Achieving Treatment Fidelity in Complex Neurological Interventions:

Application of Strategies in an Implementation Study of SENSe Therapy

Submitted by

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Statement of Authorship

Except where reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma. No other person's work has been used without due acknowledgment in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

Brittni Nielsen

21 September, 2021

Contribution of Others to Work in this Thesis

Professor Leeanne Carey was the primary supervisor for research conducted as part of this thesis. Professor Carey contributed to decisions and provided significant input regarding conceptualisation, study design and data analysis, overseeing data collection processes and critical review of written work and manuscripts.

Dr Tamara Tse was the co-supervisor for the thesis and provided significant input into the study design, data analysis of the studies, and critical review of manuscripts.

Brendon Haslam assisted with data collection for Study 2 and Study 3, as outlined under Chapter 3 and Chapter 4 of this Thesis.

Other members of the SENSe Implement and SENSe CONNECT research teams - Yvonne Mak-Yuen, Anna Butler and Cheryl Neilson - all assisted with coordination of data collected for Study 3, outlined in Chapter 4 of this research thesis.

Contribution to Thesis

As the author of this thesis, I planned and conducted the review and made substantial contributions towards the research projects conducted as part of this thesis, including research design, data collection and data analysis. I collected data in the form of documentation audits and provided feedback to clinicians involved in the SENSe Implement and SENSe CONNECT studies. My supervisors assisted with all research investigations and data analysis. I am the primary author of publications included in this thesis. The development and write-up of this thesis were the principal responsibility of the candidate, under the supervision of Professor Leeanne Carey and Dr Tamara Tse.

Author Contributions to Publications

This thesis contains one study that has been submitted for publication with Disability and Rehabilitation on 26th of June, 2021:

Development of an audit checklist to evaluate treatment fidelity of complex rehabilitation interventions

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BN drafted the manuscript and updated the manuscript in response to feedback from co-authors. BN implemented the project design, completed the majority of data collection and conducted the data analysis. TT assisted with study design, data analysis, contributed to the structure and content of the manuscript. BH assisted with data collection and reviewed the manuscript. LC conceived the project concept, assisted with study design and data analysis, and contributed to the structure, content and revisions of the manuscript.

Ethical Research Conduct

All research procedures within this thesis were approved by the La Trobe University Human Ethics Committee and Austin Human Research Ethics Committee, please see HEC approval numbers for relevant studies below.

- Study 2 (Chapter 3) – La Trobe University, SHE Low Risk Human Ethics Committee: HEC20301. CoNNECT study (original study) ethics approved on 14/03/2013 by Austin Human Research Ethics Committee: HREC/12/Austin/117.

- Study 3 (Chapter 4) –Austin Human Research Ethics Committee: HREC/13/Austin/8 (SENSe Implement), Austin Human Research Ethics Committee: HREC/18/Austin/153 (SENSe CONNECT)and La Trobe University: FHEC 14/243. Site specific ethics approval was obtained for all participating sites.

Brittni Nielsen

September, 2021

Dedication

I dedicate this thesis to my partner, Blake. Your unwavering support, care and love has

enabled me to learn and grow throughout the completion of this research degree.

Thank you for helping me to succeed.

Acknowledgements

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List of Abbreviations

CoNNECT: Connecting New Networks for Everyday Contact through Touch.

NIH BCC: National Institutes of Health (NIH) Behavior Change Consortium (BCC)

SENSe: Study of the Effectiveness of Neurorehabilitation on Sensation

TF: Treatment Fidelity

List of Definitions

Treatment Fidelity:

Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests the clinical intervention (Bellg et al. 2004, p.443).

Conceptual Framework:

A conceptual framework or model for treatment fidelity is defined by a set of guidelines or recommendations which detail a combination of strategies and methods which aim to assess, enhance and evaluate fidelity at different stages of an intervention's implementation (Borelli, 2011 p.S53).

Complex intervention/s:

Healthcare interventions that are made up of various interconnecting parts (Campbell et al., 2000, p.1), in addition to the following considerations:

- Number of interacting components within the experimental 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

- Number and variability of outcomes

- Degree of flexibility or tailoring of the intervention permitted (Craig et al., 2008, p.2)

Somatosensation: involves the detection, discrimination and recognition of body (somato) sensations such as touch, vibration, temperature, proprioception and pain (Carey, 2012, p.157).

Please note this thesis has been written using APA 7 formatting.

Where a paper has been written for publication or submitted, the formatting required for the submission is used, with the exception that figures and tables are included in the body of the manuscript and follow APA 7 formatting to facilitate readability in this thesis. The list of references for Introduction and General Discussion and Conclusion are detailed at the end of this thesis, along with appendices that include supporting material. References for the chapters written for journal submission are included in the individual chapters.

THESIS ABSTRACT

Treatment fidelity, defined as the extent to which the therapy provider delivers the intervention as per the study protocol, is critical to the successful implementation of complex rehabilitation interventions. SENSe therapy is a complex intervention at the point of implementation in clinical settings. The aim of this research was to identify, and then systematically apply, methods for assessing and monitoring treatment fidelity to enhance the implementation and delivery of SENSe therapy.

Application of a conceptual framework is recommended to guide the treatment fidelity process. An evidence review was completed to identify which frameworks enhance the treatment fidelity of complex rehabilitation interventions. The National Institutes of Health's Behavior Change Consortium (NIH BCC) framework was applied in all included studies (n=4) and benefits were identified at an individual strategy level. This framework was chosen to support the process of enhancing the fidelity of SENSe therapy.

A documentation audit checklist was developed as a resource efficient approach to evaluating treatment fidelity of complex rehabilitation interventions. The developed audit checklist comprised 29 components core to the delivery of SENSe therapy, and was tested on 38 therapy records retrospectively.

The documentation audit checklist was subsequently refined (28 components) and applied in the final study, together with strategies from the NIH BCC framework, to enhance treatment fidelity of novice clinicians (delivered 1-3 SENSe therapy programs) in *SENSe Implement* and *SENSe CONNECT* studies. Findings indicated it was feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity, when supported by documentation proformas, expert trainers and provided with regular feedback opportunities.

In summary, the process of examining and enhancing treatment fidelity is an

iterative process. For complex rehabilitation interventions to be delivered with high

fidelity, the core intervention components must be included in assessment criteria, and

clinicians given the opportunity for continued monitoring and feedback opportunities.

CHAPTER 1

INTRODUCTION

1.1 Background to the Field and Significance of this Research

Healthcare interventions are often multi-faceted, require the therapist to possess a defined level of skill and knowledge, and are dependent on clinician delivery and patient interactions (Gearing et al., 2011, Campbell et al., 2000). In order for complex rehabilitation interventions to demonstrate their effectiveness in research and clinical practice, the therapy must be implemented as intended. This requirement is broadly known by the term "Treatment Fidelity". Treatment fidelity is now widely acknowledged as the critical element to the successful implementation of complex rehabilitation interventions (Toomey, 2020), and is supported by the published Template for Intervention Description and Replication (TIDieR) reporting guidelines for intervention research (O'Shea et al., 2016, Hoffman et al., 2014).

The concept of Treatment fidelity has evolved over time, with the development of numerous terms being used interchangeably (Toomey, 2020). These terms include implementation / intervention fidelity or intervention / treatment integrity. As a result, Toomey et al. (2020) acknowledge this has created challenges for researchers to understand 'how fidelity is conceptualised and defined'. Emerging in the 1970s within psychotherapy literature, the concept of treatment fidelity was defined as 'treatment delivered as intended'. However, according to the narrative review by Toomey et al. (2020), the concept evolved to considering the fidelity of interventions undergoing testing within experimental studies (involving an experimental and control arm) and the competence or skill of the therapy provider delivering the intervention.

Although various definitions for treatment fidelity exist, a scoping review conducted by O'Shea et al. (2016) set out to identify the most frequently cited definition.

Of the 65 papers included, 34 provided a short summary of fidelity, with the definition published by Bellg et al. (2004) on behalf of the National Institutes of Health (NIH) Behavior Change Consortium (BCC) identified as the most frequently cited definition: *"Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests the clinical intervention"* (p.443).

Fidelity in the context of implementation science acts as a moderator between interventions and their expected treatment outcomes, allowing for early detection of errors during intervention delivery and preventing the frequency of protocol deviations (Borelli, 2011). It has been demonstrated in numerous research studies that the fidelity with which an intervention is implemented affects how well it succeeds, with higher levels of treatment fidelity associated with better treatment outcomes (Durlak & DuPre, 2008; Carroll et al., 2007). According to Resnick et al. (2009), many researchers consider only assessing adherence to the interventions implemented and do not examine treatment fidelity for the duration of the research. Unless fidelity is frequently assessed and evaluated throughout the course of the research project, it cannot be determined whether a lack of intervention impact is due to poor intervention adherence, or that the intervention itself is ineffective (Carroll et al., 2007).

Carroll et al. (2007) and O'Shea et al. (2016) reported the achievement of treatment fidelity in complex rehabilitation interventions as particularly challenging due to the greater scope for variation in the delivery of individual components, particularly when different sites and therapists are involved. Further, there are specific challenges associated with the evaluation of complex interventions because of the difficulties defining, recording, and reproducing the various components of the intervention (Campbell, 2000). As a result, this is one of the first challenges faced by researchers when

determining how to operationalise and measure each component of fidelity within a complex rehabilitation intervention (Ginsburg, 2021). Although it may be appropriate to adhere to the principle of fidelity of treatment design and ensure the intervention is defined and operationalised consistent with underlying theory, this approach does not always account for individual patient needs and tailoring of interventions, which is a defining element of complex rehabilitation (Ginsburg, 2021).

Further to this, successful treatment fidelity is not only dependent on the approach utilised by the therapy provider. The extent to which the treatment protocol is standardised and/or can be implemented when there is a need to tailor the treatment to the individual patient's level of ability/impairments, and preferences, is also likely to impact (Carragher, 2019). This is referred to as the process of adaptation. Perez in 2016, acknowledged that fidelity and adaptation are closely linked but remain two exclusive concepts – "The highest the level of the fidelity achieved, the less there are changes brought to the original design of an intervention. Inversely, the more an intervention is adapted, the more likely the fidelity can be threatened" (p. 2). However, Toomey and colleagues in 2020 advised that to date, there is insufficient evidence regarding how adaptations effect intervention integrity. Therefore, it is important to consider adaptation during the process of intervention development, and alongside the strategic plans for assessing and enhancing treatment fidelity of complex interventions (Toomey, 2020). Additionally, Toomey et al.(2020) recommends carefully considering from the outset which intervention adaptations are acceptable and which are likely to impact significantly on intervention integrity and therapy outcomes.

In an effort to address the above challenges, several conceptual frameworks have been developed to provide structure on how treatment fidelity can be assessed, monitored or enhanced in clinical practice and intervention studies. This is further reiterated by a recent systematic review by Holmes et al. (2020), which recommended that *"researchers*

and service providers should be cognisant of and utilise implementation theory and implementation frameworks to guide the identification and reporting of implementation issues in future studies" (p. 14).

