Mitchell, K. S., Parker-Guilbert, K., & Galovski, T. E. (2017). Fidelity to the Cognitive Processing Therapy Protocol: Evaluation of Critical Elements. *Behavior Therapy*, *48*(2), 195–206. https://doi.org/10.1016/j.beth.2016.02.009

Feiner, M., Keszte, J., Meyer, A., Stefan Tino Kulnik, Maasz, M., Harald Lothaller, Fuchs, M., Hormes, K., Jens Oeken, Vogel, H., Koscielny, S., Papst, F., & Schnittger, S. (2021). Effects of Finding the Speech-Language Pathologist Likeable on Postlaryngectomy

Speech Intelligibility Outcomes. *Folia Phoniatrica et Logopaedica*, *73*(6), 1–9. https://doi.org/10.1159/000513928

Fisher, A. G. (2003). *Assessment of motor and process skills*. Three Starts Press.

Flint-Taylor, J., Davda, A., & Cooper, C. L. (2014). Stable personal attributes and a resilient approach to work and career. *SA Journal of Industrial Psychology*, *40*(1), 1–10. https://doi.org/10.4102/sajip.v40i1.1137

Forsberg, S., Fitzpatrick, K. K., Darcy, A., Aspen, V., Accurso, E. C., Bryson, S. W., Agras, S., Arnow, K. D., Le Grange, D., & Lock, J. (2014). Development and evaluation of a treatment fidelity instrument for family-based treatment of adolescent anorexia nervosa. *International Journal of Eating Disorders*, *48*(1), 91–99. https://doi.org/10.1002/eat.22337

Frampton, S. B., Guastello, S., Brady, C., Hale, M., Horowitz, S. M., Susan Bennett Smith, Stone, S., & Picker Institute. (2008). *Patient-centered care : improvement guide*. Planetree, Inc. ; Camden, Me.

Francis-Devine, Brigid, Andy Powell, and Harriet Clark. 2022. “Coronavirus: Impact on the Labour Market.” Briefing Paper CBP 8898. London, UK: House of Commons Library.

Frank, A. O., & Thurgood, J. (2006a). Vocational rehabilitation in the UK: Opportunities for health-care professionals. *International Journal of Therapy and Rehabilitation*, *13*(3), 126–134. https://doi.org/10.12968/ijtr.2006.13.3.21364

Froman, R. D., & Schmitt, M. H. (2003). Thinking both inside and outside the box on measurement articles. *Research in Nursing & Health*, *26*(5), 335–336. https://doi.org/10.1002/nur.10090

Frostad Liaset, I., & Lorås, H. (2016). Perceived factors in return to work after acquired brain injury: A qualitative meta-synthesis. *Scandinavian Journal of Occupational Therapy*,

23(6), 446–457. https://doi.org/10.3109/11038128.2016.1152294

Gagliardi, A. R., Straus, S. E., Shojania, K. G., & Urbach, D. R. (2014). Multiple Interacting Factors Influence Adherence, and Outcomes Associated with Surgical Safety Checklists: A Qualitative Study. *PLoS ONE*, *9*(9), e108585. https://doi.org/10.1371/journal.pone.0108585

Gardner, T., Refshauge, K., Smith, L., McAuley, J., Hübscher, M., & Goodall, S. (2017). Physiotherapists' beliefs and attitudes influence clinical practice in chronic low back pain: a systematic review of quantitative and qualitative studies. *Journal of Physiotherapy*, *63*(3), 132–143. https://doi.org/10.1016/j.jphys.2017.05.017

Gianola, S., Castellini, G., Corbetta, D., & Moja, L. (2019). Rehabilitation interventions in randomized controlled trials for low back pain: proof of statistical significance often is not relevant. *Health and Quality of Life Outcomes*, *17*(1), 127. https://doi.org/10.1186/s12955-019-1196-8

Gilworth, G., Phil, M., Cert, Ad., Sansam, K. A. J., & Kent, R. M. (2009). Personal experiences of returning to work following stroke: An exploratory study. *Work*, *34*(1), 95–103. https://doi.org/10.3233/wor-2009-0906

Glasgow, R. E. (2005). Practical and Relevant Self-Report Measures of Patient Health Behaviors for Primary Care Research. *The Annals of Family Medicine*, *3*(1), 73–81. https://doi.org/10.1370/afm.261

Glasziou, P., Chalmers, I., Altman, D. G., Bastian, H., Boutron, I., Brice, A., Jamtvedt, G., Farmer, A., Ghersi, D., Groves, T., Heneghan, C., Hill, S., Lewin, S., Michie, S., Perera, R., Pomeroy, V., Tilson, J., Shepperd, S., & Williams, J. W. (2010). Taking healthcare interventions from trial to practice. *BMJ*, *341*(7769), 384–387. https://doi.org/10.1136/BMJ.C3852

Glunz, M., Frauer, C., Reu, C., Schmitz, E., Stappert, H., & Thiel, M. M. (2011). *Laryngektomie*. Springer.

Goldsmith, A. H., Veum, J. R., & Darity, W. (1996). The psychological impact of unemployment and joblessness. *The Journal of Socio-Economics*, *25*(3), 333–358. https://doi.org/10.1016/s1053-5357(96)90009-8

Grant, M. (2016). *Developing, delivering and evaluating stroke specific vocational rehabilitation: a feasibility randomised controlled trial* [PhD Thesis]. ttps://www.proquest.com/docview/1913433355?accountid=26642%0Ahttp://link.periodicos.capes.gov.br/sfxlcl41?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:dissertation&genre=dissertations+%26+theses&sid=ProQ:ProQuest+Dissertations+%26+Theses+Global&a

Grant, M., Radford, K., Sinclair, E., & Walker, M. (2014). Return to work after stroke: recording, measuring, and describing occupational therapy intervention. *British Journal of Occupational Therapy*, *77*(9), 457–465. https://doi.org/10.4276/030802214X14098207541072

Greene, J. C., & Caracelli, V. J. (1997). Defining and describing the paradigm issue in mixed-method evaluation. *New Directions for Evaluation*, *1997*(74), 5–17. https://doi.org/10.1002/EV.1068

Greenhalgh, T., Robert, G., Bate, P., Kyriakidou, O., & Macfarlane, F. (2004). *How to Spread Good Ideas A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO)*. https://www.cs.kent.ac.uk/people/staff/saf/share/great-missenden/reference-papers/Overviews/NHS-lit-review.pdf

Greenwood, N., Mackenzie, A., Wilson, N., & Cloud, G. (2009). Managing uncertainty in life after stroke: A qualitative study of the experiences of established and new informal carers in the first 3 months after discharge. *International Journal of Nursing Studies*, *46*(8), 1122–1133. https://doi.org/10.1016/j.ijnurstu.2009.02.011

Grol, R., & Grimshaw, J. (2003). From best evidence to best practice: effective implementation of change in patients' care. *Lancet*, *362*(9391), 1225–1230. https://doi.org/10.1016/S0140-6736(03)14546-1

Grol, R., & Wensing, M. (2004). What drives change? Barriers to and incentives for achieving evidence-based practice. *Medical Journal of Australia*, *180*(6 SUPPL.). https://doi.org/10.5694/j.1326-5377.2004.tb05948.x

Guba, E. G., & Lincoln, Y. S. (1989). *Fourth generation evaluation*. Sage.

Gupta, S., Paterson, M.L., Lysaght, R.M., & von Zweck, C.M. (2012). Experiences ofburnout and coping strategies utilized by occupational therapists. *Canadian Journal of Occupational Therapy*, *79*(2), 86–95.

Gustafsson, L., & Turpin, M. (2012). Analysis of one stroke survivor's transition into vocational experiences. *Brain Impairment*, *13*(1), 99–107.

Guzik, T. J., Mohiddin, S. A., Dimarco, A., Patel, V., Savvatis, K., Marelli-Berg, F. M., Madhur, M. S., Tomaszewski, M., Maffia, P., D'Acquisto, F., Nicklin, S. A., Marian, A. J., Nosalski, R., Murray, E. C., Guzik, B., Berry, C., Touyz, R. M., Kreutz, R., Wang, D. W., Bhella, D., … McInnes, I. B. (2020). COVID-19 and the cardiovascular system: implications for risk assessment, diagnosis, and treatment options. *Cardiovascular research*, *116*(10), 1666–1687. https://doi.org/10.1093/cvr/cvaa106

Hackett, M. L., Glozier, N., Jan, S., & Lindley, R. (2012). Returning to paid employment after stroke: the Psychosocial Outcomes In StrokE (POISE) cohort study. *PloS One*, *7*(7),

e41795. https://doi.org/10.1371/journal.pone.0041795

Haesler, E., Bauer, M., & Fetherstonhaugh, D. (2016). Sexuality, sexual health and older people: A systematic review of research on the knowledge and attitudes of health professionals. *Nurse Education Today*, *40*, 57–71. https://doi.org/10.1016/j.nedt.2016.02.012

Hand, B. N., Darragh, A. R., & Persch, A. C. (2018). Thoroughness and Psychometrics of Fidelity Measures in Occupational and Physical Therapy: A Systematic Review. *American Journal of Occupational Therapy*, *72*(5), 7205205050p1. https://doi.org/10.5014/ajot.2018.025510

Hardeman, W., Michie, S., Fanshawe, T., Prevost, A. T., McLoughlin, K., & Kinmonth, A. L. (2008). Fidelity of delivery of a physical activity intervention: predictors and consequences. *Psychology & Health*, *23*(1), 11–24. https://doi.org/10.1080/08870440701615948

Hart, T. (2009a). Treatment definition in complex rehabilitation interventions. *Neuropsychological Rehabilitation*, *19*(6), 824–840. https://doi.org/10.1080/09602010902995945

Hart, T., & Bagiella, E. (2012). Design and implementation of clinical trials in rehabilitation research. *Archives of Physical Medicine and Rehabilitation*, *93*(8 Suppl), S117-26. https://doi.org/10.1016/j.apmr.2011.11.039

Hart, T., Dijkers, M. P., Whyte, J., Turkstra, L. S., Zanca, J. M., Packel, A., Van Stan, J. H., Ferraro, M., & Chen, C. (2019). A Theory-Driven System for the Specification of Rehabilitation Treatments. In *Archives of Physical Medicine and Rehabilitation* (Vol. 100, Issue 1, pp. 172–180). W.B. Saunders. https://doi.org/10.1016/j.apmr.2018.09.109

Harting, J., Van Assema, P., Van Der Molen, H. T., Ambergen, T., & De Vries, N. K. (2004).

Quality assessment of health counseling: Performance of health advisors in cardiovascular prevention. *Patient Education and Counseling*, *54*(1), 107–118. https://doi.org/10.1016/S0738-3991(03)00194-0

Hasson, H. (2010). Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implementation Science*, *5*(1), 1–9. https://doi.org/10.1186/1748-5908-5-67

HCPC Diversity Data Report 2021: occupational therapists. (n.d.).

Heinonen, E., & Nissen-Lie, H. A. (2020). The professional and personal characteristics of effective psychotherapists: a systematic review. *Psychotherapy Research*, *30*(4), 417–432. https://doi.org/10.1080/10503307.2019.1620366

Hendrick, S. S., Dicke, A., & Hendrick, C. (1998). The Relationship Assessment Scale. *Journal of Social and Personal Relationships*, *15*(1), 137–142. https://doi.org/10.1177/0265407598151009

Henggeler, S. W., Sheidow, A. J., Cunningham, P. B., Donohue, B. C., & Ford, J. D. (2008). Promoting the Implementation of an Evidence-Based Intervention for Adolescent Marijuana Abuse in Community Settings: Testing the Use of Intensive Quality Assurance. *Journal of Clinical Child & Adolescent Psychology*, *37*(3), 682–689. https://doi.org/10.1080/15374410802148087

Hildebrand, M. W., Host, H. H., Binder, E. F., Carpenter, B., Freedland, K. E., Morrow-Howell, N., Baum, C. M., Doré, P., & Lenze, E. J. (2012a). Measuring treatment fidelity in a rehabilitation intervention study. *American Journal of Physical Medicine and Rehabilitation*, *91*(8), 715–724. https://doi.org/10.1097/PHM.0b013e31824ad462

Hilton, G., Unsworth, C. A., Murphy, G. C., Browne, M., & Olver, J. (2017). Longitudinal employment outcomes of an early intervention vocational rehabilitation service for

people admitted to rehabilitation with a traumatic spinal cord injury. *Spinal Cord*, *55*(8), 743–752. https://doi.org/10.1038/sc.2017.24

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A.-W. ., & Michie, S. (2014). Better Reporting of interventions: Template for Intervention Description and Replication (TIDieR) Checklist and Guide. *BMJ*, *348*(mar07 3), 1687–1687. https://doi.org/10.1136/bmj.g1687

Holmes, J. W., Fletcher-Smith, J., Jose Antionio Merchán-Baeza, Phillips, J., & Radford, K. (2021). Can a Complex Vocational Rehabilitation Intervention Be Delivered With Fidelity? Fidelity Assessment in the Fresh Feasibility Trial. *Research Square (Research Square)*. https://doi.org/10.21203/rs.3.rs-38632/v1

Houben, R. M. A., Vlaeyen, J. W. S., Peters, M., Ostelo, R. W. J. G., Wolters, P. M. J. C., & Stomp-van den Berg, S. G. M. (2004). Health Care Providers' Attitudes and Beliefs Towards Common Low Back Pain: Factor Structure and Psychometric Properties of the HC-PAIRS. *The Clinical Journal of Pain*, *20*(1), 37–44. https://doi.org/10.1097/00002508-200401000-00008

Hunt, J., Zwicker, J. G., Godecke, E., & Raynor, A. (2020). Awareness and knowledge of developmental coordination disorder: A survey of caregivers, teachers, allied health professionals and medical professionals in Australia. *Child: Care, Health and Development*. https://doi.org/10.1111/cch.12824

Huppert, J. D., Bufka, L. F., Barlow, D. H., Gorman, J. M., Shear, M. K., & Woods, S. W. (2001). Therapists, therapist variables, and cognitive-behavioral therapy outcome in a multicenter trial for panic disorder. *Journal of Consulting and Clinical Psychology*, *69*(5), 747–755. https://doi.org/10.1037//0022-006X.69.5.747

Hurst, N. P., Kind, P., Ruta, D., Hunter, M., & Stubbings, A. (1997). Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). *British Journal of Rheumatology*, *36*(5), 551–559. https://doi.org/10.1093/rheumatology/36.5.551

Intercollegiate Stroke Working Party. (2023). *National Clinical Guideline for Stroke for the UK and Ireland*. http://www.strokeguideline.org/

Jackson, B., Dimmock, J. A., Taylor, I. M., & Hagger, M. S. (2012). The tripartite efficacy framework in client–therapist rehabilitation interactions: Implications for relationship quality and client engagement. *Rehabilitation Psychology*, *57*(4), 308–319. https://doi.org/10.1037/a0030062

James, I. A., Blackburn, I., Milne, D. L., & Reichfelt, F. K. (2001). Moderators of trainee therapists' competence in cognitive therapy. *British Journal of Clinical Psychology*, *40*(2), 131–141.