A conceptual framework or model for treatment fidelity is defined by a set of guidelines or recommendations which detail a combination of strategies and methods which aim to assess, enhance and evaluate fidelity at different stages of an intervention's implementation (Carroll et al., 2007, Bellg et al., 2004, Borelli, 2011). Numerous conceptual frameworks exist within treatment fidelity literature, however, as stated by Toomey et al. (2016), few studies explain their rationale for choosing to apply a particular framework and its fidelity strategies. Within the psychology literature, there are several conceptual frameworks that have been highly recommended to guide the treatment fidelity process (Carroll et al., 2007, Bellg et al., 2004, Toomey et al., 2020). Yet, few studies have evaluated their effectiveness in the context of stroke rehabilitation and other complex rehabilitation interventions.

A preliminary search of the literature pertaining to treatment fidelity in the context of healthcare interventions not specific to rehabilitation, identified at least six different conceptual frameworks. Masterson-Algar et al. in 2014, acknowledged the lack of standardisation of available frameworks and how they are reported on and utilised in the context of guiding implementation fidelity of complex rehabilitation interventions. According to this initial search of the literature, there were no reviews systematically evaluating the quality of the evidence supporting conceptual frameworks or analysing their ability to enhance treatment fidelity outcomes when applied in the context of a complex rehabilitation intervention. However, there have been positive reports within individual studies, such as that by Bagstad et al. (2019), reporting that the conceptual framework applied highlighted the complexity of implementing the intervention and enabled "a highly systematic analysis of adherence and moderators to implementation

fidelity" (p. 16) Further to this, Carroll et al. (2007) emphasises the need to understand the factors affecting intervention adherence to make sense of fidelity as a concept, which cannot be systematically achieved without the use of a conceptual framework.

According to Toomey's narrative review in 2020, conceptual frameworks "facilitate consideration of fidelity as a broader concept, as well as an explicit focus on strategies to both enhance and assess fidelity from the outset of behaviour change intervention development" (p.140). Therefore, it is clear within the current literature that the use of a conceptual framework is recommended to provide a structured and systematic process to application, which in turn enhances treatment fidelity outcomes. However, it is recognised that there needs to be more research completed to compare existing frameworks.

In recent years there have been studies reporting the process of operationalising, establishing and measuring the treatment fidelity of complex rehabilitation interventions across a wide range of healthcare areas. For example, Toglia et al. (2020) reports on the process of measuring the treatment fidelity of a complex cognitive rehabilitation, used within clinical practice for patients with neurological impairment such as stroke and traumatic brain injury. Within this context, the authors acknowledge that the process of examining treatment fidelity is essential for research but should also guide the application of complex interventions in clinical practice.

Stroke is one of the leading causes of disability and reduced quality of life. Stroke survivors are often left with bodily impairments, and rehabilitation interventions to address these bodily impairments are considered inherently complex in stroke research (Cahill et al., 2017). Upper limb somatosensory loss after stroke is common, with over half of stroke survivors affected (Carey et al., 2011). One complex neurological intervention to address the problem of somatosensory impairment is the SENSe therapy approach (Study of the Effectiveness of Neurorehabilitation on Sensation) (Carey et al.,

2011). SENSe therapy is founded on theories of neuroscience and targets upper limb sensory loss post stroke through a set of retraining principles.

Despite there being high-level evidence for the application of sensory discrimination training, Pumpa et al. (2015) found through an online survey of occupational therapists and physiotherapists, that the dissemination of these guidelines alone was insufficient to change practice, with sensory treatment approaches utilised in the early 1990s still being applied in clinical settings. Key barriers to adoption included lack of access to appropriate training materials and resources, and a perceived lack of skills and confidence to apply the sensory retraining approach in clinical settings. Further to this, it was recommended that user-friendly protocols be developed to allow easy implementation into daily practice (Pumpa et al. 2015). To address these barriers, detailed treatment protocols for SENSe have been developed and two SENSe-specific implementation studies are currently underway across several Australian healthcare settings to facilitate delivery of SENSe therapy in routine clinical practice (Cahill, 2018) – *SENSe Implement* and *SENSe CONNECT*. For SENSe therapy to demonstrate its effectiveness within these implementation studies, the treatment fidelity must be assessed and monitored to ensure therapy providers are delivering the intervention as per the study protocol (Campbell, 2000).

1.2 Aim and Scope of this research

The aim of this research project was to demonstrate the application of several methods for assessing and monitoring the treatment fidelity of a complex rehabilitation approach – SENSe therapy. This included identifying available frameworks and tools to enhance the assessment and monitoring process in the delivery of complex interventions; developing and trialing a treatment fidelity checklist for SENSe therapy; and systematically applying

the chosen framework, its strategies and the newly developed treatment fidelity checklists (documentation audit and observation) to enhance the implementation of SENSe therapy.

1.3 Research Questions

The following research questions frame the research conducted in the thesis chapters, as outlined below.

Chapter 2 - Evidence Review:

a) What conceptual frameworks have been applied within the literature for the monitoring and evaluation of treatment fidelity in complex rehabilitation interventions? and

b) Which of these conceptual frameworks have been shown to enhance the treatment fidelity of complex rehabilitation interventions?

Chapter 3 - Can a custom designed audit checklist be developed and used to evaluate the documentation of treatment delivery, in order to measure and enhance the treatment fidelity of SENSe therapy?

Chapter 4

a) Is it feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity in clinical practice settings?

b) Which factors are associated with treatment fidelity when novice clinicians deliver SENSe therapy?

1.4 Overview of Thesis

This thesis contains five chapters and includes three manuscripts written in manuscript style, one which has been submitted for publication. Each chapter that includes a manuscript begins with an introduction to the chapter, follows with the manuscript, and ends with a summary and conclusion. The following summary provides an outline of each chapter included in this thesis.

Chapter 1: Introduction

This is the present chapter which introduces the research project, including a background to the research field and significance of this research undertaken.

Chapter 2: Evidence review of conceptual frameworks for monitoring and evalauting the treatment fidelity of complex rehabilitation interventions

This chapter contains an evidence review of conceptual frameworks for monitoring and evaluating the treatment fidelity of complex rehabilitation interventions.

Chapter 3: Development of an audit checklist to evaluate treatment fidelity of a complex rehabilitation intervention

This chapter details the development and testing of an audit checklist for evaluating treatment fidelity of existing SENSe therapy documentation.

Chapter 3 has been submitted for publication as: "Development of an audit checklist to evaluate treatment fidelity of a complex rehabilitation intervention"

Disability and Rehabilitation, submitted on 26/06/21.

Authors: Nielsen, B., Tse, T., Haslam, B. & Carey, L.M. (2021)

Chapter 4: Treatment fidelity of SENSe therapy when delivered by novice clinicians and factors associated

This chapter demonstrates the application of strategies to assess, monitor and enhance the treatment fidelity of SENSe therapy being delivered by clinicians involved in *SENSe*

Implement and *SENSe CONNECT* studies. Factors potentially associated with treatment fidelity are explored.

Chapter 5: General Discussion & Conclusion

In this chapter, the main findings of the research project are summarised and synthesised, and implications for the current body of knowledge and literature are examined.

CHAPTER 2

EVIDENCE REVIEW OF CONCEPTUAL FRAMEWORKS FOR MONITORING AND EVALUATING THE TREATMENT FIDELITY OF COMPLEX REHABILITATION INTERVENTIONS

2.1 Introduction

This chapter details the aims, methods and results of a narrative literature review on conceptual frameworks for treatment fidelity. There were two study aims, the first to identify which conceptual frameworks have been applied within the literature for the monitoring and evaluation of treatment fidelity in complex rehabilitation interventions, and the second to evaluate which of these conceptual frameworks have been shown to enhance treatment fidelity.

Please note this review has been prepared in manuscript style. Formatting and references have been prepared to comply with the author guidelines of Disability and Rehabilitation for consistency with other manuscripts submitted or written for submission in this thesis. The exception is that tables and figures are included in the body of the prepared manuscript and follow APA 7 formatting to facilitate readability in this thesis.

2.2 Evidence review of conceptual frameworks for monitoring and evaluating the treatment fidelity of complex rehabilitation interventions

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ABSTRACT

Purpose: Treatment fidelity refers to the strategies used to enhance the reliability and validity of complex rehabilitation interventions. Application of a conceptual framework is recommended to guide the treatment fidelity process, yet few studies have evaluated the effectiveness of such frameworks when delivering complex rehabilitation interventions. The purpose of this study was to identify conceptual frameworks applied within the literature to enhance treatment fidelity of complex rehabilitation interventions, and which of these frameworks enhance treatment fidelity.

Methods: Eight databases were searched to April 2020. Study quality was evaluated using the McMaster Appraisal Tool (Case Series). The body of evidence was evaluated using the National Health and Medical Research Council of Australia Body of Evidence Matrix.

Results: Four studies (from 572 identified) met pre-defined eligibility criteria; all were case series with post-test outcomes. The National Institutes of Health Behavior Change Consortium framework was applied in all studies. Inconsistencies were identified with how the framework was applied to enhance treatment fidelity.

Conclusion: For conceptual frameworks to demonstrate their effectiveness, the key elements must be systematically applied. Pre-defined performance checklists must map accurately to all core elements of the complex intervention under testing. Future research should focus on developing fidelity measures with defined parameters, to indicate when an intervention has been delivered optimally.

Introduction

In stroke research, rehabilitation interventions are considered inherently complex [1]. According to Gearing et al. [2] and Campbell et al. [3] these interventions require therapists to possess a defined level of skill and knowledge to implement several interconnecting components. An example of this type of intervention is the Study of the Effectiveness of Neurorehabilitation on Sensation (SENSe) therapy approach; developed by Carey, Macdonnell and Matyas [4]. SENSe therapy targets upper limb sensory loss post stroke through a defined set of retraining principles, that have been operationalised in the delivery of SENSe therapy [4]. For clinicians to be able to deliver this intervention with accuracy, they are required to undertake formal training and credentialing.

In order for complex rehabilitation interventions, such as SENSe therapy, to demonstrate their effectiveness in research and clinical practice, the therapy must be implemented as intended. This approach is broadly known as "Treatment Fidelity" and is now widely acknowledged as the critical element to the successful implementation of complex rehabilitation interventions, including being supported by the Template for Intervention Description and Replication (TIDieR) reporting guidelines for intervention research [5,6].

Although various definitions for treatment fidelity exist, a scoping review conducted by O'Shea et al. [5] set out to identify the most frequently cited definition. Of the 65 papers included, 34 provided a short summary of fidelity, with the definition published by Bellg et al. [7]; on behalf of the National Institutes of Health (NIH) Behavior Change Consortium (BCC) identified as the most frequently cited definition: i.e.

> *"Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to*

the methodological practices used to ensure that a research study reliably and validly tests the clinical intervention" [7] (p. 443).

Fidelity in the context of implementation science acts as a moderator between interventions and their expected treatment outcomes, allowing for early detection of errors during intervention delivery and preventing the frequency of protocol deviations [8]. It has been demonstrated in numerous research studies that the fidelity with which an intervention is implemented affects how well it succeeds, with higher levels of treatment fidelity associated with better treatment outcomes [9,10]. Unless fidelity is frequently assessed and evaluated throughout the course of the research project, it cannot be determined whether a lack of intervention impact is due to poor intervention adherence, or that the intervention itself is ineffective [10].

To address this issue several studies strongly recommend that a conceptual model or framework be applied to guide the process of enhancing treatment fidelity across the areas of intervention development, training, and implementation [8,10]. A conceptual model or framework for treatment fidelity is defined by a set of guidelines and / or recommendations, which include strategies to enhance, monitor and / or evaluate treatment fidelity during the process of implementing an intervention [7,8,10]. Several conceptual frameworks exist within treatment fidelity literature, however as stated by Toomey et al. [11], few studies explain their rationale for choosing to apply a particular framework and its fidelity strategies. Additionally, although there are conceptual frameworks recommended in psychology literature, few have evaluated their effectiveness in the context of stroke and other complex rehabilitation interventions. To address this identified gap in treatment fidelity literature, the first aim was to identify which conceptual frameworks had been applied within the literature for the monitoring and evaluation of treatment fidelity in complex rehabilitation interventions; and secondly,

which of these conceptual frameworks had been shown to enhance the treatment fidelity of complex rehabilitation interventions.

Methods

Data sources and search strategy

A structured search of the eight electronic databases was completed by the primary author (BN) up to April, 2020. The PICO tool [12] was applied to identify relevant search terms, outlined in Table 1. Combinations of the following key search terms were used across all databases: Health professional, Conceptual framework, Treatment fidelity, Implementation fidelity, Rehabilitation. Search terms were modified depending on the synonyms used by the selected databases - Medline, CINAHL, Embase, and PubMed. These databases were chosen for their inclusion of publications and journals from allied health disciplines, health, and physical sciences. Discipline specific content was searched for in PEDro, OTSEEKER, SpeechBITE, and PsycBITE. Recursive checking was also completed by scanning the reference list of relevant articles retrieved through database searching. Limitations were placed on the search for English language only and to ensure all relevant articles were located, no limitation was placed on year. Please see Figure 1 for full electronic search strategy.

The study selection process completed by first author (BN) consisted of an initial screening of articles by title and abstract against the eligibility criteria outlined in Table 2. Articles identified as potentially relevant were screened by the first author (BN) in full text, with all those considered not eligible excluded. Where there was uncertainty, this was reviewed with TT and LC and a consensus decision made.

Table 1.

PICO Search Terms

Population	Intervention	Outcome	
Health Professional	Conceptual Framework	Treatment Fidelity	Rehabilitation
Allied Health Clinician	Model	Fidelity	Rehabilitation therap*
Allied Health Profession*		Implementation Fidelity	Rehabilitation Interventions
Occupational therap*		Intervention Integrity	Complex interventions
Physiotherap*		Assessing treatment fidelity	Complex physical therapy
Physical therap*		Monitoring treatment fidelity	Evidenced-based treatment
Social Work		Evaluating treatment fidelity	Evidence-based practice
Speech Patholog*		Measuring treatment fidelity	
Psycholog*		Guideline adherence	
Rehabilitation therap*		Process evaluation	

Figure 1.

Medline Database Search Strategy

1.	Allied Health Personnel/
2.	Occupational Therapy/ or Stroke Rehabilitation/
3.	"Physiotherap*".mp.
4.	Physical Therapy Modalities/ or Physical Therapy Specialty/
5.	Physical Therapists/ or Physical Therapy Modalities/ or Physical Therapy Specialty/
6.	Social Work/
7.	Pathology/ or Speech/
8.	Rehabilitation/ or Physical Therapy Modalities/
9.	"conceptual framework".mp.
10.	Combined Modality Therapy/ or Adult/ or Rehabilitation/
11.	"complex interventions".mp.
12.	Stroke Rehabilitation/ or Rehabilitation/ or "complex rehabilitation interventions".mp. or Physical Therapy Modalities/
13.	"treatment fidelity".mp.
14.	"implementation fidelity".mp.
15.	Behavioral Research/ or Behavior Therapy/ or "evaluating treatment fidelity".mp.
16.	"evidence".mp. or Evidence-Based Medicine/
17.	"evidence".mp. or Evidence-Based Medicine/ or Evidence-Based Practice/
18.	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
19.	9 or 10 or 11 or 12

Table 2.

Inclusion / Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Types of Participants: - All studies that involve health professionals who provide rehabilitation specific treatment across the healthcare continuum.	- Studies pertaining to psychiatric rehabilitation approaches.
Types of Interventions: - Intervention will refer to a model, guideline or framework applied to enhance, monitor, or assess treatment fidelity of a rehabilitation treatment. Therefore, studies applying conceptual frameworks in this context will be included. - Conceptual Framework defined as the inclusion of a variable number of key stages in which delivery of an intervention is measured and evaluated against.	- Studies describing treatment fidelity strategies outside of a conceptual framework, or nil mention or reference to an overarching model or guideline to support the process of examining treatment fidelity.
Types of Outcome Measure: - Studies reporting on results of measuring treatment fidelity, for example frequency of desired therapist behaviour observed.	- Studies describing the application of a treatment fidelity measure without reporting of outcome/ results.
Types of Study Design: - Randomised and pseudo-randomised controlled trials. - Comparative studies with or without concurrent controls such as non-randomised experimental trials, cohort studies and case-control studies. Case Series with post-test or pre-test/post-test outcomes will also be included.	- Studies only looking at the psychometric properties of assessment tools for measuring fidelity. - Qualitative Studies - Protocol paper - Personal opinion paper or viewpoint.

The methodology of each study was evaluated and classified according to the hierarchies of evidence developed by the National Health and Medical Research Council (NHMRC) of Australia, summarised by Hoffman et al. in 2017 [13]. The quality of the studies was appraised by the primary author (BN) and checked by co-author (TT) using
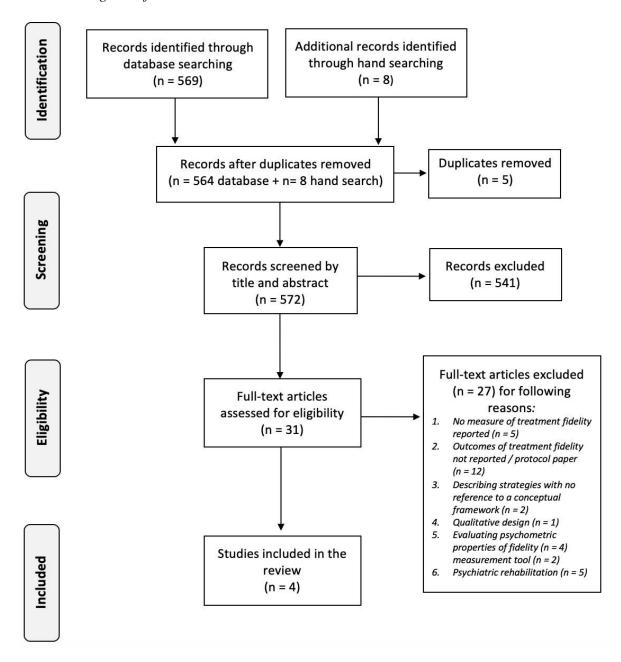
the McMaster University critical appraisal tool for Quantitative studies [14]. This tool was chosen for its ability to be applied to all four intervention studies with varying design, ensuring consistency across the appraisal process [14]. The tool prompts the reviewer to consider several critical review components including appropriateness of study design, sample size, reliability and validity of outcome measures, and analysis methods used, in the results. Findings from the application of the McMaster critical appraisal tool informed the evidence review and enabled authors to make judgments based on the body of evidence, relevant to the research question.

Results

Following completion of the database search, the study selection process was conducted as per Figure 2 [15]. Five hundred and seventy-seven articles were identified and screened for eligibility via title and abstract. Thirty-one articles were screened in full text. Four articles met the eligibility criteria and were included for critical appraisal and synthesis. All studies were classified as Case Series with post-test outcomes [13] (p. 29). All four studies included in the review were conducted in the United States. Two of the studies delivered interventions in nursing home facilities, one in an outpatient exercise centre and the other across 12 intensive care units. Two of the interventions were designed to increase participant's engagement in daily functional tasks through increasing intensity of physical and cognitive therapy [16,17], One study intervention consisted of graded treadmill walking to increase exercise endurance [18], and another focused on the use of music for anxiety self-management [19]. Three out of four interventions were individualised specifically for the participant.

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Figure 2.

PRISMA Diagram of Evidence Review

The health professionals providing the interventions varied across studies and included exercise physiologists, research nurses and nursing assistants, occupational therapists, physiotherapists, and discipline specific allied health assistants. Recipients of the study interventions included patients with chronic stroke, older adults residing in nursing facilities post medically disabling events, critically ill patients requiring

mechanical ventilation and residents of nursing home facilities. Please refer to Table 3 for

a detailed summary of individual studies and their key findings.

Table 3.

Summary of Included Studies

	Resnick et al., 2009 [16]	Hildebrand et al., 2012 [17]	Resnick et al., 2011 [18]	Chlan et al., 2011 [19]
Study aims	To describe treatment fidelity outcomes for the Res-Care Intervention Study.	Demonstrate methods used to train and supervise therapists, to achieve TF in a novel-occupational and physical therapy-based intervention.	Demonstrate a model for evaluating treatment fidelity in stroke exercise interventions.	To describe the implementation, monitoring and impact of TF in an ICU-based clinical trial, for anxiety self-management with mechanically ventilated patients.
Intervention	Group 1. 228 NAs from 6 nursing home facilities taught how to motivate residents to engage in restorative care activities. Group 2. NAs from 6 "control sites" attended a one-day inservice program focused on behavioural management.	Therapists trained in EMR versus provision of usual SOC. *NB. Experimental and control groups were not comparable and outcome measures were only reported on in experimental group.*	16 EPs trained to deliver the experimental intervention. Treatment fidelity data was collected and feedback provided at half-way and study completion.	Research nurses trained to implement *Active control intervention:* participants wore noise-cancelling headphones to block out ICU noise when desired, Or *Experimental intervention:* participants listened to preferred music assembled by music therapist. *NB: TF data was collected for both.*
Outcomes used	Documentation flow sheets reported amount of time NAs spent delivering restorative care daily with each resident. TF data was collected at 4 & 12 months during implementation.	Checklist to rate treatment adherence and competence in line with EMR intervention.	Log book to collect data on participant's exposure to correct no. of sessions, and achievement of their maximal heart rate (60-70%).	Criteria developed based on five-component TF Framework. Checklist (yes/no) to monitor integral components of active control and experimental intervention.
Findings	NAs delivered 70.5 minutes / day of restorative care to residents. NAs delivered restorative care during 60% of all interactions at 4 months, 65% at 12 months.	Videotaping and observation alone did not improve SOC therapist's adherence and competence. EMR therapists who received additional feedback and training achieved better adherence and competency ratings according to checklist.	48% of participants achieved study goal of exercising at 60 - 70% of their maximum heart rate. Mean no. sessions attended by participants in treatment arm = 72.8, compared to the control group = 65.4.	Mean equipment time use when key criteria met = 112.2 minutes, 80.3 minutes when criteria not met. Following introduction of strategies after time-point 1, overall adherence to key criteria remained between 75-80% for time-point 2 – 8.