Jarva, E., Mikkonen, K., Tuomikoski, A., Kääriäinen, M., Meriläinen, M., Karsikas, E., Koivunen, K., Jounila-Ilola, P., & Oikarinen, A. (2021). Healthcare professionals' competence in stroke care pathways: A mixed-methods systematic review. *Journal of Clinical Nursing*, *00*, jocn.15612. https://doi.org/10.1111/jocn.15612

Jellema, S., van Hees, S., Zajec, J., van der Sande, R., Nijhuis- van der Sanden, M. W., & Steultjens, E. M. (2016). What environmental factors influence resumption of valued activities post stroke: a systematic review of qualitative and quantitative findings. *Clinical Rehabilitation*, *31*(7), 936–947. https://doi.org/10.1177/0269215516671013

Jellema, S., Van Der Sande, R., Van Hees, S., Zajec, J., Steultjens, E. M., & Nijhuis-Van Der Sanden, M. W. (2016). Role of Environmental Factors on Resuming Valued Activities Poststroke: A Systematic Review of Qualitative and Quantitative Findings Archives of

Physical Medicine and Rehabilitation. *ANALYSIS) Archives of Physical Medicine and Rehabilitation*, *97*, 991–1002. https://doi.org/10.1016/j.apmr.2016.01.015

Jo, R. M., & Bucknall, T. (2010). Using theory and frameworks to facilitate the implementation of evidence into practice. *Worldviews on Evidence-Based Nursing*, *7*(2), 57–58. https://doi.org/10.1111/J.1741-6787.2010.00194.X

Johns, R. G., Barkham, M., Kellett, S., & Saxon, D. (2019). A systematic review of therapist effects: A critical narrative update and refinement to Baldwin and Imel's (2013) review. In *Clinical Psychology Review* (67), 78–93. https://doi.org/10.1016/j.cpr.2018.08.004

Johnson, R. B., Onwuegbuzie, A. J., & Turner, L. A. (2007). Toward a definition of mixed methods research. *Journal of Mixed Methods Research*, *1*(2), 112–133. https://doi.org/10.1177/1558689806298224

Johnston, V. (2009). Örebro musculoskeletal pain screening questionnaire. *Australian Journal of Physiotherapy*, *55*(2), 141.

Jones, F., Gage, H., Drummond, A., Bhalla, A., Grant, R., Lennon, S., McKevitt, C., Riazi, A., & Liston, M. (2016). Feasibility study of an integrated stroke self-management programme: a cluster-randomised controlled trial. *BMJ Open*, *6*(1), e008900. https://doi.org/10.1136/bmjopen-2015-008900

Joober, R., Schmitz, N., Annable, L., & Boksa, P. (2012). Publication bias: What are the challenges and can they be overcome? In *Journal of Psychiatry and Neuroscience* (Vol. 37, Issue 3, pp. 149–152). Canadian Medical Association. https://doi.org/10.1503/jpn.120065

Kamper, S. J., Ostelo, R. W. J. G., Knol, D. L., Maher, C. G., de Vet, H. C. W., & Hancock, M. J. (2010). Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced

by current status. *Journal of Clinical Epidemiology*, *63*(7), 760-766.e1. https://doi.org/10.1016/j.jclinepi.2009.09.009

Kauranen, T., Turunen, K., Laari, S., Mustanoja, S., Baumann, P., & Poutiainen, E. (2013). The severity of cognitive deficits predicts return to work after a first-ever ischaemic stroke. *Journal of Neurology, Neurosurgery & Psychiatry*, *84*(3), 316–321.

Kegeles, S. M., Rebchook, G., Tebbetts, S., Arnold, E., Hamiga, J., Zovod, B., Sweeney, D., Williams, R., & Maiorana, A. (2015). Facilitators and barriers to effective scale-up of an evidence-based multilevel HIV prevention intervention. *Implementation Science*, *10*(1), 1–17. https://doi.org/10.1186/S13012-015-0216-2/FIGURES/1

Kiger, M. E., & Varpio, L. (2020). Thematic analysis of qualitative data: AMEE Guide No. 131. *Medical Teacher*, *42*(8), 846–854. https://doi.org/10.1080/0142159X.2020.1755030

King, D., Wittenberg, R., Patel, A., Quayyum, Z., Berdunov, V., & Knapp, M. (2020). The future incidence, prevalence and costs of stroke in the UK. *Age and Ageing*, *49*(2), 277–282. https://doi.org/10.1093/ageing/afz163

Kissela, B. M., Khoury, J. C., Alwell, K., Moomaw, C. J., Woo, D., Adeoye, O., Flaherty, M. L., Khatri, P., Ferioli, S., De Los Rios La Rosa, F., Broderick, J. P., & Kleindorfer, D. O. (2012). Age at stroke: Temporal trends in stroke incidence in a large, biracial population. *Neurology*, *79*(17), 1781–1787. https://doi.org/10.1212/WNL.0b013e318270401d

Kitson, A. L., Rycroft-Malone, J., Harvey, G., McCormack, B., Seers, K., & Titchen, A. (2008). Evaluating the successful implementation of evidence into practice using the PARiHS framework: Theoretical and practical challenges. *Implementation Science*, *3*(1), 1–12. https://doi.org/10.1186/1748-5908-3-1/FIGURES/1

Klaic, M., Kapp, S., Hudson, P., Chapman, W., Denehy, L., Story, D., & Francis, J. J. (2022). Implementability of healthcare interventions: an overview of reviews and development

of a conceptual framework. *Implementation Science*, *17*(1). https://doi.org/10.1186/s13012-021-01171-7

Knappertsbusch, F., Langfeldt, B., & Kelle, U. (2021). Mixed-Methods and Multimethod Research. *Soziologie - Sociology in the German-Speaking World*, 261–272. https://doi.org/10.1515/9783110627275-018

Kolt, G. S., Brewer, B. W., Pizzari, T., Schoo, A. M. M., & Garrett, N. (2007). The Sport Injury Rehabilitation Adherence Scale: a reliable scale for use in clinical physiotherapy. *Physiotherapy*, *93*(1), 17–22. https://doi.org/https://doi.org/10.1016/j.physio.2006.07.002

Koltai, J., Bierman, A., & Schieman, S. (2018). Financial circumstances, mastery, and mental health: Taking unobserved time-stable influences into account. *Social Science and Medicine*, *202*, 108–116. https://doi.org/10.1016/j.socscimed.2018.01.019

Kooijman, M. K., Buining, E. M., Swinkels, I. C. S., Koes, B. W., & Veenhof, C. (2020). Do therapist effects determine outcome in patients with shoulder pain in a primary care physiotherapy setting?. *Physiotherapy*, *107*, 111–117. https://doi.org/https://dx.doi.org/10.1016/j.physio.2019.08.009

Kopec, J. A., Esdaile, J. M., Abrahamowicz, M., Abenhaim, L., Wood-Dauphinee, S., Lamping, D. L., & Williams, J. I. (1996). The Quebec Back Pain Disability Scale: conceptualization and development. *Journal of Clinical Epidemiology*, *49*(2), 151–161. https://doi.org/10.1016/0895-4356(96)00526-4

Kowalchuk Horn, K., Jennings, S., Richardson, G., Van Vliet, D., Hefford, C., & Abbott, J. H. (2012). The patient-specific functional scale: Psychometrics, clinimetrics, and application as a clinical outcome measure. *Journal of Orthopaedic and Sports Physical Therapy*, *42*(1), 30–42. https://doi.org/10.2519/jospt.2012.3727

Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606–613. https://doi.org/10.1046/J.1525-1497.2001.016009606.X

Kumpfer, K. L., Scheier, L. M., & Brown, J. (2020). Strategies to Avoid Replication Failure With Evidence-Based Prevention Interventions: Case Examples From the Strengthening Families Program. *Evaluation and the Health Professions*, *43*(2), 75–89. https://doi.org/10.1177/0163278718772886

Kwakkel, G., Wagenaar, R. C., Koelman, T. W., Lankhorst, G. J., & Koetsier, J. C. (1997). Effects of intensity of rehabilitation after stroke. A research synthesis. *Stroke*, *28*(8), 1550–1556. https://doi.org/10.1161/01.str.28.8.1550

La Marche, J. A., Reed, L. K., Martha Anne Rich, Cash, A. W., Lucas, L. H., & Boll, T. J. (1995). The interactive community-based model of vocational rehabilitation. *Journal of Head Trauma Rehabilitation*. https://doi.org/10.1097/00001199-199508000-00008

La Torre, G., Lia, L., Francavilla, F., Chiappetta, M., & De Sio, S. (2022). Factors that facilitate and hinder the return to work after stroke: an overview of systematic reviews. *La Medicina Del Lavoro*, *113*(3), 2022029. https://doi.org/10.23749/MDL.V113I3.13238

Labuschagne, A. (2015). Qualitative Research - Airy Fairy or Fundamental? *The Qualitative Report*, *8*(1), 100–103. https://doi.org/10.46743/2160-3715/2003.1901

Lambert, M. J., Gregersen, A. T., & Burlingame, G. M. (2004). The Outcome Questionnaire-45. In M. E. Maruish (Ed.), *The use of psychological testing for treatment planning and outcomes assessment: Instruments for adults* (pp. 191–234). Lawrence Erlbaum Associates Publishers.

Langhorne, P., & Pollock, A. (2002). What are the components of effective stroke unit care? *Age and Ageing*, *31*(5), 365–371.

Langhorne, P., Williams, B. O., Gilchrist, W., & Howie, K. (1993). Do stroke units save lives?. *Lancet (London, England)*, *342*(8868), 395–398. https://doi.org/10.1016/0140-6736(93)92813-9

Lau, R., Stevenson, F., Ong, B. N., Dziedzic, K., Treweek, S., Eldridge, S., Everitt, H., Kennedy, A., Qureshi, N., Rogers, A., Peacock, R., & Murray, E. (2015). Achieving change in primary care—effectiveness of strategies for improving implementation of complex interventions: systematic review of reviews. *BMJ Open*, *5*(12), e009993. https://doi.org/10.1136/bmjopen-2015-009993

Law, M., Baptiste, S., McColl, M., Opzoomer, A., Polatajko, H., & Pollock, N. (1990). The Canadian Occupational Performance Measure: An Outcome Measure for Occupational Therapy. *Canadian Journal of Occupational Therapy*, *57*(2), 82–87. https://doi.org/10.1177/000841749005700207

Lawthers, A. G. (2003). Rethinking quality in the context of persons with disability. *International Journal for Quality in Health Care*, *15*(4), 287–299. https://doi.org/10.1093/intqhc/mzg048

Levack, W M M, Weatherall, M., Hay-Smith, E. J. C., Dean, S. G., Mcpherson, K., & Siegert, R. J. (2015). Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation. *Cochrane Database of Systematic Reviews*, *2015*(7), CD009727. https://doi.org/https://dx.doi.org/10.1002/14651858.CD009727.pub2

Levack, William M.M., Dean, S. G., Siegert, R. J., & McPherson, K. M. (2011). Navigating patient-centered goal setting in inpatient stroke rehabilitation: How clinicians control the process to meet perceived professional responsibilities. *Patient Education and Counseling*, *85*(2), 206–213. https://doi.org/10.1016/J.PEC.2011.01.011

Lim, A., Nakamura, B. J., Higa-McMillan, C. K., Shimabukuro, S., & Slavin, L. (2012). Effects of workshop trainings on evidence-based practice knowledge and attitudes among youth community mental health providers. *Behaviour Research and Therapy*, *50*(6), 397–406. https://doi.org/10.1016/j.brat.2012.03.008

Lincoln, N. B., Bradshaw, L. E., Constantinescu, C. S., Day, F., Drummond, A. E., Fitzsimmons, D., Harris, S., Montgomery, A. A., & Nair, R. das. (2020). *Assessing intervention fidelity in the CRAMMS trial*. https://www.ncbi.nlm.nih.gov/books/NBK552437/

Liness, S., Beale, S., Lea, S., Byrne, S., Hirsch, C. R., & Clark, D. M. (2019). The Sustained Effects of CBT Training on Therapist Competence and Patient Outcomes. *Cognitive Therapy and Research*, *43*(3), 631–641. https://doi.org/10.1007/s10608-018-9987-5

Lingiardi, V., Muzi, L., Tanzilli, A., & Carone, N. (2018). Do therapists' subjective variables impact on psychodynamic psychotherapy outcomes? A systematic literature review. *Clinical Psychology & Psychotherapy*, *25*(1), 85–101. https://doi.org/10.1002/CPP.2131

Lipsey, M. W., & Cordray, D. S. (2000). Evaluation Methods for Social Intervention. *Annual Review of Psychology*, *51*(1), 345–375. https://doi.org/10.1146/annurev.psych.51.1.345

Lockett, H., Waghorn, G., & Kydd, R. (2018). A framework for improving the effectiveness of evidence-based practices in vocational rehabilitation. *Journal of Vocational Rehabilitation*, *49*(1), 15–31. https://doi.org/10.3233/JVR-180951

Loisel, P., Buchbinder, R., Hazard, R., Keller, R., Scheel, I., Van Tulder, M., & Webster, B. (2005). Prevention of work disability due to musculoskeletal disorders: the challenge of implementing evidence. *Journal of Occupational Rehabilitation*, *15*(4), 507–524.