Abbreviations: *NA=Nursing Assistants, TF= Treatment fidelity, EMR= Enhanced Medical Rehabilitation, SOC = standard of care, EP= Exercise Physiologist, ICU= intensive care unit.*

The body of evidence was evaluated as poor due to methodological limitations identified across sample size and recruitment, and a high risk of bias in fidelity measurement. There were inconsistencies in findings across the studies and high levels of heterogeneity in study outcomes and quality, restricting the clinical impact of the combined evidence and its ability to be generalised to the target population.

Conceptual frameworks applied to monitor and evaluate treatment fidelity

The framework developed by the National Institutes of Health (NIH) Behavior Change Consortium (BCC) was applied throughout all four studies to monitor and evaluate treatment fidelity. The NIH BCC framework was first published by Bellg and colleagues in 2004 [7] and was further updated by Borelli in 2011 [8]. The framework details a combination of strategies and methods, which aim to assess, enhance, and evaluate fidelity at different stages of an intervention's implementation. The framework categorises treatment fidelity into five specific domains [7,8]

1. *Study design:* addresses factors that should be considered when designing the trial and are intended to enable the study to adequately assess its hypothesis in relation to the underlying theory and mechanisms of action of the study.

2. *Training of providers:* aims to ensure and assess that providers are able to deliver the treatment intervention satisfactorily and as intended.

3. *Treatment delivery:* relates to processes that assess and enhance the actual delivery of the treatment so that it is delivered as intended.

4. *Treatment receipt:* involves using strategies to enhance and assess recipient knowledge and use of treatment skills and learning during the intervention. It also considers factors that aim to enhance the acceptability of the intervention to the participant.

5.   *Treatment enactment:* uses strategies to enhance and assess their actual practice of

the treatment skills and knowledge in daily life.

Application of NIH BCC framework domains in included studies

Training of Providers

All studies developed treatment manuals to operationalise their intervention and its core

components, and included details on the theoretical underpinnings. Face to face training

time varied between the studies, with some studies providing 1 – 2 days of training versus

other studies including a 2-week training period [17,19]. One study used a graded 6-week

education program with education sessions running for 20 - 30minutes. These trainers

also received their own monthly support with the principal investigator to prevent

protocol drift [16]. Strategies applied during training sessions across all four studies

included use of role-plays and videos of expert clinicians delivering the intervention with

high fidelity prior to commencing delivery. Two studies provided their intervention

therapists with ongoing support throughout the delivery of the intervention, with weekly

or monthly group supervision and role modelling provided by site-specific expert trainers

[16,19].

Measures used to assess treatment delivery

All four studies reported developing and using a checklist to measure treatment fidelity.

Only one study reported on the validity and reliability of the measurement tool used [17].

Two of the four studies reported that the developed checklist was based on the core

components of the specific intervention [16,19]. Chlan et al. [19] reported using a yes/no

scoring method for their checklist that intervention providers were required to complete

on a daily basis. Another study reported on their scoring method for determining fidelity

of intervention delivery, using a scale of 1 – 3, which was associated with low, medium or

high delivery of core components [17]. One study completed a pre-test and post-test

knowledge survey following baseline training to understand baseline levels of fidelity, however did not report on baseline fidelity levels at the start of intervention delivery. Three of the studies reported using the outcomes of the treatment fidelity assessment as feedback and supervision tools to prevent protocol drift [16,17,18].

Frequency of measuring treatment fidelity

One study provided immediate observation and feedback for the first intervention session delivered by all trained health professionals, following on with formal feedback on intervention delivery by expert clinicians at halfway and study completion [18]. Informal feedback was also provided through regular weekly supervision and 20 random observation sessions [18]. This was the only study that reported on a measure of baseline treatment fidelity. One study observed a total of 60 therapy sessions on a weekly basis approximately 12 months post initial training, with feedback provided immediately post sessions [17]. In the study by Chlan et al. [19], treatment fidelity was measured on a quarterly basis via site visits from expert trainers. Resnick et al. [16] used site trainers to review daily intervention logs on a monthly basis. Direct observation was also provided by expert trainers at two time points; 4 and 12 months during intervention delivery. These final two studies encouraged their trained health professionals delivering the intervention to monitor their own fidelity performance by completing a daily checklist.

Treatment receipt and enactment

Three of the four studies reported on treatment receipt and / or enactment. Chlan et al. [19] described using visual prompts as a strategy to enhance participant's receipt and enactment of the study intervention. Resnick et al. [18] described receipt as being characterised by evidence of participants attending the outpatient therapy centre and participating in the prescribed therapy program. Resnick et al. [16] looked at receipt and enactment of intervention as it pertained to the nursing assistants trained to deliver a

restorative care intervention, and did not report on the residents (intervention recipients) application of the intervention.

Discussion

The results of this evidence review have been summarised and synthesised narratively due to the large variability across outcome measures, intervention types and participants, and will be discussed in the context of the two-part research question.

Part A: Conceptual frameworks applied in complex rehabilitation interventions

The framework developed by the National Institutes of Health Behaviour Change Consortium (NIH BCC) was applied in all four studies to monitor and evaluate treatment fidelity, however there were inconsistencies with the accuracy of framework application across studies. There were limitations also identified in relation to how individual studies demonstrated the NIH BCC framework's ability to enhance treatment fidelity outcomes. As stated under results, despite a stringent study selection process, the body of evidence identified through database searching was evaluated as weak. Despite the methodological limitations identified across the studies, it is important to acknowledge that treatment fidelity is an emerging area of practice in Implementation Science. Therefore, the case series design chosen by each of the authors was appropriately applied to suit the infancy of the treatment fidelity literature [13].

The NIH BCC framework recommends that treatment fidelity should be measured using a tool that can rate the occurrence or non-occurrence, quality and frequency of core components that are key to an intervention's delivery. However, studies by Resnick et al. in 2009 [16] and 2011 [18], did not clearly define the behaviours and skills that should be delivered by a therapist in order to provide an intervention with high fidelity. This suggested that the chosen tools and methods for measuring treatment fidelity may not have been representative of the core components of the intervention, therefore impacting

on the ability of the tool to determine if the intervention had been delivered accurately. In addition, all studies except for Hildebrand et al. [16] failed to comment on or demonstrate exploration of their measurement tool's inter-rater reliability. This further impacts on the applicability of these measures to other complex rehabilitation interventions and limits the generalisability of the study's findings. Additionally, the NIH BCC framework recommends, but does not mandate, which of the multiple strategies should be applied to address treatment fidelity. It is possible this led to inconsistencies with how aspects of the framework were applied to monitor and evaluate treatment fidelity, increasing the risk of measurement bias across all four studies.

Part B: Effectiveness of conceptual frameworks

It is important to discuss key findings from three individual studies, which did demonstrate a positive link between the NIH BCC conceptual framework and treatment fidelity outcomes. The study by Hildebrand et al. [17] applied a treatment fidelity checklist that was used to rate treatment adherence and competence. The authors reported the checklist demonstrated sound inter-rater reliability on testing. Key findings from the study suggested that videotaping and observation alone was insufficient to improve therapist's adherence to providing the control intervention. In comparison, the therapists in the intervention group who received additional feedback and training strategies based on the NIH BCC conceptual framework, achieved greater adherence according to ratings of intervention checklist.

Additionally, the findings of Chan et al. [19] demonstrated that overall adherence to key criteria remained between 75-80% following the introduction of NIH BCC strategies such as structured supervision and role modelling with the use of site-specific expert trainers. The study by Resnick in 2009 [16] reported that adherence to criterion was 60% at 4 months and 65% at 12 months following the use of monthly support with the principal investigator to prevent protocol drift. Borelli in 2011 [8], reports that the

current literature suggests that high fidelity has been achieved when the level of optimal adherence is between 80-100%, with adherence levels at 50% or lower indicative of low fidelity. The findings from these individual studies suggest that the application of NIH BCC strategies during the monitoring of provider skills and assessment of treatment delivery may be beneficial, especially when applied by health professionals who value the intervention and recognise the importance of its implementation through research.

Although the small number of studies in this review (n=4) demonstrated potential benefits, the overall findings regarding the framework's efficacy remain inconclusive. None of the studies compared the application of the conceptual framework to a control group or reported on baseline measures of treatment fidelity prior to the framework's application. During this review there were limitations identified across sample size and recruitment and high levels of heterogeneity in outcomes, restricting the clinical impact and ability to generalise these findings to clinical practice settings. However, the NIH BCC was the only framework to have been applied to all four studies, suggesting a preference by researchers implementing complex rehabilitation interventions to use the NIH BCC framework.

Implications for future research

Future research into the area of treatment fidelity should ensure greater attention be given to the following areas, particularly in relation to study design and methodology:

- Studies must systematically apply the key elements of a chosen model or framework when examining treatment fidelity
- Baseline treatment fidelity measures should be taken prior to the application of a conceptual framework to enable more rigorous data analysis

- Studies should use comparative designs with intervention and control or 'usual care' groups to determine the effectiveness of a conceptual framework or model on treatment fidelity outcomes

- Pre-defined performance checklists must map to all core elements of the complex intervention under testing

- Treatment fidelity measures should be developed with defined parameters and thresholds, which can clearly indicate when an intervention's core components have been delivered successfully

- Standardised approach to outcome measurement development, focusing on ensuring the tool's reliability and validity is tested and clearly reported on

Limitations

The body of literature pertaining to treatment fidelity is a relatively new and an emerging area of implementation science. Consequently, there was a limited number of articles which were of high quality and quantitative in study design available for review.

Due to the narrative and exploratory nature of the review, the study search and screening process was not exhaustive. The authors acknowledge limitations within the study selection process as a result of the first author completing all screening and data extraction processes. This may have impacted on the quantity, type and recency of the articles located. Never-the-less, it is important to acknowledge that this narrative review has still provided a broad and foundational perspective on this area of implementation research.