Lonsdale, C., Hall, A. M., Murray, A., Williams, G. C., McDonough, S. M., Ntoumanis, N., Owen, K., Schwarzer, R., Parker, P., Kolt, G. S., & Hurley, D. A. (2017). Communication Skills Training for Practitioners to Increase Patient Adherence to Home-Based

Rehabilitation for Chronic Low Back Pain: Results of a Cluster Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation*, *98*(9), 1732-1743.e7. https://doi.org/10.1016/j.apmr.2017.02.025

Lopez, A., Schwenk, S., Schneck, C. D., Griffin, R. J., & Mishkind, M. C. (2019). Technology-based mental health treatment and the impact on the therapeutic alliance. *Current psychiatry reports*, *21*, 1-7.

Lorencatto, F., West, R., Christopherson, C., & Michie, S. (2013). Assessing fidelity of delivery of smoking cessation behavioural support in practice. *Implementation Science*, *8*(1), 1–10.

Lutz, B. J., Ellen Young, M., Cox, K. J., Martz, C., & Rae Creasy, K. (2011). The Crisis of Stroke: Experiences of Patients and Their Family Caregivers. *Topics in Stroke Rehabilitation*, *18*(6), 786–797. https://doi.org/10.1310/tsr1806-786

Lutz, B. J., Young, M. E., Creasy, K. R., Martz, C., Eisenbrandt, L., Brunny, J. N., & Cook, C. (2017). Improving Stroke Caregiver Readiness for Transition From Inpatient Rehabilitation to Home. *The Gerontologist*, *57*(5), 880–889. https://doi.org/10.1093/GERONT/GNW135

Malec, J. F., Buffington, A. L. H., Moessner, A. M., & Thompson, J. M. (1995). Maximizing vocational outcome after brain injury: integration of medical and vocational hospital-based services. *Mayo Clinic Proceedings*, *70*(12), 1165–1171. https://doi.org/10.4065/70.12.1165

Malec, J. F., & Moessner, A. M. (2000). Self-awareness, distress, and postacute rehabilitation outcome. *Rehabilitation Psychology*, *45*(3), 227–241. https://doi.org/10.1037/0090-5550.45.3.227

Malec, J. F., & Moessner, A. M. (2006). Replicated positive results for the VCC model of

vocational intervention after ABI within the social model of disability. *Brain Injury*, *20*(3), 227–236. https://doi.org/10.1080/02699050500488124

Marques, L., Valentine, S. E., Kaysen, D., Mackintosh, M. A., Dixon De Silva, L. E., Ahles, E. M., Youn, S. J., Shtasel, D. L., Simon, N. M., & Wiltsey-Stirman, S. (2019). Provider fidelity and modifications to cognitive processing therapy in a diverse community health clinic: Associations with clinical change. *Journal of Consulting and Clinical Psychology*, *87*(4), 357–369. https://doi.org/10.1037/CCP0000384

Martin, D. J., Garske, J. P., & Davis, M. K. (2000). Relation of the therapeutic alliance with outcome and other variables: a meta-analytic review. *Journal of Consulting and Clinical Psychology*, *68*(3), 438.

Masterson-Algar, P, Burton, C. R., Rycroft-Malone, J., Sackley, C. M., & Walker, M. F. (2014). Towards a programme theory for fidelity in the evaluation of complex interventions. *Journal of Evaluation in Clinical Practice*, *20*(4), 445–452. https://doi.org/https://dx.doi.org/10.1111/jep.12174

May, C., & Finch, T. (2009). Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology*, *43*(3), 535–554. https://doi.org/10.1177/0038038509103208

May, C. R., Cummings, A., Girling, M., Bracher, M., Mair, F. S., May, C. M., Murray, E., Myall, M., Rapley, T., & Finch, T. (2018). Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science*, *13*(1), 80. https://doi.org/10.1186/s13012-018-0758-1

May, C. R., Mair, F., Finch, T., MacFarlane, A., Dowrick, C., Treweek, S., Rapley, T., Ballini, L., Ong, B. N., Rogers, A., Murray, E., Elwyn, G., Légaré, F., Gunn, J., & Montori, V. M. (2009). Development of a theory of implementation and integration: Normalization

Process Theory. *Implementation Science*, *4*(1), 1–9. https://doi.org/10.1186/1748-5908-4-29/COMMENTS

McCormack, B., Kitson, A., Harvey, G., Rycroft-Malone, J., Titchen, A., & Seers, K. (2002). Getting evidence into practice: the meaning of context. *Journal of Advanced Nursing*, *38*(1), 94–104.

McGee, D., Lorencatto, F., Matvienko-Sikar, K., & Toomey, E. (2018). Surveying knowledge, practice and attitudes towards intervention fidelity within trials of complex healthcare interventions. *Trials*, *19*(1). https://doi.org/10.1186/s13063-018-2838-6

McHugh, M. L. (2012). Interrater reliability: The kappa statistic. *Biochemia Medica*, *22*(3), 276–282. https://doi.org/10.11613/bm.2012.031

McHugh, R. K., & Barlow, D. H. (2010). The dissemination and implementation of evidence-based psychological treatments. A review of current efforts. *The American Psychologist*, *65*(2), 73–84. https://doi.org/10.1037/a0018121

McHugh, R. K., Murray, H. W., & Barlow, D. H. (2009). Balancing fidelity and adaptation in the dissemination of empirically-supported treatments: The promise of transdiagnostic interventions. *Behaviour Research and Therapy*, *47*(11), 946–953. https://doi.org/10.1016/j.brat.2009.07.005

McHugo, G. J., Drake, R. E., Teague, G. B., & Xie, H. (1999). Fidelity to assertive community treatment and client outcomes in the New Hampshire dual disorders study. *Psychiatric Services*, *50*(6), 818–824.

McNulty, T., & Ferlie, E. (2002). *Reengineering health care: the complexities of organizational transformation*. OUP Oxford.

Meier, A., McGovern, M. P., Lambert-Harris, C., McLeman, B., Franklin, A., Saunders, E. C., & Xie, H. (2015). Adherence and competence in two manual-guided therapies for co-

occurring substance use and posttraumatic stress disorders: Clinician factors and patient outcomes. *The American Journal of Drug and Alcohol Abuse*, *41*(6), 527–534.

Michie, S., Van Stralen, M. M., & West, R. (2011). The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science*, *6*(1), 1–12.

Miller, C. J., Wiltsey-Stirman, S., & Baumann, A. A. (2020). Iterative Decision-making for Evaluation of Adaptations (IDEA): A decision tree for balancing adaptation, fidelity, and intervention impact. *Journal of Community Psychology*, *October 2019*, 1–15. https://doi.org/10.1002/jcop.22279

Minami, T., Davies, D. R., Tierney, S. C., Bettmann, J. E., McAward, S. M., Averill, L. A., ... & Wampold, B. E. (2009). Preliminary evidence on the effectiveness of psychological treatments delivered at a university counseling center. *Journal of Counseling Psychology*, *56*(2), 309.

Minary, L., Trompette, J., Kivits, J., Cambon, L., Tarquinio, C., & Alla, F. (2019). Which design to evaluate complex interventions? Toward a methodological framework through a systematic review. *BMC Medical Research Methodology*, *19*(1), 1–9. https://doi.org/10.1186/S12874-019-0736-6/FIGURES/2

Monaghan, J., Channell, K., Mcdowell, D., & Stroke, S. (2005). Improving patient and carer communication, multidisciplinary team working and goal-setting in stroke rehabilitation. *Clinical Rehabilitation*, *19*, 194–199.

Moncher, F. J., & Prinz, R. J. (1991a). Treatment fidelity in outcome studies. *Clinical Psychology Review*, *11*(3), 247–266. https://doi.org/https://doi.org/10.1016/0272-7358(91)90103-2

Moncher, F. J., & Prinz, R. J. (1991b). Treatment fidelity in outcome studies. *Clinical*

Psychology Review, *11*(3), 247–266. https://doi.org/10.1016/0272-7358(91)90103-2

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D., & Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, *350*. https://doi.org/10.1136/BMJ.H1258

Mousteri, V., Daly, M., & Delaney, L. (2018). The scarring effect of unemployment on psychological well-being across Europe. *Social Science Research*, *72*, 146–169. https://doi.org/10.1016/j.ssresearch.2018.01.007

Mousteri, V., Daly, M., & Delaney, L. (2020). Underemployment and psychological distress: Propensity score and fixed effects estimates from two large UK samples. *Social Science and Medicine*, *244*(September 2019), 112641. https://doi.org/10.1016/j.socscimed.2019.112641

Murray, E., Treweek, S., Pope, C., MacFarlane, A., Ballini, L., Dowrick, C., Finch, T., Kennedy, A., Mair, F., & O'Donnell, C. (2010). Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Medicine*, *8*, 1–11.

Nannoni, S., de Groot, R., Bell, S., & Markus, H. S. (2021). Stroke in COVID-19: A systematic review and meta-analysis. *International journal of stroke : official journal of the International Stroke Society*, *16*(2), 137–149. https://doi.org/10.1177/1747493020972922

Nascimento, L. R., Scianni, A. A., Ada, L., Fantauzzi, M. O., Hirochi, T. L., & Teixeira-Salmela, L. F. (2021). Predictors of return to work after stroke: a prospective, observational cohort study with 6 months follow-up. *Disability and Rehabilitation*, *43*(4), 525–529.

National Institute for Health Research (NIHR). (2015). Clinical trials guide for trainees:

guidance to support NIHR trainees interested in getting involved in clinical trials. https://www.nihr.ac.uk/documents/clinical-trials-guide/20595

Nelson, M. L. A., McKellar, K. A., Yi, J., Kelloway, L., Munce, S., Cott, C., Hall, R., Fortin, M., Teasell, R., & Lyons, R. (2017). Stroke rehabilitation evidence and comorbidity: a systematic scoping review of randomized controlled trials. *Topics in Stroke Rehabilitation*, *24*(5), 374–380.

NICE (National Institute for Health and Care Excellence). (2013). Stroke rehabilitation in adults. In *Clinical guideline/cg162*. https://www.nice.org.uk/guidance/cg162

Nilsen, P. (2020). Making sense of implementation theories, models, and frameworks. In *Implementation Science 3.0* (pp. 53–79). Springer.

Nissen-Lie, H. A., Heinonen, E., & Delgadillo, J. (2023). Therapist factors. In *The field guide to better results: Evidence-based exercises to improve therapeutic effectiveness.* (pp. 79–106). American Psychological Association. https://doi.org/10.1037/0000358-005

Norcross, J. C., & Lambert, M. J. (2019). Evidence-Based Psychotherapy Relationship: The Third Task Force. *Psychotherapy Relationships That Work*, 1–23. https://doi.org/10.1093/MED-PSYCH/9780190843953.003.0001

Northen, J. G., Rust, D. M., Nelson, C. E., Watts, J. H., J.G., N., D.M., R., & C.E., N. (1995). Involvement of adult rehabilitation patients in setting occupational therapy goals. *The American Journal of Occupational Therapy : Official Publication of the American Occupational Therapy Association*, *49*(3), 214–220.

Ntsiea, M. V., Van Aswegen, H., Lord, S., & Olorunju, S. (2015a). The effect of a workplace intervention programme on return to work after stroke: A randomised controlled trial. *Clinical Rehabilitation*, *29*(7), 663–673. https://doi.org/10.1177/0269215514554241

Ntsiea, M. V., Van Aswegen, H., Lord, S., & Olorunju, S. (2015b). The effect of a workplace

intervention programme on return to work after stroke: A randomised controlled trial. *Clinical Rehabilitation*, *29*(7), 663–673. https://doi.org/10.1177/0269215514554241

O'Cathain, A., Murphy, E., & Nicholl, J. (2010). Three techniques for integrating data in mixed methods studies. *BMJ*, *341*(7783), 1147–1150. https://doi.org/10.1136/BMJ.C4587

O'Connor, B., Kerr, C., Shields, N., & Imms, C. (2016). A systematic review of evidence-based assessment practices by allied health practitioners for children with cerebral palsy. *Developmental Medicine & Child Neurology*, *58*(4), 332–347.

O'Halloran, P. D., Blackstock, F., Shields, N., Holland, A., Iles, R., Kingsley, M., Bernhardt, J., Lannin, N., Morris, M. E., & Taylor, N. F. (2014). Motivational interviewing to increase physical activity in people with chronic health conditions: a systematic review and meta-analysis. *Clinical Rehabilitation*, *28*(12), 1159–1171.

O'Shea, O., McCormick, R., Bradley, J. M., & O'Neill, B. (2016). Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions. *Physical Therapy Reviews*, *21*(3-6), 207–214. https://doi.org/10.1080/10833196.2016.1261237

Occupational Therapy Board of Australia. (2014). Supervision guidelines for occupational therapy. Retrieved from http://www.occupationaltherapyboard.gov.au/Codes-Guidelines.aspx

Ostelo, R. W. J. G., Stomp-van den Berg, S. G. M., Vlaeyen, J. W. S., Wolters, P. M. J. C., & de Vet, H. C. W. (2003). Health care provider's attitudes and beliefs towards chronic low back pain: the development of a questionnaire. *Manual Therapy*, *8*(4), 214–222.

Overmeer, T., Boersma, K., Denison, E., Linton, S. J., T., O., K., B., E., D., Overmeer, T., Boersma, K., Denison, E., & Linton, S. J. (2011). Does teaching physical therapists to

deliver a biopsychosocial treatment program result in better patient outcomes? A randomized controlled trial. *Physical Therapy*, *91*(5), 804–819. https://doi.org/http://dx.doi.org/10.2522/ptj.20100079

Owolabi, M. O., Thrift, A. G., Mahal, A., Ishida, M., Martins, S., Johnson, W. D., Pandian, J., Abd-Allah, F., Yaria, J., Phan, H. T., Roth, G., Gall, S. L., Beare, R., Phan, T. G., Mikulik, R., Akinyemi, R. O., Norrving, B., Brainin, M., & Feigin, V. L. (2021). Primary stroke prevention worldwide: translating evidence into action. *The Lancet Public Health*, *7*(1). https://doi.org/10.1016/s2468-2667(21)00230-9

Palinkas, L. A., Aarons, G. A., Horwitz, S., Chamberlain, P., Hurlburt, M., & Landsverk, J. (2011). Mixed method designs in implementation research. *Administration and Policy in Mental Health*, *38*(1), 44–53. https://doi.org/10.1007/s10488-010-0314-z

Palstam, A., Westerlind, E., Persson, H. C., & Sunnerhagen, K. S. (2019). Work-related predictors for return to work after stroke. *Acta Neurologica Scandinavica*, ane.13067. https://doi.org/10.1111/ane.13067

Parvaneh, S., Cocks, E., Buchanan, A., & Ghahari, S. (2015). Development of a fidelity measure for community integration programmes for people with acquired brain injury. *Brain Injury*, *29*(3), 320–328. https://doi.org/10.3109/02699052.2014.976592

Paul, K. I., & Moser, K. (2009). Unemployment impairs mental health: Meta-analyses. *Journal of Vocational Behavior*, *74*(3), 264–282. https://doi.org/10.1016/j.jvb.2009.01.001

Pawson, R., & Tilley, N. (1997). Realistic evaluation. Sage Publications, Inc.