Conclusion

The evidence to support the recommended use of a conceptual framework to enhance treatment fidelity of complex interventions in stroke rehabilitation remains inconclusive. This review was unable to determine if the NIH BCC framework enhances the treatment

fidelity of complex rehabilitation interventions delivered by allied health professionals. For conceptual frameworks to be able to demonstrate their effectiveness in future research, the key elements and recommended strategies must be systematically applied. More research is required, with attention given to ensuring fidelity measures are standardised, representative of the core components of the intervention under testing and can clearly indicate when an intervention has been delivered as intended.

Abbreviations

SENSe: Study of the Effectiveness of Neurorehabilitation on Sensation

NIH BCC: National Institutes of Health (NIH) Behavior Change Consortium (BCC)

CoNNECT: Connecting New Networks for Everyday Contact through Touch.

TF: Treatment Fidelity

Disclosure statement

The authors alone are responsible for the content and writing of this paper. BN completed the search and quality review of studies. TT and LMC assisted with the structure and revised content of the paper. The authors have no conflict of interest to declare.

References

[1]   Cahill LS, Carey LM, Lannin NA, et al. Implementation interventions to

promote the uptake of evidence-based practices in stroke rehabilitation.

Cochrane Database Syst Rev. 2017;(10). Art. No.:CD012575.

[2]   Gearing, RE, El-Bassel N, Ghesquiere A, et al. Major ingredients of fidelity: A

review and scientific guide to improving quality of intervention research

implementation. Clin Psychol Rev. 2011;31:79–88.

[3]   Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and

evaluation of complex interventions to improve health. BMJ. 2000;321(7262):

694–96.

[4]   Carey LM, Macdonell R, Matyas TA. SENSe: Study of the effectiveness of

neurorehabilitation on sensation: A randomized controlled trial. Neurorehabil

Neural Repair. 2011;25(4):304-13.

[5]   O'Shea O, McCormick R, Bradley JM, et al. Fidelity review: A scoping review

of the methods used to evaluate treatment fidelity in behavioural change

interventions. Phys Ther Rev. 2016;21(3-6):207-14.

[6]   Hoffman TC, Glasziou PP, Boutron I, et al. Better reporting of interventions:

Template for Intervention Description and Replication (TIDieR) checklist and

guide. BMJ. 2014;348:g1687.

[7]   Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health

behavior change studies: Best practices and recommendations from the NIH

behavior change consortium. Health Psychol. 2004;23(5):443–51.

[8]   Borelli B. The assessment, monitoring, and enhancement of treatment fidelity In

public health clinical trials. J Public Health Dent. 2011;71(s1):S52–63.

[9] Durlak JA, DuPre EP. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol. 2008;41(3-4):327-50.

[10] Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. Implement Sci. 2007;2(40):1-9.

[11] Toomey E, Matthews J, Guerin S, et al. Development of a feasible implementation fidelity protocol within a complex physical therapy-led self-management intervention. Phys Ther. 2016;96:1287-98.

[12] Higgins JPT, Thomas J, Chandler J, et al. Cochrane handbook for systematic reviews of interventions (Vers 6.2). Cochrane. 2021; Ch 2-2.3.

[13] Hoffman T, Bennett S, Del Mar CB. Evidence-based practice across the health professions, 3rd ed. Elsevier; 2017. p28-30.

[14] Law M, Stewart D, Pollock N, et al. Guidelines for critical review form – Quantitative studies. McMaster University; 1998. Retrieved via Latrobe University Learning Management System on April 4, 2018.

[15] Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. BMJ. 2009;339:b2535.

[16] Resnick B, Galik E, Pretzer-Aboff I, et al. Treatment fidelity in nursing home research: The Res-Care intervention study. Res Gerontol Nurs. 2009;2(1):30-8.

[17] Hildebrand MW, Host HH, Binder EF, et al. Measuring treatment fidelity in a rehabilitation intervention study. Am J Phys Med Rehabil. 2012;91(8):715 –24.

[18] Resnick B, Michael K, Shaughnessy M, et al. Exercise intervention research in stroke: Optimizing outcomes through treatment fidelity. Top Stroke Rehab. 2011;18(1):611–619.

[19] Chlan L, Guttormson JL, Savik K. Tailoring a treatment fidelity framework for an intensive care unit clinical trial. Nursing Res. 2011;60(5):348–53.

2.3 Summary and Conclusion – Chapter 2

This Chapter 2 detailed the outcomes of an evidence review, which aimed to identify conceptual frameworks applied within the literature, and which of these frameworks enhanced treatment fidelity of complex rehabilitation interventions. As concluded, the *National Institutes of Health Behavior Change Consortium* (NIH BCC) framework was found to have been applied across all studies included in this review. Overall findings regarding the framework's efficacy remain inconclusive, with limited testing of the framework, and how the NIH BCC framework enhances treatment fidelity outcomes. Despite these limitations, the small number of studies in this review (n=4) demonstrated potential benefits at an individual strategy level.

Although the efficacy of the framework has not been formally tested, it is frequently referenced throughout the literature and has been applied to behaviour change studies across the healthcare continuum (Borelli, 2011). The strategies outlined in the framework have also been developed by an expert panel from the Treatment Fidelity Workgroup, as part of the NIH BCC (Borelli, 2011). Thus, the NIH BCC framework and its included strategies, were identified as the preferred conceptual framework to support the treatment fidelity and implementation of the SENSe therapy approach across the two implementation studies – *SENSe Implement* and *SENSe CONNECT*.

Additionally, the review identified the need for pre-defined performance checklists to map accurately to all core components of the complex intervention under testing, and to possess a method for indicating when an intervention has been delivered as intended. To address this, the next chapter of this thesis (Chapter 3) demonstrates the development of an audit checklist to assess and enhance the fidelity with which SENSe therapy is delivered across the implementation studies.

CHAPTER 3

DEVELOPMENT OF AN AUDIT CHECKLIST TO EVALUATE

TREATMENT FIDELITY OF A COMPLEX REHABILITATION

INTERVENTION

3.1 Introduction

Examining treatment fidelity is viewed as a critical element to the successful implementation of complex rehabilitation interventions (Carroll et al., 2007). Video and audiotaping are recommended methods for assessing intervention delivery, however these approaches are resource-intensive and may be considered intrusive for some intervention providers and patients (Borelli, 2011). An audit checklist is an alternative approach recommended in the literature (Toomey et al., 2016).

This Chapter details the development of an audit checklist to evaluate the documentation of treatment delivery, to measure and enhance the treatment fidelity of SENSe therapy. As part of the study aim, the developed checklist was tested on a sample of 38 documented therapy programs obtained retrospectively from an existing data set (CoNNECT trial), and further evaluated using a sub-set of 10 therapy programs to determine rater agreement. It is intended that this chapter will demonstrate how the process of audit checklist development and testing can be applied to complex rehabilitation interventions.

Please note this manuscript has been submitted to Disability and Rehabilitation. Formatting and references have been adjusted to comply with the author guidelines of this journal. The only exception is that Tables and Figures are included in the body of the prepared manuscript and follow APA7 formatting to facilitate readability in this thesis.

3.2 Development of an audit checklist to evaluate treatment fidelity of a complex rehabilitation intervention

(manuscript submitted 26/06/21, resubmitted 7/02/22)

Development of an audit checklist to evaluate treatment fidelity of a complex rehabilitation intervention

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Audit checklist to evaluate treatment fidelity

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ABSTRACT

Purpose: The process of examining treatment fidelity is critical to the successful implementation of rehabilitation interventions. Videotaping is considered the recommended assessment; however, may be considered resource-intensive and intrusive for intervention providers and patients. An audit checklist is an alternative approach recommended in the literature. The purpose of this study was to develop a documentation audit checklist for assessing treatment fidelity during delivery of SENSe therapy, a complex rehabilitation intervention targeting upper limb somatosensory impairment post-stroke.

Methods: Checklist development comprised: content determination and design; checklist testing via audit of 38 therapy records from an existing data set; and exploration of rater agreement between two assessors, using a subset of 10 therapy records.

Results: The developed audit checklist comprised 29 components core to the delivery of SENSe therapy. Six SENSe therapy records were delivered with high fidelity (>80% adherence to core components), and 32 with moderate fidelity (51-79%). Rater agreement was 80% across the subset of 10 records.

Conclusion: Findings highlight the importance of using a theoretically-guided approach to checklist development, with the use of rater agreement to identify areas for refinement. A documentation audit checklist was developed that can be used to evaluate treatment fidelity of complex rehabilitation interventions.

Keywords: somatosensory, treatment fidelity, audit, rehabilitation, framework, intervention

Introduction

Rehabilitation interventions are considered inherently complex [1,2], require the provider to possess a defined level of skill and knowledge, and are dependent on clinician delivery and patient interactions [3,4]. For these interventions to demonstrate their effectiveness in research and clinical practice, the therapy must be implemented as intended [1]. Yet, the implementation of rehabilitation interventions is often difficult to assess due to the several interconnecting components which define these complex interventions [5,6].

Treatment fidelity is broadly defined as the extent to which the therapy provider delivers the intervention as per the study protocol [7,8]. Within the psychotherapy field it is widely acknowledged that the process of examining treatment fidelity is a critical element to the successful implementation of complex rehabilitation interventions [1,2,7]. More recently, there has been greater consideration for applying the concept within rehabilitation research [4], with monitoring and enhancing treatment fidelity forming part of the recommendations outlined in the *Template for Intervention Description and Replication (TIDieR)* reporting guidelines for intervention research [8,9]. Various definitions for treatment fidelity, sometimes referred to as implementation fidelity or intervention integrity, exist in the literature. A scoping review conducted by O'Shea et al. [2] identified the definition published by Bellg et al. [10] on behalf of the National Institutes of Health Behavioral Change Consortium (NIH BCC) as the most frequently cited definition. This definition states:

> *Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests the clinical intervention [10, p.443].*

Fidelity in the context of implementation science acts as a moderator between interventions and their intended outcomes, allowing for early detection of errors to

prevent protocol deviations from becoming widespread and long lasting [1,11]. It has been demonstrated in numerous research studies that the fidelity of an intervention at time of implementation affects how well it succeeds, with higher levels of treatment fidelity associated with better treatment outcomes [1,12]. Assessment of treatment fidelity does not only lie with the therapy provider. The extent to which the treatment protocol is standardised and/or can be implemented when there is a need to tailor the treatment to the individual patient's level of ability/impairments, and preferences, is also likely to impact [7]. Further, there are specific challenges associated with the evaluation of complex interventions because of the difficulties defining, recording, and reproducing the various components of the intervention. Often researchers have not defined the active components of the intervention prior to evaluation [5]. To avoid this issue, several studies strongly recommend a conceptual framework or model be applied to guide the treatment fidelity

A conceptual framework or model for treatment fidelity is defined by a set of guidelines or recommendations which detail a combination of strategies and methods which aim to assess, enhance and evaluate fidelity at different stages of an intervention's implementation [1,11-13]. Numerous conceptual frameworks and models exist within treatment fidelity literature, however as stated by Toomey et al. [14], few studies fully explain their rationale for choosing to apply a particular framework and its fidelity strategies. Additionally, few have evaluated their effectiveness in the context of stroke and other complex rehabilitation interventions.