Peek, K., Sanson-Fisher, R., Mackenzie, L., & Carey, M. (2016). Interventions to aid patient adherence to physiotherapist prescribed self-management strategies: a systematic review. *Physiotherapy*, *102*(2), 127–135. https://doi.org/10.1016/j.physio.2015.10.003

Perepletchikova, F., Treat, T. A., & Kazdin, A. E. (2007). Treatment Integrity in Psychotherapy Research: Analysis of the Studies and Examination of the Associated Factors. *Journal of Consulting and Clinical Psychology*, *75*(6), 829–841. https://doi.org/10.1037/0022-006X.75.6.829

Pérez, D., Van der Stuyft, P., Zabala, M. C., Castro, M., & Lefèvre, P. (2016). A modified theoretical framework to assess implementation fidelity of adaptive public health interventions. *Implementation Science*, *11*(1), 1–11. https://doi.org/10.1186/s13012-016-0457-8

Peters-Scheffer, N., Didden, R., Korzilius, H., & Sturmey, P. (2013). Therapist characteristics predict discrete trial teaching procedural fidelity. *Intellectual and Developmental Disabilities*, *51*(4), 263–272. https://doi.org/10.1352/1934-9556-51.4.263

Phillips, J., Drummond, A., Radford, K., & Tyerman, A. (2010). Return to work after traumatic brain injury: Recording, measuring and describing occupational therapy intervention. *British Journal of Occupational Therapy*, *73*(9), 422–430. https://doi.org/10.4276/030802210X12839367526138

Plano Clark, V. L., & Ivankova, N. V. (2016). *Mixed Methods Research: A Guide to the Field*. https://doi.org/10.4135/9781483398341

Poulsen, A. A., Meredith, P., Khan, A., Henderson, J., Castrisos, V., & Khan, S. R. (2014). Burnout and Work Engagement in Occupational Therapists. *British Journal of Occupational Therapy*, *77*(3), 156–164. https://doi.org/10.4276/030802214x13941036266621

Powers, K., Clarke, S., Phillips, J., Holmes, J. A., Cripps, R., Craven, K., Farrin, A., das Nair, R., & Radford, K. A. (2022). Developing an implementation fidelity checklist for a vocational rehabilitation intervention. *Pilot and Feasibility Studies*, *8*(1), 1–12.

https://doi.org/10.1186/s40814-022-01194-x

Powers, K., das Nair, R., Phillips, J., Farrin, A., & Radford, K. A. (2023). Exploring the Association between Individual-Level Attributes and Fidelity to a Vocational Rehabilitation Intervention within a Randomised Controlled Trial. *International Journal of Environmental Research and Public Health*, *20*(6), 4694–4694. https://doi.org/10.3390/ijerph20064694

Proctor, E. K., Landsverk, J., Aarons, G., Chambers, D., Glisson, C., & Mittman, B. (2009). Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Administration and Policy in Mental Health and Mental Health Services Research*, *36*, 24–34.

Radford, K., Grant, M. I., Sinclair, E. J., Kettlewell, J., & Watkin, C. (2020). Describing Return to Work after Stroke: A Feasibility Trial of 12-month Outcomes. *Journal of Rehabilitation Medicine*, *52*(4), 1–8. https://doi.org/10.2340/16501977-2647

Radford, K. A., Craven, K., McLellan, V., Sach, T. H., Brindle, R., Holloway, I., Hartley, S., Bowen, A., O'Connor, R., Stevens, J., Philips, J., Walker, M., Holmes, J., McKevitt, C., Murray, J., Watkins, C., Powers, K., Shone, A., & Farrin, A. (2020). An individually randomised controlled multi-centre pragmatic trial with embedded economic and process evaluations of early vocational rehabilitation compared with usual care for stroke survivors: study protocol for the RETurn to work After stroKE (RETAKE). *Trials*, *21*(1), 1010. https://doi.org/https://dx.doi.org/10.1186/s13063-020-04883-1

Radford, K. A., McKevitt, C., Clarke, S., Powers, K., Phillips, J., Craven, K., Watkins, C., Farrin, A., Holmes, J., Cripps, R., McLellan, V., Sach, T., Brindle, R., Holloway, I., Hartley, S., Bowen, A., O'Connor, R. J., Stevens, J., Walker, M., … Clarke, D. (2022). RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods process evaluation using

normalisation process theory. *BMJ Open*, *12*(3), e053111. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2021-053111

Rainville, J., Bagnall, D., & Phalen, L. (1995). Health care providers' attitudes and beliefs about functional impairments and chronic back pain. *The Clinical Journal of Pain*, *11*(4), 287–295. https://doi.org/10.1097/00002508-199512000-00006

Richmond, H., Copsey, B., Hall, A. M., Davies, D., & Lamb, S. E. (2017). A systematic review and meta-analysis of online versus alternative methods for training licensed health care professionals to deliver clinical interventions. *BMC Medical Education*, *17*(1). https://doi.org/10.1186/s12909-017-1047-4

Rixon, L., Baron, J., McGale, N., Lorencatto, F., Francis, J., & Davies, A. (2016). Methods used to address fidelity of receipt in health intervention research: a citation analysis and systematic review. *BMC Health Services Research*, *16*(1), 1–24.

Robins, C. S., Ware, N. C., dosReis, S., Willging, C. E., Chung, J. Y., & Lewis-Fernández, R. (2008). Dialogues on Mixed-Methods and Mental Health Services Research: Anticipating Challenges, Building Solutions. *Psychiatric Services (Washington, D.C.)*, *59*(7), 727–731. https://doi.org/10.1176/appi.ps.59.7.727

Robison, J., Wiles, R., Ellis-Hill, C., McPherson, K., Hyndman, D., & Ashburn, A. (2009). Resuming previously valued activities post-stroke: who or what helps? *Disability and Rehabilitation*, *31*(19), 1555–1566. https://doi.org/10.1080/09638280802639327

Roland, M., & Fairbank, J. (2000). The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine*, *25*(24), 3115–3124. https://doi.org/10.1097/00007632-200012150-00006

Rose, A., Rosewilliam, S., & Soundy, A. (2017). Shared decision making within goal setting in rehabilitation settings: A systematic review. *Patient Education and Counseling*, *100*(1),

65–75. https://doi.org/10.1016/J.PEC.2016.07.030

Rothwell, P. M., Coull, A. J., Giles, M. F., Howard, S. C., Silver, L. E., Bull, L. M., Gutnikov, S. A., Edwards, P., Mant, D., Sackley, C. M., Farmer, A., Sandercock, P. A. G., Dennis, M. S., Warlow, C. P., Bamford, J. M., & Anslow, P. (2004). Change in stroke incidence, mortality, case-fatality, severity, and risk factors in Oxfordshire, UK from 1981 to 2004 (Oxford Vascular Study). *Lancet*, *363*(9425), 1925–1933. https://doi.org/10.1016/S0140-6736(04)16405-2

Ryan, R. M., & Connell, J. P. (1989). Perceived locus of causality and internalization: examining reasons for acting in two domains. *Journal of Personality and Social Psychology*, *57*(5), 749.

Ryan, R. M., Lynch, M. F., Vansteenkiste, M., & Deci, E. L. (2011). Motivation and Autonomy in Counseling, Psychotherapy, and Behavior Change: A Look at Theory and Practice 1ψ7. *The Counseling Psychologist*, *39*(2), 193–260. https://doi.org/10.1177/0011000009359313

Rye, M., Rognmo, K., Aarons, G. A., & Skre, I. (2019). Attitudes towards the use of routine outcome monitoring of psychological therapies among mental health providers: The EBPAS–ROM. *Administration and Policy in Mental Health and Mental Health Services Research*, *46*(6), 833–846.

Rye, M., Torres, E. M., Friborg, O., Skre, I., & Aarons, G. A. (2017). The Evidence-based Practice Attitude Scale-36 (EBPAS-36): a brief and pragmatic measure of attitudes to evidence-based practice validated in US and Norwegian samples. *Implementation Science : IS*, *12*(1), 44. https://doi.org/10.1186/s13012-017-0573-0

Saeki, S., & Toyonaga, T. (2010). Determinants of early return to work after first stroke in Japan. *Journal of Rehabilitation Medicine*, *42*(3), 254–258.

https://doi.org/10.2340/16501977-0503

Safikhani, S., Sundaram, M., Bao, Y., Mulani, P., & Revicki, D. A. (2013). Qualitative assessment of the content validity of the Dermatology Life Quality Index in patients with moderate to severe psoriasis. *Journal of Dermatological Treatment, 24*(1), 50–59. https://doi.org/10.3109/09546634.2011.631980

Salbach, N. M., & Jaglal, S. B. (2011). Creation and validation of the evidence-based practice confidence scale for health care professionals. *Journal of Evaluation in Clinical Practice*, *17*(4), 794–800. https://doi.org/10.1111/j.1365-2753.2010.01478.x

Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing Research*, *53*(1), 63–66. https://doi.org/10.1097/00006199-200401000-00010

Saxon, D., & Barkham, M. (2012). Patterns of therapist variability: therapist effects and the contribution of patient severity and risk. *Journal of Consulting and Clinical Psychology*, *80*(4), 535–546. https://doi.org/10.1037/A0028898

Saxon, D., Firth, N., & Barkham, M. (2017). The relationship between therapist effects and therapy delivery factors: Therapy modality, dosage, and non-completion. *Administration and Policy in Mental Health and Mental Health Services Research*, *44*(5), 705–715.

Schaufeli, W.N. & Bakker, A.B. (2003) *UWES – Utrecht Work Engagement Scale:Test Manual.* Utrecht, The Netherlands: Department of Psychology, Utrecht University.

Schoenwald, S. K., Garland, A. F., Chapman, J. E., Frazier, S. L., Sheidow, A. J., & Southam-Gerow, M. A. (2011). Toward the effective and efficient measurement of implementation fidelity. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(1), 32–43. https://doi.org/10.1007/s10488-010-0321-0

Schwarz, B., Claros-Salinas, D., & Streibelt, M. (2017). Meta-Synthesis of Qualitative

Research on Facilitators and Barriers of Return to Work After Stroke. *Journal of Occupational Rehabilitation*, *28*(1), 28–44. https://doi.org/10.1007/s10926-017-9713-2

Sijercic, I., Lane, J. E. M., Gutner, C. A., Monson, C. M., & Stirman, S. W. (2020). The Association Between Clinician and Perceived Organizational Factors with Early Fidelity to Cognitive Processing Therapy for Posttraumatic Stress Disorder in a Randomized Controlled Implementation Trial. *Administration and Policy in Mental Health and Mental Health Services Research*, *47*(1), 8–18.

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021a). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*, *374*. https://doi.org/10.1136/BMJ.N2061

Slaughter, S. E., Hill, J. N., & Snelgrove-Clarke, E. (2015). What is the extent and quality of documentation and reporting of fidelity to implementation strategies: a scoping review. *Implementation Science*, *10*(1), 129. https://doi.org/10.1186/s13012-015-0320-3

Smart, A. (2006). A multi-dimensional model of clinical utility. *International Journal for Quality in Health Care*, *18*(5), 377–382. https://doi.org/10.1093/intqhc/mzl034

Solberg, L. I. (2000). Guideline implementation: what the literature doesn't tell us. *The Joint Commission Journal on Quality Improvement*, *26*(9), 525–537.

Song, F., Parekh, S., Hooper, L., Loke, Y., Ryder, J., Sutton, A., Hing, C., Kwok, C., Pang, C., & Harvey, I. (2010). Dissemination and publication of research findings: an updated review of related biases. *Health Technology Assessment*, *14*(8). https://doi.org/10.3310/hta14080

Southam-Gerow, M. A., Chapman, J. E., Martinez, R. G., McLeod, B. D., Hogue, A., Weisz, J. R., & Kendall, P. C. (2021). Are therapist adherence and competence related to clinical outcomes in cognitive-behavioral treatment for youth anxiety? *Journal of Consulting and Clinical Psychology*, *89*(3), 188–199. https://doi.org/10.1037/ccp0000538

Speers, A. J. H., Bhullar, N., Cosh, S., & Wootton, B. M. (2022). Correlates of therapist drift in psychological practice: A systematic review of therapist characteristics. *Clinical Psychology Review*, *93*(July 2021), 102132. https://doi.org/10.1016/j.cpr.2022.102132

Spencer, J. C., & Wheeler, S. B. (2016). A systematic review of Motivational Interviewing interventions in cancer patients and survivors. *Patient Education and Counseling*, *99*(7), 1099–1105.

Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of Internal Medicine*, *166*(10), 1092–1097. https://doi.org/10.1001/ARCHINTE.166.10.1092

Stein, D. M., & Lambert, M. J. (1995). Graduate training in psychotherapy: are therapy outcomes enhanced?. *Journal of consulting and clinical psychology*, *63*(2), 182–196. https://doi.org/10.1037//0022-006x.63.2.182

Stemler, S. (2001). An overview of content analysis. *Practical Assessment, Research and Evaluation*, *7*(17), 2000–2001. https://doi.org/10.1362/146934703771910080

Stevens, E., Emmett, E., Wang, Y., McKevitt, C., & Wolfe, C. (2017). The burden of stroke in Europe. *London: Stroke Alliance for Europe*, 30–125.

Stirman, S. W., Baumann, A. A., & Miller, C. J. (2019). The FRAME: An expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*, *14*(1), 1–10. https://doi.org/10.1186/s13012-019-0898-y

Strandh, M., Winefield, A., Nilsson, K., & Hammarström, A. (2014). Unemployment and

mental health scarring during the life course. *European Journal of Public Health*, *24*(3), 440–445. https://doi.org/10.1093/eurpub/cku005

Strunk, D. R., Brotman, M. A., & DeRubeis, R. J. (2010). The process of change in cognitive therapy for depression: Predictors of early inter-session symptom gains. *Behaviour Research and Therapy*, *48*(7), 599–606.

Strunk, D. R., Brotman, M. A., DeRubeis, R. J., & Hollon, S. D. (2010). Therapist competence in cognitive therapy for depression: predicting subsequent symptom change. *Journal of Consulting and Clinical Psychology*, *78*(3), 429.

Sulli, S., Scala, L., Berardi, A., Conte, A., Baione, V., Belvisi, D., Leodori, G., & Galeoto, G. (2021). The efficacy of rehabilitation in people with Guillain-Barrè syndrome: a systematic review of randomized controlled trials. *Expert Review of Neurotherapeutics*, *21*(4), 455–461.

Sullivan, M. J. L., Bishop, S., & Pivik, J. (1996). The Pain Catastrophizing Scale: Development and Validation. *Psychological Assessment*, *7*, 524–532. https://doi.org/10.1037//1040-3590.7.4.524

Sumner, J., Harrison, A., & Doherty, P. (2017). The effectiveness of modern cardiac rehabilitation: A systematic review of recent observational studies in non-attenders versus attenders. *PloS One*, *12*(5), e0177658.

Tanaka, H., Toyonaga, T., & Hashimoto, H. (2014). Functional and occupational characteristics predictive of a return to work within 18 months after stroke in Japan: implications for rehabilitation. *International Archives of Occupational and Environmental Health*, *87*(4), 445–453. https://doi.org/10.1007/s00420-013-0883-8

Teddlie, C., & Tashakkori, A. (2009). *Foundations of Mixed Methods Research: Integrating Quantitative and Qualitative Approaches in the Social and Behavioral Sciences*. SAGE

Publications.

Teunisse, S., & Derix, M. M. A. (1997). The interview for deterioration in daily living activities in dementia: agreement between primary and secondary caregivers. *International Psychogeriatrics*, *9 Suppl 1*(SUPPL. 1), 155–162. https://doi.org/10.1017/S1041610297004845

Thijssen, J., Albrecht, G., Muris, P., & de Ruiter, C. (2017). Treatment fidelity during therapist initial training is related to subsequent effectiveness of parent management training—Oregon model. *Journal of Child and Family Studies*, *26*(7), 1991–1999.

Tichenor, V., & Hill, C. E. (1989). A comparison of six measures of working alliance. *Psychotherapy: Theory, Research, Practice, Training*, *26*(2), 195.

Toglia, J., Lee, A., Steinberg, C., & Waldman-Levi, A. (2020). Establishing and measuring treatment fidelity of a complex cognitive rehabilitation intervention: The multicontext approach. *British Journal of Occupational Therapy*, *83*(6), 363–374. https://doi.org/10.1177/0308022619898091

Tomaszewski, W, Manko, G., Ziolkowski, A., & Pachalska, M. (2013). An evaluation of health-related quality of life of patients aroused from prolonged coma when treated by physiotherapists with or without training in the “academy of life” programme. *Annals of Agricultural and Environmental Medicine*, *20*(2), 361–365. https://aaem.pl/fulltxt.php?ICID=1052346

Tomaszewski, Wiesław. (2012). The impact of therapist training in interpersonal communication on rehabilitation outcome for traumatic brain injury patients. *Acta Neuropsychologica*, *10*(4), 509–518. https://doi.org/10.5604/17307503.1030212

Turner-Stokes, L. (2003). Rehabilitation following Acquired Brain Injury. National Clinical Guidelines. *London (United Kingdom): Royal College of Physicians; British Society of*

Rehabilitation Medicine.

U.S. General Accounting Office. (1996). *Content analysis: A Methodology for Structuring and Analyzing Written Material*.

United Way of America. (1996). *Measuring program outcomes: A practical approach*. United Way of America.

van der Kemp, J., Kruithof, W. J., Nijboer, T. C. W., van Bennekom, C. A. M., van Heugten, C., & Visser-Meily, J. M. A. (2019). Return to work after mild-to-moderate stroke: work satisfaction and predictive factors. *Neuropsychological Rehabilitation*, *29*(4), 638–653. https://doi.org/10.1080/09602011.2017.1313746

van Velzen, J. M., de Groot, S., Post, M. W. M., Slootman, J. H. R., van Bennekom, C. A. M., & van der Woude, L. H. V. (2009). Return to work after spinal cord injury: is it related to wheelchair capacity at discharge from clinical rehabilitation?. *American Journal of Physical Medicine & Rehabilitation*, *88*(1), 47–56. https://doi.org/https://dx.doi.org/10.1097/PHM.0b013e31818e6140

Vernon, H. (2008). The Psychometric Properties of the Neck Disability Index. *Archives of Physical Medicine and Rehabilitation*, *89*(7), 1414–1415. https://doi.org/10.1016/j.apmr.2008.05.003

Vestling, M., Tufvesson, B., & Iwarsson, S. (2003). Indicators for return to work after stroke and the importance of work for subjective well-being and life satisfaction Decision Support System for Improved Accessibility in Multi-Family Housing View project Short hospital stay after total hip replacement. *Journal of Rehabilitation Medicine*, *35*, 127–131. https://www.researchgate.net/publication/10706427

Voigt-Radloff, S., Leonhart, R., Schutzwohl, M., Jurjanz, L., Reuster, T., Gerner, A., Marschner, K., van Nes, F., Graff, M., Vernooij-Dassen, M., Rikkert, M. O., Holthoff, V.,

& Hull, M. (2012). Interview for Deterioration in Daily Living Activities in Dementia: construct and concurrent validity in patients with mild to moderate dementia. *International Psychogeriatrics*, *24*(3), 382–390. https://doi.org/https://dx.doi.org/10.1017/S1041610211001785

Volz, M., Ladwig, S., & Werheid, K. (2022). Return to work and depressive symptoms in young stroke survivors after six and twelve months: cross-sectional and longitudinal analyses. *Https://Doi.Org/10.1080/10749357.2022.2026562*. https://doi.org/10.1080/10749357.2022.2026562

Volz, M., Voelkle, M. C., & Werheid, K. (2018). General self-efficacy as a driving factor of post-stroke depression: A longitudinal study. *Neuropsychological Rehabilitation*, *29*(9), 1–13. https://doi.org/10.1080/09602011.2017.1418392

Von Thiele Schwarz, U., Förberg, U., Sundell, K., & Hasson, H. (2018). Colliding ideals - An interview study of how intervention researchers address adherence and adaptations in replication studies. *BMC Medical Research Methodology*, *18*(1), 1–10. https://doi.org/10.1186/s12874-018-0496-8

von Thiele Schwarz, U., Hasson, H., & Lindfors, P. (2015). Applying a fidelity framework to understand adaptations in an occupational health intervention. *Work*, *51*(2), 195–203.

Waddell, G, Newton, M., Henderson, I., Somerville, D., & Main, C. J. (1993). A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain*, *52*(2), 157–168. https://doi.org/10.1016/0304-3959(93)90127-b

Waddell, Gordon, Burton, K., & Kendall, N. (2008). Vocational Rehabilitation What Works, for Whom, and When?. *Vocational Rehabilitation Task Group*, 1–309.

Wade, D. T. (2005). Investigating the effectiveness of rehabilitation professions - a misguided enterprise? *Clinical Rehabilitation*, *19*(1), 1–3. https://doi.org/10.1191/0269215505cr848ed

Wade, D. T. (2020a). What is rehabilitation? An empirical investigation leading to an evidence-based description. *Clinical Rehabilitation*, *34*(5), 571–583. https://doi.org/10.1177/0269215520905112

Wade, D. T. (2020b). What attributes should a specialist in rehabilitation have? Seven suggested specialist Capabilities in Practice. *Clinical Rehabilitation*, *34*(8), 995–1003. https://doi.org/10.1177/0269215520925869/

Wade, D. T. (2021). Defining rehabilitation: An exploration of why it is attempted, and why it will always fail. *Clinical Rehabilitation*, *35*(12), 1650–1656. https://doi.org/10.1177/02692155211028018

Wade, D. T., & Halligan, P. W. (2017). The biopsychosocial model of illness: a model whose time has come. *Clinical Rehabilitation*, *31*(8), 995–1004. https://doi.org/10.1177/0269215517709890

Waje-Andreassen, U., Thomassen, L., Jusufovic, M., Power, K. N., Eide, G. E., Vedeler, C. A., & Naess, H. (2013). Ischaemic stroke at a young age is a serious event--final results of a population-based long-term follow-up in Western Norway. *European Journal of Neurology*, *20*(5), 818–823. https://doi.org/10.1111/ene.12073

Walker, M. F., Hoffmann, T. C., Brady, M. C., Dean, C. M., Eng, J. J., Farrin, A. J., Felix, C., Forster, A., Langhorne, P., Lynch, E. A., Radford, K. A., Sunnerhagen, K. S., & Watkins, C. L. (2017). Improving the development, monitoring and reporting of stroke rehabilitation research: Consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable. *International Journal of Stroke*, *12*(5), 472–

479. https://doi.org/10.1177/1747493017711815

Waller, G., & Turner, H. (2016). Therapist drift redux: Why well-meaning clinicians fail to deliver evidence-based therapy, and how to get back on track. *Behaviour Research and Therapy*, *77*, 129–137. https://doi.org/10.1016/J.BRAT.2015.12.005

Waltman, S. H., Sokol, L., & Beck, A. T. (2017). Cognitive behavior therapy treatment fidelity in clinical trials: review of recommendations. *Current Psychiatry Reviews*, *13*(4), 311–315.

Walton, H., Spector, A., Roberts, A., Williamson, M., Bhatt, J., Tombor, I., & Michie, S. (2020). Developing strategies to improve fidelity of delivery of, and engagement with, a complex intervention to improve independence in dementia: a mixed methods study. *BMC Medical Research Methodology*, *20*(1), 153. https://doi.org/10.1186/s12874-020-01006-x

Walton, H., Spector, A., Tombor, I., & Michie, S. (2017). Measures of fidelity of delivery of, and engagement with, complex, face-to-face health behaviour change interventions: A systematic review of measure quality. *British Journal of Health Psychology*, *22*(4), 872–903.

Walton, H., Spector, A., Williamson, M., Tombor, I., & Michie, S. (2020). Developing quality fidelity and engagement measures for complex health interventions. *British Journal of Health Psychology*, *25*(1), 39–60. https://doi.org/10.1111/bjhp.12394

Walton, H., Tombor, I., Burgess, J., Groarke, H., Swinson, T., Wenborn, J., Spector, A., Orrell, M., Mountain, G., & Michie, S. (2019). Measuring fidelity of delivery of the Community Occupational Therapy in Dementia-UK intervention. *BMC Geriatrics*, *19*(1). https://doi.org/10.1186/s12877-019-1385-7

Wampold, B. E., Baldwin, S. A., Holtforth, M. grosse, & Imel, Z. E. (2017). What characterizes

effective therapists? *How and Why Are Some Therapists Better than Others?: Understanding Therapist Effects.*, 37–53. https://doi.org/10.1037/0000034-003

Wang, S., Moss, J. R., & Hiller, J. E. (2005). Applicability and transferability of interventions in evidence-based public health. *Health Promotion International*, *21*(1), 76–83. https://doi.org/10.1093/heapro/dai025

Wang, Y. C., Kapellusch, J., & Garg, A. (2014). Important factors influencing the return to work after stroke. *Work*, *47*(4), 553–559. https://doi.org/10.3233/wor-131627

Webb, C. A., DeRubeis, R. J., & Barber, J. P. (2010). Therapist Adherence/Competence and Treatment Outcome: A Meta-Analytic Review. *Journal of Consulting and Clinical Psychology*, *78*(2), 200–211. https://doi.org/10.1037/a0018912

Wehman, P., Bricout, J., & Targett, P. (2000). Supported employment for persons with traumatic brain injury: A guide for implementation. In *Traumatic brain injury rehabilitation: Practical vocational, neuropsychological, and psychotherapy interventions.* (pp. 201–240). CRC Press.

Wei, X. J., Liu, X. F., & Fong, K. N. K. (2016). Outcomes of return-to-work after stroke rehabilitation: A systematic review. *British Journal of Occupational Therapy*, *79*(5), 299–308. https://doi.org/10.1177/0308022615624710/ASSET/IMAGES/LARGE/10.1177_0308022615624710-FIG1.JPEG

Westerlind, E., Persson, H. C., Eriksson, M., Norrving, B., & Sunnerhagen, K. S. (2020). Return to work after stroke: A Swedish nationwide registry-based study. *Acta Neurologica Scandinavica*, *141*(1), 56. https://doi.org/10.1111/ANE.13180

Westerlind, E., Persson, H. C., & Sunnerhagen, K. S. (2017). Return to work after a stroke in working age persons; a six-year follow up. *PLoS One*, *12*(1), e0169759.

Wholey, J. S. (1979). *Evaluation--promise and Performance*. Urban Institute. https://books.google.co.uk/books?id=OQ1rQgAACAAJ

Whyte, J., & Hart, T. (2003). It's More Than a Black Box; It's a Russian Doll. *American Journal of Physical Medicine & Rehabilitation*, *82*(8), 639–652. https://doi.org/10.1097/01.phm.0000078200.61840.2d

Williams, G. C., Grow, V. M., Freedman, Z. R., Ryan, R. M., & Deci, E. L. (1996). Motivational predictors of weight loss and weight-loss maintenance. *Journal of Personality and Social Psychology*, *70*(1), 115–126. https://doi.org/10.1037//0022-3514.70.1.115

Wiltsey Stirman, S., Calloway, A., Toder, K., Miller, C. J., Devito, A. K., Meisel, S. N., Xhezo, R., Evans, A. C., Beck, A. T., & Crits-Christoph, P. (2013). Community mental health provider modifications to cognitive therapy: implications for sustainability. *Psychiatric Services (Washington, D.C.)*, *64*(10), 1056–1059. https://doi.org/10.1176/appi.ps.201200456

Wiltsey Stirman, S., Gamarra, J. M., Bartlett, B. A., Calloway, A., & Gutner, C. A. (2017). Empirical Examinations of Modifications and Adaptations to Evidence-Based Psychotherapies: Methodologies, Impact, and Future Directions. *Clinical Psychology : A Publication of the Division of Clinical Psychology of the American Psychological Association*, *24*(4), 396–420. https://doi.org/10.1111/CPSP.12218

Wiltsey Stirman, S., Gutner, C. A., Crits-Christoph, P., Edmunds, J., Evans, A. C., & Beidas, R. S. (2015). Relationships between clinician-level attributes and fidelity-consistent and fidelity-inconsistent modifications to an evidence-based psychotherapy. *Implementation Science*, *10*(1), 1–10. https://doi.org/10.1186/s13012-015-0308-z

Wray, F., Clarke, D., & Forster, A. (2018). Post-stroke self-management interventions: a systematic review of effectiveness and investigation of the inclusion of stroke survivors

with aphasia. *Disability and Rehabilitation*, *40*(11), 1237–1251.