Review of the literature identified the conceptual framework developed by the *National Institutes of Health Behavioral Change Consortium (NIH BCC)*, as the most frequently applied and referenced framework across treatment fidelity studies. Although the framework's efficacy has not been formally tested, it was applied to 15 behaviour change studies during its development through the Treatment Fidelity Workgroup of the National Institutes of Health Behavioral Change Consortium. During pilot testing, the

framework was shown to have good inter-rater reliability when used to evaluate levels of treatment fidelity [10,11].

The framework was first published by Bellg and colleagues in 2004 [10], and updated by Borelli in 2011 [11]. The framework details a combination of strategies and methods, which aim to assess, enhance, and evaluate fidelity at different stages of an intervention's implementation. The framework categorises treatment fidelity into five specific domains; Study Design, Training of Providers, Treatment Delivery, Treatment Receipt, Treatment Enactment [10,11].

The most commonly applied strategies from the NIH BCC framework pertain to the domains of *Training of Providers* and *Treatment Delivery.* One strategy frequently applied is the use of videotaping to objectively verify intervention delivery [1,12].

However, Toomey and colleagues [14] acknowledged that this recommended approach can be time-consuming, resource-intensive and considered intrusive for some intervention providers and patients. Toomey and colleagues [14] tested the feasibility of three methods outlined in the NIH BCC framework for assessing treatment fidelity within treatment delivery – direct observations, audio recordings and self-report checklists. They found good to excellent agreement between direct observations and audio recordings, and direct observations and self-report checklists. This study highlighted the importance of considering the use of multiple methods of data collection to comprehensively address implementation fidelity.

An example of a complex rehabilitation intervention that is individually targeted is the *Study of the Effectiveness of Neuro-rehabilitation on Sensation (SENSe) therapy* approach developed and tested by Carey, Macdonnell and Matyas [15]. SENSe therapy is founded on theories of neuroscience and targets upper limb somatosensory loss post-stroke through a core set of retraining principles. Yet, SENSe therapy is not currently implemented in routine clinical practice [16]. To help address this issue treatment

manuals have been developed and an implementation study has been proposed to facilitate delivery of SENSe therapy in routine clinical practice [17] and to increase access to SENSe therapy [18]. Core principles and treatment protocols for SENSe have been operationalised in treatment manuals, intervention videos and an upskilling program [19]. The protocol and treatment forms specify different levels of skill training aligned to the patient's level of ability/impairment for that somatosensory domain and/or occupational task. Progression through therapy is also operationalised as part of the training protocol. Further, as per the SENSe research protocol, standardised assessments are performed prior to intervention delivery. This enables SENSe therapy to be tailored to individual patient's needs and abilities [17].

With the above considerations in mind, the overall aim of this research project was to develop an audit checklist to evaluate the documentation of treatment delivery for a complex neurological intervention of the upper limb – specifically to measure and enhance the treatment fidelity of SENSe therapy. Further, we aimed to do this in manner consistent with current implementation science recommendations; i.e. following the Treatment Delivery domain of the NIH BCC framework [11], and recommended stages relating to checklist development [20], as below.

Recommended stages of audit checklist development have been outlined by Burian and colleagues in 2018 [20], and pertain to five key areas when developing a checklist in healthcare: (i) conception; (ii) content determination and design; (iii) testing and validation; (iv) training and implementation; and (v) ongoing evaluation and revision. Stages i to iii are relevant to this project. During the conception phase, developers must thoroughly explore the purpose of the fidelity checklist and desired outcomes, with consideration given to how the checklist will be used, how it will fit into existing workflow processes, and how it will relate to existing checklists [20]. During the content and design phase, the use of literature reviews, focus groups with content experts and task

analysis are well–established methods for identifying checklist content. Further to this, the NIH BCC framework advises that both adherence to core treatment components, and competence to deliver the treatment as outlined in the treatment protocol, needs to be assessed within the checklist [11]. It is recommended the checklist should also include details on dosage, key features on content of intervention, a list of theory-based active ingredients, and a method to determine the degree to which active components are implemented as intended [11]. During the testing and validation phase it is recommended that following refinement, the final version of the checklist be subjected to validation before implementation, to determine how accurately the checklist achieves its purpose. Feasibility studies consulted in the literature recommend a minimum of 24 files are utilised during initial instrument development within pilot studies [10].

Methods

This Methods section includes description of the process of developing an audit checklist to assess fidelity of the entire SENSe therapy program (delivered per patient), and pilot testing of the developed audit checklist. The process follows strategies suggested under the Treatment Delivery domain of the NIH BCC framework [11], and stages i– iii of checklist development outlined by Burian and colleagues [20].

Development of an audit checklist:

Conception: The aim was to use the developed checklist as one of several methods for assessing the fidelity of SENSe therapy being delivered as part of future implementation studies, comprising the SENSe Implement [17] and SENSe CONNECT studies [18]. By using this audit checklist as a measure of treatment fidelity, the accuracy with which SENSe therapy is being delivered by rehabilitation clinicians will be determined. The

audit checklist will also be used as a method for providing objective feedback to clinicians delivering SENSe therapy as part of these implementation studies, enabling them to acquire and maintain the skills required to deliver the core components of the intervention.

Determining content & design: To determine content and design of the checklist, experts familiar with the application and active ingredients of SENSe therapy, including the originator of SENSe therapy, gathered to discuss and decide on the content of the checklist. Three expert clinicians consulted throughout this development phase were chosen as they were actively delivering SENSe therapy as part of ongoing clinical trials at the time of checklist development. Content of the checklist was developed based on documented core ingredients of SENSe therapy and detailed therapy protocols, including the SENSe training manual and training forms [19] and detailed patient therapy record forms used in research. All components included were judged, by consensus, to be core and of relatively equal importance to successful delivery and reporting of SENSe therapy. The checklist was structured according to the detailed therapy protocols, and included schedule and dosage, component training of discrimination functions, and application to occupations.

The content and format of the checklist was also reviewed and piloted relative to three example SENSe therapy files obtained from an existing data set; the CoNNECT trial. The CoNNECT (Connecting New Networks for Everyday Contact through Touch) trial is an interventional study involving clinical and neuroimaging outcomes associated with delivery of SENSe therapy [21]. SENSe therapy was delivered to stroke patients who were living in the community. Additional criteria included: first episode of cortical or sub-cortical stroke; Somatosensory impairment clinically apparent or queried; Medically stable; able to give informed consent and comprehend simple instructions; right hand dominant [21]. Delivery of SENSe therapy during the CoNNECT trial comprised of 15 training sessions of SENSe Therapy at a rate of approximately 2-3

sessions per week and duration of 60 minutes per session [21]. Following content review, a panel discussion was held with feedback provided by the expert clinicians to evaluate the utility of the checklist, as recommended by Burian and colleagues [20]. Consensus was achieved based on this discussion.
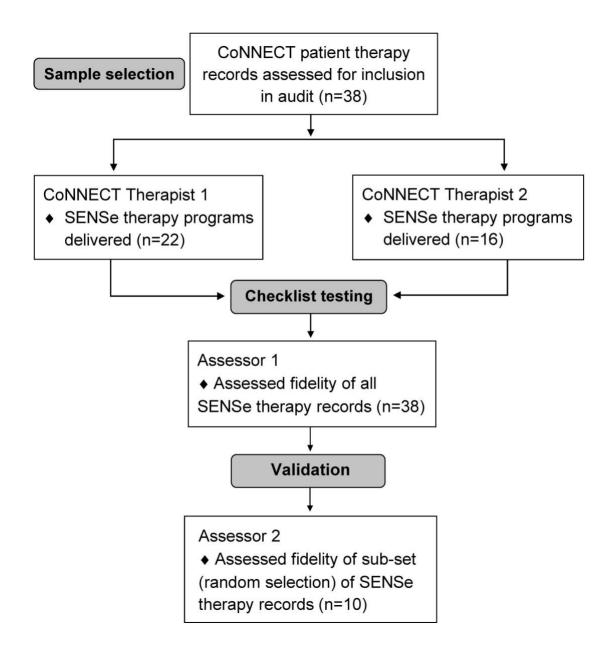
Pilot testing of an audit checklist: Testing and Validation

Utilising the developed documentation checklist, a case audit of 38 data sets (therapy records) was completed by a blinded assessor using the pre-existing data set within the CoNNECT study. This assessor (Assessor 1) was an experienced rehabilitation professional, who had been upskilled in the delivery of SENSe therapy. A subset of 10 randomly-selected therapy records were independently reviewed by a second blinded assessor, and compared with scores of Assessor 1, to explore the consistency of the treatment fidelity scoring system. Assessor 2 was a clinical educator of SENSe therapy and had delivered SENSe therapy within the context of the CoNNECT study, but had not previously used the checklist. Figure 1 visually represents the process of sample selection and piloting of the checklist. Ethics approval for the current study was obtained through La Trobe University (HEC20301). At time of recruitment to the original study, the CoNNECT participants consented to the use of their data for related studies and future analysis by members of the research team.

Sample selection: Available and complete data sets from the SENSe therapy programs delivered during the CoNNECT trial were used for this study. A total of 38 CoNNECT therapy records with complete data sets delivered by two primary therapists were available for analysis (90% of total study files). All 38 data sets were included in the sample to maximise confidence in the results following data analysis. This included 22 data files relating to delivery of SENSE therapy by Therapist 1 and 16 files pertaining to Therapist 2. Both therapists underwent the same expert training prior to commencing in the CoNNECT trial and had access to expert support throughout the course of the trial.

Figure 1.

Flow Chart Representing Sample Selection and Piloting of the Checklist.

Measurement Tool: Fidelity of treatment delivery was objectively assessed using the developed audit checklist that outlined the core components of SENSe therapy. The checklist comprises 29 items (core components) grouped as follows: documentation of the Training Schedule Overview (summarises the therapy delivered across 15 treatment sessions); documentation of training of Texture Discrimination, Limb Position Sense, and Tactile Object Recognition (the three sensory discrimination modules delivered); and

documentation of Occupation-based training (a fourth training module designed to transfer sensory discrimination skills into patient-selected daily activities). The Training Schedule Overview comprises of five core components, with six or seven core components in each sensory discrimination module and four within Occupation-based training. Please see Table 1 for summary of core components included in the checklist.

Table 1.

Summary of Core Components Included in the Checklist for Assessing Fidelity of SENSe Documentation.