Yasuda, S., Wehman, P., Targett, P., Cifu, D. X., & West, M. (2002). Return to work after spinal cord injury: A review of recent research. *NeuroRehabilitation*, *17*(3), 177–186. https://doi.org/10.3233/NRE-2002-17302

Young, J., & Forster, A. (2007). Review of stroke rehabilitation. *Bmj*, *334*(7584), 86–90.

Zadro, J., O'Keeffe, M., & Maher, C. (2019). Do physical therapists follow evidence-based guidelines when managing musculoskeletal conditions? Systematic review. *BMJ Open, 9* (10). https://doi.org/10.1136/bmjopen-2019-032329

Zamanzadeh, V., Ghahramanian, A., Rassouli, M., Abbaszadeh, A., Alavi-Majd, H., & Nikanfar, A. R. (2015). Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. *Journal of Caring Sciences*, *4*(2), 165–178. https://doi.org/10.15171/jcs.2015.017

Zenner, H. P. (1986). The Postlaryngectomy Telephone Intelligibility Test (PLTT). *Speech Restoration Via Voice Prostheses*, 148–152. https://doi.org/10.1007/978-3-642-71415-3_27

Zhong, B. (2009). How to Calculate Sample Size in Randomized Controlled Trial? *Journal of Thoracic Disease*, *1*(1), 51. /pmc/articles/PMC3256489/

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, *67*(6), 361–370. https://doi.org/10.1111/j.1600-0447.1983.tb09716.x

Zuroff, D. C., McBride, C., Ravitz, P., Koestner, R., Moskowitz, D. S., & Bagby, R. M. (2017). Autonomous and controlled motivation for interpersonal therapy for depression: Between-therapists and within-therapist effects. *Journal of Counseling Psychology 64*(5), 525–537. https://doi.org/10.1037/cou0000239

8. Appendices

8.1 MeSH and non-MeSH Search Terms

{therapist*} OR {chiropodist*} OR {podiatrist*} OR {dietitian*} OR {nutritionist*} OR {occupational therapist*} OR {operating department practitioner*} OR {orthoptist*} OR {osteopath*} OR {paramedic*} OR {physiotherapist*} OR {physical therapist*} OR {prosthetist*} OR {orthotist*} OR {radiographer*} OR

{speech and language therapist*} OR {speech and language pathologist*} OR

{allied health profession*} OR {AHP*} OR {allied health personnel} AND {attribute*} OR {trait*} OR {attitude*} OR {belief*} OR {personalit*} OR {factor*} OR {goal consensus} OR {goal agreement} OR {collaboration} OR {warmth} OR {experience} OR {alliance} OR {therapeutic alliance} OR {rapport} OR {empathy} OR {competence} OR {common factor*} OR {therapist effect*} AND {intervention} OR {programme} OR {program} OR {therapy} OR {treatment} AND {rehabilitation} AND {outcome*} OR {fidelity} OR {quality of life} OR {activities of daily living} OR {ADL*} OR {self-efficacy}

8.2 Systematic Review Screening Form

Review question: Do therapist-level attributes affect patient outcome in complex healthcare intervention studies?

Inclusion criteria: (based on PICO)
Population – Adults (18+)
Intervention – Any complex rehabilitation intervention, can be targeted at any condition, but must be targeted at an individual
Comparator - None
Outcomes - consequence related to the patient
Studies - peer-reviewed publications and grey literature of study findings

SCREENING AND SELECTION TOOL

Reviewer Name:	Screening date:
Author name:	Study ID:
Title:	Publication Source:
Abstract:	

	Include	**Exclude**	**Unclear**
Patient Population:	18 years and over	17 years and younger	Age of population is unclear
Intervention:	Complex rehabilitation intervention	Intervention not considered complex. Intervention is delivered to therapists only.	Unclear

		Intervention is delivered to carers only. Intervention is surgical or pharmacological only. Report only relates to training of therapists delivering intervention (with no delivery of intervention to patients). Protocol only.	
Outcome of interest:	Reports patient outcomes of intervention. Reports a therapist-level attribute.	Does not report and participant outcomes of intervention. Does not report a therapist-level attribute. Reported outcomes are solely regarding therapist.	Reported outcomes are unclear in whether they pertain to the therapist or the patient.
Study Design:	Any design allowable. Published or grey literature.	Opinion piece Study protocol	Study design unclear.
Language:	English	Not English	N/A

Further comments/describe further action required:

Overall decision:
Decision made by:
Agreement by:
Disagreement by:
Adjudication by:

Further definitions:

Therapist: Person delivering a complex healthcare intervention. For the purposes of this review, this will be taken to also include research assistants, assistant and trainee psychologists.

Complex healthcare intervention: as defined by MRC 2008, Hart 2009 - Interventions that are experienced-based and contain several interacting components. See https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/ for more information

Outcome: a consequence of an intervention

Developed, developing and underdeveloped countries: as listed in the UN Composition of macro geographical (continental) regions, geographical sub-regions and selected economic and other groupings: https://unstats.un.orh/unsd/methods/m49/m49regin.htm

8.3 Data Extraction Tool

Study ID (Surname of first author and year of publication):

1. General Information	Description in report/paper	Location in text (page #/figure/table)
Date Form Completed (dd/mm/yyyy)		
Name of Extractor		
Paper/Abstract/Report Title		
Date of Publication		
Authors		
Publication type		
Country study conducted in		
Possible Conflicts of Interest		
Notes:		

2. Study Characteristics	Description in report/paper	Location in text (page #/figure/table)
Type of Study		
Sample Description		
Focused patient group/condition		
Notes:		

3. Therapists	Description in report/paper	Location in text (page #/figure/table)
Total number of participants/sample size		
Male		
Female		
Age range		
Ethnicity		
Inclusion Criteria		
Exclusion Criteria		
Notes:		

4. Patients/clients	Description in report/paper	Location in text (page #/figure/table)
Total number of patients/clients		
Male		
Female		
Age range		
Ethnicity		
Inclusion criteria		
Exclusion criteria		
Notes:		

5. Methods	Description in report/paper	Location in text (page #/figure/table)
Aim of study		
Design		
Study start date		
Study end date/duration		

Notes:		

6. Outcomes	Description in report/paper	Location in text (page #/figure/table)
Primary outcome (give definition)		
How was the outcome measured? (List tools, measures, etc)		
Is measurement tool validated?		
Measurement time points		
Results (report stats where possible)		
Notes:		
Secondary outcome(s) (give definition)		
How was/were the secondary outcome(s) measured? (List tools, measures, etc)		

Are the measurement tools validated?		
Measurement time points (note whether the time points are from randomisation or from start of intervention)		
Results (report stats where possible)		
Notes:		

7. Intervention Characteristics	Description in report/paper	Location in text (page #/figure/table)
Description of intervention		
Aim of intervention		
Who provided the intervention? (e.g. therapist, nurse, etc)		
Mode of delivery (e.g. face-to-face)		

Where was the intervention delivered?		
How frequently were patients receiving intervention sessions?		
What was the total duration of the intervention?		
Was the intervention individually tailored (if yes, how)?		
Was the intervention modified during the study (if yes, why and how)?		
Was intervention fidelity assessed? (If yes, how and to what extent was the intervention delivered to fidelity? Report stats if available)		
Control group		
Notes:		

8. Therapist Attributes	Description in report/paper	Location in text (page #/figure/table)
NOTE: Please duplicate for multiple attributes		
Attribute measured		
How is it defined?		
How was it measured? (list tools, measures, etc)		
Is the measurement tool validated?		
Did the attribute impact outcome?		
If yes, what outcome?		
How is this reported (e.g. odds ratios, etc - extract full statistic, not just p value)		
Notes:		

9. Proposed Mechanism	Description in report/paper	Location in text (page #/figure/table)

Is there a proposed mechanism by which the attributes affect outcome (e.g. fidelity)?		
Notes:		

8.4 ESSVR Fidelity Checklist

Fidelity Checklist	Participant ID:		Researcher Initials:			ime Taken to Complet	Hours	Minutes
Stage One: Early Recovery								
Component Number	Core/Desirable	Component Description	Evidence of compon	Data Extraction			Data Source	
1.1	Core	RETAKE OT intervenes within 12 weeks of stroke	SELECT	Date of stroke dd/mm/yyyy Date of first contact dd/mm/yyyy	OT must have interevened by: #VALUE!	Reason (if not within 12 weeks):	SELECT	
1.2	Core	RETAKE OT assesses the impact of the stroke on the participant	SELECT				SELECT	
1.3	Core	RETAKE OT assesses the impact of the stroke on the participant's job	SELECT				SELECT	
1.4	Desirable	RETAKE OT assesses the impact of the stroke on the participant's family	SELECT				SELECT	
1.5	Core	RETAKE OT helps the participant plan a return to work and prepares them to return to work	SELECT				SELECT	
1.6	Core	RETAKE OT communicates in writing with relevant stakeholders regarding work status	SELECT				SELECT	
1.7	Core	RETAKE OT coordinates VR across relevant sectors	SELECT				SELECT	

Stage 1

Core		Desirable	
Evidence	0	Evidence	0
No Evidence	0	No Evidence	0
Not Deliverab	0	Not Deliverab	0
Total	0		

Stage Two: Graded Return to Work

Component Number	Core/Desirable	Component Description	Evidence of compone...	Data Extraction	
2.1	Core	RETAKE OT provides education and advice to the participant	SELECT		SELECT
2.2	Desirable	RETAKE OT provides emotional support to the	SELECT		SELECT
2.3	Core	RETAKE OT provides education and advice to the	SELECT		SELECT
2.4	Desirable	RETAKE OT provides emotional support to the	SELECT		SELECT
2.5	Desirable	RETAKE OT provides education and advice to the participant's family	SELECT		SELECT
2.6	Desirable	RETAKE OT provides emotional support to the participant's family	SELECT		SELECT
2.7	Core	RETAKE OT negotiates a phased return to work	SELECT		SELECT
2.8	Core	RETAKE OT mediates workplace adjustments	SELECT		SELECT
2.9	Core	RETAKE OT provides mechanism for feedback based on work performance	SELECT		SELECT
2.10	Core	RETAKE OT continuously monitors the participant's return to work to ensure sustainability and job retention	SELECT		SELECT

Stage 2

Core		Desirable	
Evidence	0	Evidence	0
No Evidence	0	No Evidence	0
Not Deliverabl	0	Not Deliverabl	0
Total	0		

Stage Three: Job Retention

Component Number	Core/Desirable	Component Description	Evidence of compone	Data Extraction	
3.1	Core	**RETAKE OT identifies issues that arise within the return to work process with relevant stakeholders.**	SELECT		SELECT
3.2	Core	**RETAKE OT addresses the issues that arise within the return to work process with all stakeholders**	SELECT		SELECT
3.3	Core	**alternative duties and/or job roles for the participant where current work could not be sustained/ was not feasible**	SELECT		SELECT
3.4	Core	**OT practices gradual, appropriate disengagement from the intervention with the participant**	SELECT		SELECT
3.5	Core	**gradual, appropriate disengagement from the intervention with the participant's employer**	SELECT		SELECT

Stage 3

Core		Desirable	
Evidence	0	Evidence	0
No Evidence	0	No Evidence	0
Not Deliverabl	0	Not Deliverabl	0
	0		

Stage Four: Discharge Process

Component Number	Core/Desirable	Component Description	Evidence of compone	Data Extraction	
4.1	Core	**RETAKE OT and participant agree an appropriate timepoint for withdrawing from the intervention**	SELECT		SELECT
4.2	Core	**RETAKE OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant**	SELECT		SELECT
4.3	Core	**RETAKE OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant's employer**	SELECT		SELECT
4.4	Desirable	**RETAKE OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant's family**	SELECT		SELECT
4.5	Core	**RETAKE OT provides the participant's GP and other relevant health care professionals with a copy of the Discharge Letter**	SELECT		SELECT

Stage 4

Core		Desirable	
Evidence	0	Evidence	0
No Evidence	0	No Evidence	0
Not Deliverabl	0	Not Deliverabl	0
Total	0		

This table shows the percentage of components delivered (Core and Desireable).

Stage	Core	%	Desirable	%
Stage One	0	0	0	0
Stage Two	0	0	0	0
Stage Three	0	0	NONE	NONE
			0	
Stage Four	0	0		0
Total	0	0.0	0	0.0

This table shows the **overall** fidelity score, taking desirable components and non-deliverable components into account.

Stage	
Stage One	0
Stage Two	0
Stage Three	0
Stage Four	0
Total	0

Totals	Core		Desirable	
	Evidence	0	Evidence	0
	No Evidence	0	No Evidence	0
	Not Deliverabl	0	Not Deliverabl	0

Without	0
With desirable	0

8.5 ESSVR Fidelity Checklist Guidance Notes

8.5.1. Stage One: Early Recovery and Work Preparation

8.5.1.1. ESSVR OT intervenes within 12 weeks of stroke

For the intervention to have been considered to have been delivered 'early', the ESSVR OTs must have intervened within 12 weeks of the participant's stroke. 'Intervening' can include the initial phone call to introduce themselves as the participant's ESSVR OT. This first contact should be documented on the **Occupational Therapy ESSVR Assessment Form** and/or the **Therapy Case Notes**. Input the date of the participant's stroke where indicated in the spreadsheet in dd/mm/yyyy format. The spreadsheet will calculate the date by which the participant will have needed to be seen by. Input the date of first contact as evidence. Select the source of evidence. Instances where participants were still in hospital should be considered as 'No' in most cases as many OTs are able to contact the participant in hospital. 'Not Deliverable' would be an appropriate selection if the participant is not engaging with the OT despite the OT's attempts to contact the participant.

Select 'Yes' if ESSVR OT made contact with participant within 12 weeks of their stroke.

Select 'No' if ESSVR OT did not make contact with participant within 12 weeks of their stroke and record any reason that this was delayed.

Select 'Undeliverable' if ESSVR OT did not make contact with participant despite many evident attempts to do so.

8.5.1.2. ESSVR OT assesses the impact of the stroke on the participant

This could be evidenced/documented in the Occupational Therapy ESSVR Assessment Form and/or the Therapy Case Notes:

Functional assessments: This will help the ESSVR OT determine what skills and areas have been affected by the stroke. ESSVR OTs have been encouraged to begin with physical skills as they are easier for the participant to identify. In addition to attempting to gain an overall picture of the impact of the stroke on the participant, these functional assessments should also attempt to assess skills that might be similar to work tasks (computer skills, telephone skills, emails, report writing, manual tasks at home). ESSVR OTs are encouraged to think about fatigue and impact on performance.

Standardised assessments: These should be conducted if they are required and available locally. In cases where standardised assessments have been or may have been conducted by another service, there should be evidence of liaison with the appropriate healthcare services (i.e., physiotherapy, neuropsychological, OT, and speech and language services).

Social impact: ESSVR OTs might assess whether the stroke has had an impact on the participant's ability to cope with social interaction.

Select 'Yes' if ESSVR OT assessed the impact of the stroke on the participant and extract evidence verbatim from case file.

Select 'No' if ESSVR OT did not assess the impact of the stroke on the participant and detail any reasons for why this was not completed.

Select ‘Not Deliverable’ if there is a reason perceived for not assessing the impact of the stroke and detail the reason.

8.5.1.3. ESSVR OT assesses the impact of the stroke on the participant’s job

Analysis of work ability and/or worksite assessment:

The ESSVR OT should conduct a thorough assessment of the participant’s job-related needs. This should include the following, where appropriate (evidence of this should be found in the **Occupational Therapy ESSVR Assessment Form** and/or the **Therapy Case Notes***):*

Job analysis: This could include discussing the participant’s job in detail, taking note of their role and related tasks, relationships, history of work, pre-existing work issues (e.g., performance difficulties or personality clashes) and logistics around getting to and from work (e.g., driving, walking, public transport). This could also include a worksite visit. There should be some consideration about what work-related tasks/skills might be affected by the stroke.

Select ‘Yes’ if ESSVR OT assessed the impact of the stroke on the participant’s job and extract evidence verbatim from case file.

Select ‘No’ if ESSVR OT did not assess the impact of the stroke on the participant’s job and detail any reasons for why this was not completed.

Select ‘Not Deliverable’ if the participant did not have a job prior to their stroke. Detail the reason.

8.5.1.4. ESSVR OT assesses the impact of the stroke on the participant's family (desirable)

If appropriate, the impact on the family should be assessed. This can include any emotional, logistical, or financial impact on family members (e.g., if the participant was the sole earner, there may be other pressures that will facilitate/act as a barrier to RTW).

Select 'Yes' if ESSVR OT assesses the impact of the stroke on the participant's family and extract evidence verbatim from case file.

Select 'No' if ESSVR OT does not assess the impact of the stroke on the participant's family where the participant has mentioned family members and detail any reasons for why this was not completed.

Select 'Not Deliverable' if the participant does not report any family members. Detail the reason.

8.5.1.5. ESSVR OT helps the participant plan a return to work and prepares them to return to work

Work preparation and RTW planning:

Once the job assessment has been completed, the ESSVR OT should use the analysis to inform the participant's work preparation and return-to-work planning. Evidence of this would include:

Discussion of RTW options: The ESSVR OT should have a discussion with the participant about a RTW timeline and goals. Consideration should be given to potential facilitators and barriers to RTW. A RTW plan may be explicitly detailed in the **Therapy Case Notes**.

Work preparation: As informed by the job analysis, the ESSVR OT should begin to prepare the participant to return to work. Evidence of this could include the following:

***Getting to work**: If the participant used to drive to work, or if their ability to drive is essential for them to RTW, this might include helping the participant reinstate their driving status. If the participant will need to use public transport, practice of doing so may also be included as evidence. If the participant is unable to take public transport independently, consideration of other resources (e.g., Access to Work) may be included as evidence.*

***Building work tolerance**: Participants may require assistance in setting a structured work routine. ESSVR OTs may encourage the participant to begin to mimic the work routine/schedule and monitor and fatigue or other barriers/facilitators. Methods of building up stamina and tolerance may be considered (e.g., pacing).*

***Demands of the job role**: ESSVR OTs may review the physical demands of the job, as detailed in the job analysis, and begin to incorporate activities to build on skills to support those demands. Possible domains for these demands include:*

***Physical demands**: Manual dexterity, strength, coordination, long periods of standing or sitting, bending, lifting and working at height. Potential activities to address these demands*

might include beginning to take regular walks, going to the gym, DIY, gardening and resuming previous hobbies).

Cognitive demands:

Memory: Potential activities to address any memory difficulties may include use of a diary, notes, emails or phone reminder for remembering appointments or other important tasks.

Concentration: This might include detailing how long the participant might be able to cope at a computer or sustain attention during a specific task. Potential activities to address concentration difficulties might include devising a routine to test and monitor attention/concentration span.

Communication: Participants may face difficulties in verbal communication, reading/writing emails, understanding verbal instructions. Participants may also be affected by aphasia. Liaison with Speech and Language Therapy services may be required (see Item 5).

Executive functioning:

Organisation/Planning: This might include a participant's ability to plan a project. Possible activities to address these demands might include creating job-related project timelines.

Time management: This might include a participant's ability to set and maintain routines. Possible activities to address these demands might include a timed practice of getting to work.

Multi-tasking: Possible activities to address this might include asking the participant to take notes of the session or asking them to work on the computer while watching TV.

Problem solving: Possible activities to address this might include the participant creating a monthly budget system to manage their money whilst on reduced pay/benefits or solve a work-related problem.

Emotional/ behaviour demands: *Participants may experience mood swings, emotional lability, low mood, anxiety, loss of confidence, irritability, aggressive outburst and/or impulsivity/disinhibition. If the ESSVR OT feels the participant would benefit from further support to address these demands, there should be evidence of a referral to psychological/counselling services (see Item 5).*

Social demands: *Participants may find social interaction difficult following their stroke. ESSVR OTs may encourage the participants to explore different social environments (e.g., coffee shop, pub, supermarket, family gatherings). They may also encourage the participant to maintain contact with friends and discuss strategies to address this.*

Select 'Yes' if ESSVR OT helps the participant plan a return to work and prepares them to return to work and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT does not help the participant plan a return to work or does not help the participant prepare to return to work and detail any reasons for why this was not completed.

Select 'Not Applicable' if the participant no longer intends to return to work. The participant does not have to return to the same role or employer to make a return to work. Instances

where the participant intends to return to a different role/employer will still require return to work plan and work prep. Provide detail verbatim from the file.

8.5.1.6. ESSVR OT communicates in writing with stakeholders regarding work status

If written consent is given for the ESSVR OT to contact the participant's employer, which will be detailed in the **VR Consent Form**, they should contact the employer as soon as possible. Disclosure to the employer regarding the participant's status should be discussed with the participant beforehand. A conversation should take place around assessing work skills/competencies and whether there is a person in the workplace who may be responsible for these assessments. There should be evidence of a conversation around a graded return to work. If there is evidence of the employer not wanting to speak about return to work until the participant is more likely to return to work, there may be evidence of the ESSVR OT arranging to speak to the employer again in a few weeks. There should be written evidence of these conversations which should be included in the **Therapy Case Notes** and should be sent as letters to the participant and the employer. There should also be written evidence of notifying the GP/consultant of any plans around returning to work.

Select 'Yes' if the ESSVR OT communicated with the key stakeholders they had consent to communicate with, where appropriate, regarding the participant's work status and extract evidence verbatim from the case notes. Select the source of evidence.

Select 'No' if the ESSVR OT did not communicate with key stakeholders they had the participant's consent to communicate with and detail any reasons for why this was not completed. Select the source of evidence.

Select ‘Not Applicable’ if the ESSVR OT did not have the participant’s consent to contact stakeholders. Provide detail verbatim from the file. Select the source of evidence.

8.5.1.7. Coordinates VR across relevant sectors

Coordinating the participant’s VR across all sectors may involve the ESSVR OT liaising with other services (neuropsychological, OT, physio, SALT) that may have administered relevant assessments. Evidence of coordinating VR across all sectors may include:

Liaising with SALT for support with participants experiencing aphasia, for working out the best format for written/verbal communication and for establishing areas of deficit which might affect communication in the workplace.

Referring the participant to psychology/counselling/IAPT services to support mood and behavioural difficulties.

Liaising with neuropsychology services to assess and address cognitive difficulties where appropriate.

Liaising with a physiotherapist to assess and address any physical difficulties that may impact work.

Liaising with an exercise provider to support the participant in achieving their physical goals in the gym.

General Practitioner: The ESSVR OTs are asked to provide written communication to the participant's GP to keep them aware of any plans to return to work.

Employer: If appropriate, the OT will be the one to coordinate the VR with the participant's employer. They will arrange any meetings or worksite visits with the employer that may be required and communicate the outcomes of these meetings in written format (a copy of this will be stored in the case file).

Select 'Yes' if the ESSVR OT coordinated the participant's VR across relevant sectors and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT did not coordinate the participant's VR across the relevant sectors they had the participant's consent to communicate with and detail any reasons for why this was not completed.

Select 'Not Applicable' if the participant did not give consent for the ESSVR OT to communicate with any relevant sectors.

8.5.2. Stage Two: Graded Return to Work

8.5.2.1. Provides education and advice to the participant

The ESSVR OT is expected to provide information and advice to the participant, the participant's employer and, if appropriate, the participant's family regarding the difficulties and likely limitations (as determined by the job assessment and the work preparation).

There should be evidence of written correspondence (email or letter) and a copy stored in the **Therapy Case Notes**. There might also be evidence of the ESSVR OT using the 'Work Checklist' as detailed by the ESSVR manual.

Select 'Yes' if the ESSVR OT provides education and advice to the participant and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT does not provide needed education and advice to the participant and detail any reasons why this was not completed.

Select 'Not Applicable' if the participant did not have any questions, concerns etc that would require education or advice.

8.5.2.2. ESSVR OT provides emotional support to the participant (desirable)

Evidence of emotional support may include the ESSVR OT acknowledging and/or identifying contributing or maintaining factors of low mood, anxiety etc. and suggesting ways to mitigate the problem (including signposting or referral).

Select 'Yes' if the ESSVR OT provides emotional support to the participant and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT does not provide needed emotional support to the participant and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not appear to need emotional support.

8.5.2.3. Provides education and advice to the employer

The ESSVR OT is expected to provide information and advice to the participant, the participant’s employer and, if appropriate, the participant’s family regarding the difficulties and likely limitations (as determined by the job assessment and the work preparation). There should be evidence of written correspondence (email or letter) and a copy stored in the **Therapy Case Notes**. There might also be evidence of the ESSVR OT using the ‘Work Checklist’ as detailed by the ESSVR manual.

Select ‘Yes’ if the ESSVR OT provides education and advice to the employer and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not provide needed education and advice to the employer and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give the ESSVR OT consent to contact their employer or if the employer did not have any questions, concerns etc that would require education or advice.

8.5.2.4. ESSVR OT provides emotional support to the employer (desirable)

Select ‘Yes’ if the ESSVR OT provides emotional support to the participant’s employer and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not provide needed emotional support to the participant’s employer and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact their employer or the participant’s employer did not appear to need emotional support.

8.5.2.5. Provides education and advice to the participant’s family (desirable)

The ESSVR OT is expected to provide information and advice to the participant, the participant’s employer and, if appropriate, the participant’s family regarding the difficulties and likely limitations (as determined by the job assessment and the work preparation). There should be evidence of written correspondence (email or letter) and a copy stored in the **Therapy Case Notes**. There might also be evidence of the ESSVR OT using the ‘Work Checklist’ as detailed by the ESSVR manual.

Provides education and advice to the participant’s family (desirable)

Select ‘Yes’ if the ESSVR OT provides education and advice to the participant's family and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not provide needed education and advice to the participant's family and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant’s family did not give the ESSVR OT consent to contact or discuss the participant with their family or if the participant’s family did not have any questions, concerns etc that would require education or advice.

8.5.2.6. ESSVR OT provides emotional support to the participant’s family (desirable)

Select ‘Yes’ if the ESSVR OT provides emotional support to the participant’s family and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not provide needed emotional support to the participant’s family and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact their family or the participant’s family did not appear to need emotional support.

8.5.2.7. ESSVR OT negotiates a phased return to work

In negotiating the phased return to work, the ESSVR OT may be able to create a time limit based on the participant’s needs, but some employers may have a time limit on graded return to work (e.g., 4-8 weeks). In some cases, this may be flexible. The ESSVR OT must negotiate a graded return to work plan that suits both the employer and the participant.

Select ‘Yes’ if the ESSVR OT negotiated a phased return to work and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not negotiate a phased return to work where return to work was feasible and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact the employer, if return to work was not feasible or if the participant requested to self-manage their return to work.

8.5.2.8. ESSVR OT mediates workplace adjustments

Following the negotiation of a phased return to work, the ESSVR OT will also advocate for the participant in negotiating any workplace adaptations or adjustments to assist the participant in returning to work. This will include a worksite visit, if possible. Evidence of this will be written correspondence (email or letter) and a copy stored in the **Therapy Case Notes**.

The ESSVR OT, if permitted, should ideally conduct a worksite assessment which can include the following:

Assessing the participant whilst they are conducting their job role

A walk-through/talk-through through the job role

Monitoring the participant through their first day of the graded return to work plan.

There should be a discussion to agree the participant's hours, duties and relevant supervision.

Select 'Yes' if the ESSVR OT mediated workplace adjustments and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT did not mediate workplaces adjustments where adjustments were required and detail any reasons why this was not completed.

Select 'Not Applicable' if the participant did not give consent for the ESSVR OT to contact the employer, if return to work was not feasible, if the participant requested to self-manage their return to work or if no workplace adjustments were required.