Core components of documented program (number of components)	*Absent from session (Score 0)*	*Partially performed (Score 1)*	*Competently performed (Score 2)*
TRAINING SCHEDULE OVERVIEW (5)			
2 - 3 training elements per session			
Evidence of grading within and across component of training, and across sessions.			
2 x Occupations to be trained clearly documented on schedule, at least 4-6sessions in total.			
Evidence of occupations selected and plan documented			
Therapist initials and date on training schedule			
COMPONENT TRAINING – Texture & Grid discrimination (6)*, Limb Position Sense (6), Tactile Object Recognition (7)			
Training forms dated and / or session no. documented			
Evidence of response recorded *e.g. same or different, texture surface identified.*			
Number of trials consistent with training protocol and / or documented abilities *i.e. at least 75% correct before progressing to next level*			
Documentation of sessions trained			
Evidence of progression across levels for component of training *e.g. comments on number of attempts, patient's confidence with performance, method of exploration, calibration strategies and feedback provided, transition across levels appropriate to documented abilities.*			
Commences at appropriate level *i.e. level 1 or modified level, supported by clinical reasoning / assessment results.*			
OCCUPATION-BASED TRAINING (4)			
2 x Occupations identified to be trained are documented			
Occupation based training delivered in line with sensory and / or activity goal.			
Commences at appropriate level *i.e. considers task complexity*			
Grades sensory demands of task *e.g. sensory challenges, discrimination difficulty, presence of other cues/feedback.*			

Key:* relates to the number of core components listed for each modality of component training.

Adherence to documentation of each of the core components was assessed using a 3-point rating scale; a score of 0 indicates the core component has not been documented, a score of 1 indicates the core component was documented with partial adherence or quality, and a score of 2 is awarded when the clinician documents the core component with a high degree of adherence and quality according to the criterion. In line with recommendations by Borelli et al. [11] and Burian et al. [20], this ordinal rating minimises assessor subjectivity. Not Applicable (N/A) is recorded when a core component is deemed, by the assessor, not to be applicable to the particular therapy program or patient. As part of content and design development, individual definitions were specified for a score of 0 (n=16) and 1 (n=8) across several of the core components to reduce scoring subjectivity. Definitions were included for those core components where the expert panel felt additional information would improve scoring accuracy.

The score for each core component documented was then summed to provide a total raw score for the treatment program. The total possible raw score for a treatment program documented with 100% fidelity (inclusive of 15 treatment sessions in total) was 58; with total score adjusted for not applicable (N/A) components where necessary. To calculate the percentage of Treatment Fidelity (TF) documented by each therapist for each patient, the total raw score of all documented core components is divided by the total possible raw score and then multiplied by 100 to achieve a percentage score. For example, if the total raw score = 36 this would equate to a TF percentage of 62% (36 / 58 = 62%).

Data collection and analysis: A single assessor (Assessor 1) obtained treatment fidelity data from the 38 therapy records using the finalised documentation audit checklist. The discrete data retrieved from the audit checklist was used to determine a percentage of

treatment fidelity, as outlined above in the Measurement tool section, for each therapy record and each therapist.

The treatment fidelity percentage scores were then classified and sorted to describe relationships between treatment fidelity percentage and individual therapists. Classification of fidelity percentage was based on recommendations outlined by Borelli [11] as part of the NIH BCC framework. The criterion of 80% is the recommended benchmark for treatment fidelity [11]. This percentage score indicates that the intervention has been provided with a high level of treatment fidelity. In contrast, a treatment fidelity percentage of 50% and lower is suggestive of low treatment fidelity [13]. Analyses included the portion of patient files where fidelity was documented to be high (>80%), moderate (51-79%) and low (<50%). Frequency data was also used to highlight the number of therapy records where a rating of "absent", "criterion partially met" and "competently performed" was awarded for each core component.

With the small number of files reviewed by the two assessors (n=10; Figure 1), formal inter-rater reliability statistical analysis was not performed. The process of evaluating and reporting on the consistency of the treatment fidelity scoring is thus referred to as rater agreement throughout this paper. Rater agreement was determined according to which fidelity percentage range, high (>80%), moderate (51-79%) or low (<50%), each assessor rated the file documentation to fall within. A score of 1 was awarded if both assessor's treatment fidelity percentages fell into the same fidelity range, and a 0 if there was a discrepancy for each individual file. For example, Assessor 1 rated file 27 a fidelity percentage of 78% (moderate fidelity), however Assessor 2 rated the same file as 84% (high fidelity), therefore this was marked as a discrepancy or non-agreement. The total number of files with a rater-agreement score of 1 was summed and reported in relation to the total file number.

Results

Overall Treatment fidelity

The checklist identified six SENSe therapy records (15%) that were documented with high fidelity (>80%); four of these therapy records were delivered by Therapist 1. Thirty-two records were of moderate fidelity (18 delivered by Therapist 1 and 14 by Therapist 2). Neither therapist's records were documented within the low fidelity range (<50%).

Fidelity related to individual core components

The frequency with which core components were rated as absent, partially performed, and competently performed across the documented training sections varied. All training sections had more than 50% of the core components documented as competently performed, except for Occupation-based training, as depicted in Figure *2*. The core components within the three somatosensory discrimination training modules (Texture Discrimination, Limb Position Sense, and Tactile Object Recognition) were documented as competently performed in 71-81% of files. A rating of absent occurred in 53% of therapy records for Occupation-based training and in 40% of records pertaining to the Training Schedule Overview. In comparison, only a small proportion of the therapy records (4-7%) were rated as having absent core components for the sensory discrimination training modules.

Rater agreement

Rater agreement was achieved in 8/10 files, i.e. total treatment fidelity percentage score was within the same fidelity category. The overall treatment fidelity percentages determined by Assessor 1 compared with Assessor 2 when applying the audit checklist to 10 random CoNNECT study therapy records are summarised in Table 2. Exploratory comparison of actual total treatment fidelity scores (%), revealed the average score

difference on a 100-point percentage scale was 3.5%, with a minimum difference of 1% and maximum difference of 6% between the two raters. The four core components within Occupation-based training were found to have the largest number of scoring discrepancies between the assessors. Two out of 10 patient therapy records had a scoring difference of more than 1 point for a particular component (e.g. Assessor 1 marked one component as absent (score = 0) versus Assessor 2 marked the documentation as competently performed (score = 2)).

Figure 2.

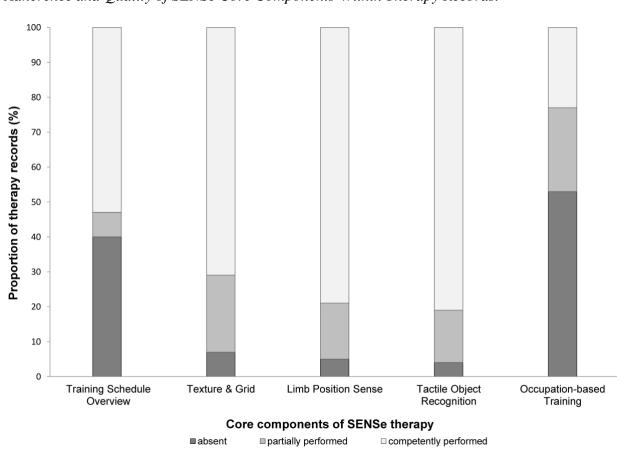*Adherence and Quality of SENSe Core Components Within Therapy Records.*

Table 2.

Rater Agreement Between Assessor 1 and Assessor 2.

Sample no.	Assessor 1 (%)	Assessor 2 (%)	Rater agreement (Y=1, N=0)
8	88	93	1
9	86	91	1
16	74	77	1
22	87	90	1
27	78	84	0
32	81	82	1
33	76	81	0
40	69	66	1
42	65	62	1
44	63	64	1

Key: % = Treatment fidelity percentage per file
Treatment Fidelity cut off scores = Low ≤50%, Moderate 51-79%, High 80-100%

Discussion

The results from this retrospective audit of patient therapy records demonstrate it is feasible to use a documentation audit checklist to determine the level of treatment fidelity within SENSe therapy documentation. The checklist was able to identify a small number of files (n=6) that were documented with high overall fidelity (≥80%), with the remaining 32 files documented with moderate fidelity (51 – 79%). Although rater agreement was high across 8/10 files when assessed at the overall level of treatment fidelity (i.e. high, moderate or low), there were discrepancies across individual core components.

In relation to treatment fidelity of core components, the findings of the audit (shown in Figure 2) indicate that all three sensory discrimination training modules – Texture and Grid discrimination, Limb Position Sense, and Tactile Object Recognition were rated as competently performed (>70% in each) and had only a few files where the core components were rated as absent. These therapy modules are well structured and have nominated treatment forms and documentation processes, to facilitate

documentation of patient responses and guide delivery. This was found to contrast with the Training Schedule Overview and Occupation-based training module, where almost half of the core components were found to be absent from documentation across most files. The absence of clear documentation was most likely to be impacted by the lack of formal documentation processes for therapists to follow when recording occupation-based training as part of the CoNNECT study. Based on these observations, it is strongly recommended that a documentation proforma be developed for the occupation-based training module, which will ensure core components are documented consistently and enable more structured auditing using the developed checklist. It is also recommended that the Training Schedule Overview be reviewed for purpose and clarity.

The individual core components were frequently rated as partially completed across all three sensory discrimination modules. The SENSe therapy manual specifies that clinicians should document their reasoning for certain clinical decisions (e.g. when a clinician commenced a patient at a higher component training level or if they were progressed before achieving the 75% criterion) however, there was a lack of documentation throughout the sensory discrimination modules, in particular the Texture and Grid discrimination training component. Therefore, as part of the documentation guidelines for future implementation studies it is important that clinicians are informed of when and where they need to document justification for a clinical decision such as the scenarios outlined above. As part of the documentation processes, it is recommended that clinicians at each site receive feedback on their documentation audit at key intervals throughout the study as a way of monitoring the fidelity of treatment delivery and most importantly, ensuring adherence to documentation processes.

The rater agreement testing identified areas where the checklist could be further refined to improve validity; with consideration also given to the training requirements for assessors applying the checklist during future studies. Testing of rater agreement also

identified the importance of ensuring there were individual definitions available for scoring each core component as either absent, partially performed or competently performed. For example, several of the core components within the applied checklist only had individualised definitions for 1 or 2 items of the 3-point rating scale. This likely lead to subjective interpretation by the assessors to determine what constituted the core component as partially performed versus competently performed. It is important to note that the core components of the occupation-based training was the only section which did not have any individual definitions to assist the scorer in determining what constituted a component as absent, partially performed or competently performed. This lack of definition may have contributed to the discrepancies in scoring between Assessor 1 and Assessor 2. Further to this, documentation of the occupation-based training is not modularised, as is the case for the three discrimination-training modules that demonstrated high treatment fidelity, and thus likely also contributed to the lower agreement rates.

With the above checklist improvements in mind, a revised version will be finalised and applied to the implementation of SENSe therapy. The SENSe implementation study will apply several strategies recommended by the NIH BCC framework, including the documentation audit checklist. The documentation checklist will be applied alongside an observation checklist which will be used to assess the treatment fidelity of SENSe therapy being delivered by clinicians in real-time therapy sessions. The process of audit checklist development and piloting undertaken in the current study may also be of value for others planning to monitor treatment fidelity of complex rehabilitation interventions.