8.5.2.9. ESSVR OT provides mechanism for feedback based on work performance

There should be a discussion around a monitoring plan. This should include who is going to provide feedback as well as when feedback should be given and a plan for a situation where the participant might require an earlier review date (I.e., if they are struggling). There should be evidence of discussion around what points the participant will be assessed on.

Select 'Yes' if the ESSVR OT provided a mechanism for feedback based on work performance and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not provide mechanism for feedback based on work performance where return to work was feasible and channels for feedback available and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact the employer, if return to work was not feasible, if the participant requested to self-manage their return to work or if there were no channels for feedback available.

8.5.2.10. ESSVR OT continuously monitors the participant’s return to work to ensure sustainability and job retention

The ESSVR OT should review the feedback from any assessment of the participant’s return to work whether the feedback is from the employer or the participant themselves. There might be evidence of review in a **Tailored Adjustments Agreement Form** or a **Work Review Letter** in the **Therapy Case Notes**. The ESSVR OT should address concerns that arise from the review and communicate with the employer and participant about ways to approach these concerns (e.g., if a participant is experiencing fatigue, the ESSVR OT should provide information about managing fatigue and support the participant with this). Monitoring should be apparent throughout the graded return to work, at least until the participant is working the maximum attainable hours and achieving their desired work-related goals. The ESSVR OT should continue to monitor the participant through their consolidation period of their graded return to work.

Select ‘Yes’ if the ESSVR OT continuously monitored the participant’s return to work to ensure sustainability and job retention and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not continuously monitor the participant’s return to work to ensure sustainability and job retention where return to work was feasible and detail any reasons why this was not completed.

Select ‘Not Applicable’ if return to work was not feasible.

8.5.3. Stage Three: Job Retention

8.5.3.1. ESSVR OT identifies issues that arise within the return-to-work process with relevant stakeholders

There should be evidence of 'checking in' with the participant and/or employer and documentation in the **Therapy Case Notes** if any further issues arise.

Select 'Yes' if the ESSVR OT identified issues that arose within the return-to-work process with all relevant stakeholders and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT did not identify issues that arose within the return-to-work process with all relevant stakeholders where return to work was feasible and detail any reasons why this was not completed.

Select 'Not Applicable' if the participant did not give consent for the ESSVR OT to contact the employer or other stakeholders or if there were no apparent issues that arose.

8.5.3.2 ESSVR OT addresses the issues that arise within the return-to-work process with all stakeholders

There should be evidence, where necessarily and appropriate, of the ESSVR OT attempting to address the issues that arise in the return-to-work process. It should be noted that the ESSVR OTs are not expected to address or 'solve' issues outside of their remit.

Select ‘Yes’ if the ESSVR OT addressed issues that arose within the return-to-work process with all relevant stakeholders and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not address issues that arose within the return-to-work process with all relevant stakeholders where return to work was feasible and the issues were in their remit to address and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact the employer or other stakeholders or if there were no apparent issues that arose.

8.5.3.3. ESSVR OT explores alternative duties and/or job roles for the participant where current work could not be sustained/ was not feasible

If the participant is not able to return to their previous role, the ESSVR OT should explore if there are alternative duties or job roles. This might be evidenced in liaison with HR or the participant’s employer’s Occupational Health team. This will be documented in the **Therapy Case Notes** and the **Therapy Content Form**

Select ‘Yes’ if the ESSVR OT explored alternative duties and/or job roles for the participant where current work could not be sustained/ was not feasible and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not explore alternative duties and/or job roles for the participant where current work could not be sustained/ was not feasible and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant made a successful return to work in same job role with same duties.

8.5.3.4. ESSVR OT practices gradual, appropriate disengagement from the intervention with the participant

Once the ESSVR OT is satisfied that the participant has had a stable and sustainable return to work, there should be evidence of their role gradually resembling more of a monitoring role, addressing any problems that may arise. This should continue until the employer and participant feel that no further work visits or contact is required.

Select ‘Yes’ if the ESSVR OT practices gradual, appropriate disengagement from the intervention with the participant and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not practice gradual, appropriate disengagement from the intervention with the participant, where disengagement from the intervention is feasible and detail any reasons why this was not completed.

Select ‘Not Applicable’ if gradual disengagement from the intervention is not feasible (I.e., in cases where the participant requires the intervention until the 1-year post-randomisation cuff-off point.

8.5.3.5. ESSVR OT discusses gradual, appropriate disengagement from the intervention with the participant's employer

Ideally, the ESSVR OT will write a letter to the employer to detail the disengagement from the intervention to thank them and to encourage them to make contact in the future should any difficulties arise. A copy of the **Exit Letter to the Employer** might be filed in the **Therapy Case Notes**.

Select 'Yes' if the ESSVR OT practices gradual, appropriate disengagement from the intervention with the participant's employer and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT does not practice gradual, appropriate disengagement from the intervention with the participant's employer, where disengagement from the intervention is feasible and detail any reasons why this was not completed.

Select 'Not Applicable' if gradual disengagement from the intervention is not feasible (I.e., in cases where the participant requires the intervention until the 1-year post-randomisation cuff-off point) or the participant has not given consent for the ESSVR OT to contact the employer.

8.5.4. Stage Four: Discharge Process

8.5.4.1. ESSVR OT and participant agree an appropriate time point for withdrawing from the intervention

This involves agreeing the point at which the participant feels able to cope independently and no further intervention is needed from the vocational service. The discharge process must be agreed between the ESSVR OT and the participant's family. This should be noted in the **Discharge Letter.**

Select 'Yes' if the ESSVR OT and participant agreed an appropriate time point for withdrawing from the intervention and extract evidence verbatim from the case notes.

Select 'No' if the ESSVR OT and participant did not agree an appropriate time point for withdrawing from the intervention where withdrawing from the intervention is feasible.

Select 'Not Applicable' if withdrawing from the intervention is not feasible or if participant becomes uncontactable.

8.5.4.2 Discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant

The ESSVR OT must offer a re-accessible service to the participant, so long as the participant re-accesses the services within the 12-month post-randomisation window. The **Discharge Letter** will detail this fact as well as how the participant can re-access the service and a copy of this will be stored in the **Therapy Case Notes**.

Select ‘Yes’ if the ESSVR OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not discuss and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant and detail any reasons why this was not completed.

There should not be a reason for this component to be undeliverable. Even in instances where a participant has disengaged from the intervention, the ESSVR OT should have communicated the mechanism for re-accessing the service in a letter to the participant.

8.5.4.3. Discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant’s employer

Select ‘Yes’ if the ESSVR OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant’s employer and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not discuss and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant’s employer, where present, and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give the ESSVR OT consent to contact their employer or if the participant is self-employed.

8.5.4.4. ESSVR OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant/ participant’s employer/ participant’s family (desirable)

Select ‘Yes’ if the ESSVR OT discusses and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant’s family and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT does not discuss and communicates the mechanism for re-accessing the vocational service or provides information about access to further avenues of support to the participant’s family, where present, and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give the ESSVR OT consent to contact or discuss the participant with their family.

8.5.4.5. ESSVR OT provides the participant’s GP and other relevant health care professionals with a copy of the Discharge Letter

The **Discharge Letter** should be copied and sent to the participant’s GP and other healthcare professionals. This should be documented within the **Therapy Case Notes**.

Select ‘Yes’ if the ESSVR OT provided the participant’s GP and other relevant health care professionals with a copy of the Discharge Letter and extract evidence verbatim from the case notes.

Select ‘No’ if the ESSVR OT did not provide the participant’s GP and other relevant healthcare professionals with a copy of the Discharge Letter and detail any reasons why this was not completed.

Select ‘Not Applicable’ if the participant did not give consent for the ESSVR OT to contact their GP or other relevant healthcare professionals.

8.5.5. Other Modifications to the ESSVR Protocol

Participant does not want the ESSVR OT to go into work:

1. *If the participant does not want the ESSVR OT to go into work due to concerns (e.g., manager support, attitudes of colleagues), the ESSVR OT must keep in contact with the participant and attempt their concerns over time. There should be evidence of monitoring this situation and addressing the workplace concerns with the participant in the* **Therapy Case Notes**.

2. *If the participant is willing, the ESSVR OT should supply the participant’s employer with relevant resources (e.g., a guide written for employers about how to support their employee after stroke). There should be evidence of the ESSVR OT discussing this with the participant in the* **Therapy Case Notes**.

The participant is self-employed, or their employer is no longer present:

1. *If the participant is self-employed, or the employer is uncontactable, the ESSVR OT must supply the participant with the same information that would have been given to the employer.*

2. *There should be evidence of the ESSVR OT attempting to create a graded return to work plan with the participant. This evidence will be found in the* **Therapy Case Notes***.*

3. The ESSVR OT should also encourage the participant to find a means to receive feedback on their performance. Evidence of this should be found in the **Therapy Case Notes**.

8.5.6. Fidelity Checklist Completion

1. Fill in Participant ID, located at the top of the spreadsheet. This will be made up of a site code followed by a participant-specific ID number.

2. Fill in Researcher Initials. This will help us keep track of who has scored which participant.

3. For all components, you will be asked if there is evidence of the component. To answer, select from the drop-down menu either 'Yes', 'No' or 'Not Deliverable'

4. For all components, you will be asked which data source you have extracted from. Select from the drop-down list. If you have extracted from multiple sources, please make a note where possible.

5. For component 1.1, input the date of the participant's stroke into the spreadsheet. An automatic formula will calculate the date that the ESSVR OT must have made first contact by. Input the date of first contact (format: DD/MM/YYYY) and list any moderating factors in the appropriate box if the OT did not manage to contact the participant within 12 weeks.

6. A formula has been calculated to automatically take the fidelity scores from the 'Yes/No/Not Deliverable' boxes and tally the scores overall and per each individual stage. Please double check to make sure there are no errors.

7. At the top of the spreadsheet, please estimate the amount of time it took you to complete the checklist to the nearest quarter of an hour and enter it into the box titled ‘Time Taken to Complete’.

8.6 Therapist Details Form (Form 51)

RETAKE

FORM 51
Page 1 of 2

Therapist Details

For RETAKE trial team use: Site Code | Therapist ID

To be completed for all intervention trained therapists at the initial workshop

- **By providing the below data, I agree to this and any associated study data collection being held by the Clinical Trials Research Unit for the purposes of the study. All information will be securely stored on paper and electronically, under the provisions of the 1998 Data Protection Act and any subsequent updates.**
- **At the end of the study, this data and associated study data will be securely stored for a minimum of 7 years, in line with Good Clinical Practice guidelines. Arrangements for confidential destruction will then be made.**

Your name *(Please print)* First name | Last name

Site name

What team do you usually work for? *(E.g. Early Supported Discharge Team, community NHS trust)*

Your email address

Your gender ☐ Male ☐ Female

Clinical role
- ☐ Staff occupational therapist
- ☐ Occupational Therapy Team Leader
- ☐ Service Lead / Therapy Manager
- ☐ Therapy coordinator
- ☐ Other, please specify

Afc band
- ☐ Band 5
- ☐ Band 6
- ☐ Band 7
- ☐ Band 8 → ☐ a ☐ b ☐ c ☐ d

WTE spent on this role ☐.☐

Your signature | Date signed Day Month Year | *Form continues on next page ►►*

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site.
CTRU, University of Leeds (please see Investigator Site File for full contact details).

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Version 1.0 16/02/2018

RETAKE

FORM 51
Page 2 of 2

Therapist Details

For RETAKE trial team use: Site Code | Therapist ID

Professional qualifications *(Please tick all that apply)*

- ☐ Occupational Therapy, please specify
- ☐ Postgraduate qualification, please specify
- ☐ Other, please specify

Country professional qualification obtained

Year qualification obtained

Professional Registration HCPC number

Relevant Work Experience

Length of **stroke** rehabilitation experience *(Post-qualification)* ☐ Years ☐ Months

Length of **vocational** rehabilitation experience *(Post-qualification)* ☐ Years ☐ Months

Do you have at least two years recent clinical experience working in the rehabilitation of neurological patients? ☐ Yes ☐ No

Do you have theoretical knowledge of vocational rehabilitation for people with neurological conditions including stroke? ☐ Yes ☐ No

Do you have experience of vocational rehabilitation for people with stroke or neurological conditions? ☐ Yes ☐ No

Do you have experience of managing others and working independently? ☐ Yes ☐ No

Do you have recent health research experience? ☐ Yes ☐ No

Have you received GCP training? ☐ Yes ☐ No

Your signature | Date signed: Day Month Year | Last Page ■

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site. CTRU, University of Leeds (please see Investigator Site File for full contact details).

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

Version 1.0 16/02/2018

8.7 Mentoring Record (Form 53)

RETAKE

FORM 53 Page 1 of 4 **Therapist Mentor Record**

To be completed by the ESSVR mentor following each mentor session

Mentor name

Date of session

Duration of session minutes

Method of session delivery

☐ Telephone / teleconference ☐ Face-to-face

☐ Other, please specify

Please specify who **was present** at the session:

Full name *(Please print)*	**Site name**	Office use only **Therapist ID**

Please specify who **did not attend** the session:

Full name *(Please print)*	**Reason**	Office use only **Therapist ID**

Clinical Issues and Actions

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site. CTRU, University of Leeds (please see Investigator Site File for full contact details).

Form continues on next page ▶▶

For office use only	*Computerised* Date	Initials	*Verified/Checked* Date	Initials

Version 1.2 18/06/2018

RETAKE

FORM 53 Therapist Mentor Record

Implementing ESSVR and Actions

Trial-related Issues and Actions

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site. CTRU, University of Leeds (please see Investigator Site File for full contact details).

Form continues on next page ▶▶

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

Version 1.2 18/06/2018

RETAKE

FORM 53 Therapist Mentor Record

RETAKE Therapist Issues

Including any staffing issues e.g. extended periods of leave, change of therapist, identification of training needs

Any other Issues or Comments

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site. CTRU, University of Leeds (please see Investigator Site File for full contact details).

Form continues on next page ►►

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

RETAKE

FORM 53 Therapist Mentor Record

Any other Issues or Comments *(Continued)*

Completed by (Mentor) | Date

Prior to returning this form to CTRU you must make a copy of the form and any amendments for retention at site. CTRU, University of Leeds (please see Investigator Site File for full contact details).

Last Page ■

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

Version 1.2 18/06/2018