Limitations

Limitations of the study included that there was only one assessor (Assessor 1) who rated 38 patient files, with a small sample of 10 files audited by a second assessor (Assessor 2),

to verify use of the checklist and for preliminary evidence of rater agreement. Due to time and the exploratory nature of the study, it was not feasible for Assessor 2 to review all 38 files. Also, pilot testing was conducted on a relatively small sample of pre-existing records from the CoNNECT trial, and formal inter-rater reliability statistical analysis was not performed due to the low number of files compared. Thus, generalisation of this checklist beyond this study must be treated with caution. While the authors recognise the need for formal inter-rater reliability testing with a larger file sample and greater number of assessors, preliminary investigation of rater agreement with an experienced SENSe educator and therapist has provided valuable information regarding the tool's ability to be applied consistently between assessors. It has also highlighted areas for improvement that can ensure the tool is more accurate and user-friendly.

The percentage treatment fidelity score involves summing ratings across core components. It is recognised that this approach does not empirically account for the relative importance/weighting of the different items. However, as part of the panel discussion and checklist development, the authors only included core components within the fidelity checklist that were deemed critical and core to quality delivery and reporting of SENSe therapy and were judged to be relatively equal in terms of importance.

In interpreting these findings, it is important to recall that the current study was a retrospective audit of therapy records. Therapists were not prospectively told that therapy records would be audited but were given forms to help record progress through therapy. Never-the-less, there is possibility of a Hawthorne effect in the reporting. It is also important to acknowledge that Assessor 2 was a CoNNECT therapist, and hence may have been familiar with the content documented in some patient files. Despite the potential for rater bias, Assessor 1 and 2 achieved agreement on 8/10 files that were also assessed by Assessor 2.

Another limitation was the informal training provided to Assessor 2 using the checklist and how this likely influenced consistency across raters. The lack of

standardised training provided to Assessor 2, who was relatively unfamiliar with the audit checklist, may have impacted on the consistent application of scoring methods. Assessor 2 was provided with a 30-minute education session on the checklist, its key components and how it should be applied. However, given that many core components did not have clear definitions for all 3 items on the rating scale, the importance of completing formalised training for assessors has been recognised. Further testing with therapists and assessors who are unfamiliar with SENSe therapy audit trials is needed. As a result of this it is recommended that all assessors are given the opportunity to score a minimum of 2-3 SENSe therapy files with support and feedback from the checklist trainer to ensure any scoring discrepancies are identified early and addressed immediately.

Conclusion

Findings from this study demonstrate the value of using a structured and theoretically-guided approach to checklist development to ensure the core components of complex interventions are accurately assessed, with the use of rater agreement testing to identify areas for refinement. This approach has shown to be feasible to develop an audit checklist that can be used as one strategy to assess and evaluate treatment fidelity of complex rehabilitation interventions such as SENSe therapy. However, it has also identified the importance of providing structured education for assessors using the developed checklist. Finally, it supports the use of standardised documentation proformas and processes for clinicians documenting therapy programs as part of implementing complex rehabilitation interventions.

Abbreviations

SENSe: <u>S</u>tudy of the <u>E</u>ffectiveness of <u>N</u>eurorehabilitation on <u>Se</u>nsation

NIH BCC: National Institutes of Health (NIH) Behavior Change Consortium (BCC)

CoNNECT: <u>C</u>onnecting <u>N</u>ew <u>N</u>etworks for <u>E</u>veryday <u>C</u>ontact through <u>T</u>ouch.

TF: Treatment Fidelity

Disclosure statement

The authors alone are responsible for the content and writing of this paper. The authors have no conflict of interest to declare.

Data Availability Statement

The data that support the findings of this study are available on reasonable request from Principal Investigator of the CoNNECT study (LMC).

References

[1]   Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. Implement Sci. 2007;2(40):1-9.

[2]   O'Shea O, McCormick R, Bradley JM, et al. Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions. Phys Ther Rev. 2016;21(3-6):207-14.

[3]   Gearing, RE, El-Bassel N, Ghesquiere A, et al. Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. Clin Psychol Rev. 2011;31:79–88.

[4]   Hildebrand MW, Host HH, Binder EF, et al. Measuring treatment fidelity in a rehabilitation intervention study. Am J Phys Med Rehabil. 2012;91(8):715 –24.

[5]   Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000;321(7262): 694–96.

[6]   Cahill LS, Carey LM, Lannin NA, et al. Implementation interventions to promote the uptake of evidence-based practices in stroke rehabilitation. Cochrane Database Syst Rev. 2017, Issue 3. Art. No.: CD012575.

[7]   Carragher M, Ryan B, Worrall L, et al. Fidelity protocol for the Action Success Knowledge (ASK) trial: a psychosocial intervention administered by speech and language therapists to prevent depression in people with post-stroke aphasia. BMJ Open. 2019;9:e023560.

[8]   Persch AC, Page SJ. Protocol development, treatment fidelity, adherence to treatment, and quality control. American Journal of Occupational Therapy. 2013;67, 146–153.

[9]   Hoffman TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: Template for Intervention Description and Replication (TIDieR) checklist and guide. BMJ. 2014;348:1687.

[10] Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. Health Psychol. 2004;23:443–51.

[11] Borelli B. The Assessment, Monitoring, and Enhancement of treatment fidelity In public health Clinical trials. J Public Health Dent. 2011;71(s1):S52–63.

[12] Durlak JA, DuPre EP. Implementation matters: a reviewof research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol. 2008;41(3-4):327-50.

[13] Resnick B, Galik E, Pretzer-Aboff I, et al. Treatment Fidelity in nursing home research: The Res-Care Intervention Study. Res Gerontol Nurs. 2009;2(1):30-8.

[14] Toomey E, Matthews J, Guerin S, et al. Development of a feasible implementation fidelity protocol within a complex physical therapy-led self-management intervention. Phys Ther. 2016;96:1287-98.

[15] Carey LM, Macdonell R, Matyas TA. SENSe: Study of the effectiveness of neurorehabilitation on sensation: A randomized controlled trial. Neurorehabil Neural Repair. 2011;25:304-13.

[16] Pumpa LU, Cahill LS, Carey LM. Somatosensory assessment and treatment after stroke: An evidence-practice gap. Australian Occupational Therapy Journal. 2015; *62*(2), 93-104.

[17] Cahill LS, Lannin NA, Mak-Yuen Y, et al. Changing practice in the assessment and treatment of somatosensory loss in stroke survivors: protocol for a knowledge translation study. BMC Health Serv Res. 2018;18:34.

[18] Carey, LM. Network of sites and 'upskilled' therapists to deliver best-practice stroke rehabilitation of the upper limb. 2018 [cited 2020 September 19]. Available from: https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375706&isReview=true

[19] SENSe: Helping stroke survivors regain a sense of touch: A manual for therapists (with DVD). Melbourne, Australia: The Florey Institute of Neuroscience and Mental Health and La trobe University. 2012. Available from: https://sensetherapy.net.au/resources/sense-manual-and-dvd/

[20] Burian BK, Clebone A, Dismukes K, et al. More than a tick box: Medical checklist development, design, and use. Aneth Analg. 2018;126(1):223-32

[21] Carey LM, Seitz R, Levi C, et al. Effective sensory rehabilitation after stroke: Targeting viable brain networks. 2011 [cited 2019 March 30]. Available from: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=364147& isReview=true

3.3 Summary and Conclusion – Chapter 3

This Chapter detailed the first quantitative study presented in this thesis. Findings from this study demonstrate the feasibility of developing a documentation checklist that can be used as one strategy to assess and evaluate treatment fidelity of complex rehabilitation interventions. SENSe therapy has been used as an exemplar to demonstrate how the chosen methods can be systematically applied. The importance of frequently monitoring treatment fidelity and providing clinicians with feedback is justified by the findings highlighted in this chapter, demonstrating that increasing levels of therapist experience did not relate to higher levels of documented treatment fidelity results. The results suggest that the treatment fidelity in relation to therapy documentation can fluctuate despite an increase in clinical experience, further supporting the NIH BCC recommendation to closely monitor fidelity of treatment delivery at regular time points throughout the course of a study. Thus, enabling trainers to identify when booster training sessions and feedback is required to return intervention delivery to a level of high fidelity (≥80%).

Findings presented in this chapter support the need to use a structured and theoretically-guided approach to checklist development to ensure all core components of an intervention are included in measurement tools being used to assess treatment fidelity of complex interventions. The use of rater agreement testing to identify areas for refinement was particularly important within the context of developing the checklist for SENSe therapy, as it identified the need for more structured documentation guidelines and a proforma for therapists to use when recording intervention sessions, particularly within the occupation-based training unit.

The study also identified the importance of providing structured education for assessors using the developed checklist; and setting clear documentation expectations for clinicians who are required to document therapy programs as part of implementing complex interventions. The developed documentation audit checklist was used to evaluate

the treatment fidelity of SENSe therapy being documented as part of the prospective

SENSe implementation studies reported on in Chapter 4.

CHAPTER 4

TREATMENT FIDELITY OF SENSE THERAPY WHEN DELIVERED BY

NOVICE CLINICIANS AND FACTORS ASSOCIATED

4.1 Introduction

Examining treatment fidelity is viewed as a critical element to the successful

implementation of complex rehabilitation interventions (Carroll et al., 2007). According

to the framework by the *National Institutes of Health's Behavioral Change Consortium*

(NIH BCC) video and audiotaping are recommended methods for the assessment of

intervention delivery, however this approach is resource-intensive and may be considered

intrusive for some intervention providers and patients (Borelli, 2011). Findings from

Chapter 3 demonstrated the feasibility of using an audit checklist as a successful

alternative approach, which can be used as one strategy to assess and evaluate treatment

fidelity of complex rehabilitation interventions (Toomey et al., 2016), such as SENSe

therapy. The developed audit checklist has therefore been applied to the next phase of the

research project.

This chapter details the implementation of several strategies from the NIH BCC

framework, including the audit checklist, to measure and enhance the treatment fidelity of

SENSe therapy delivered by clinicians across a knowledge translation partnership (Carey,

2018) comprising two implementation studies – *SENSe Implement* and *SENSe*

CONNECT. Please note that the current research reports on preliminary analysis of data

as the study is ongoing.

Please note this research has been prepared for submission to Disability and

Rehabilitation. Formatting and references have been adjusted to comply with the author

guidelines of this journal. The only exception is that Tables and Figures are included in

4.2 Treatment fidelity of SENSe therapy when delivered by novice clinicians and factors associated

(manuscript prepared for submission)

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Word count: 4821

ABSTRACT

Purpose: Examining Treatment fidelity (TF) is critical to the successful implementation of complex rehabilitation interventions. This study applied strategies from the National Institutes of Health Behavioral Change Consortium framework to enhance treatment fidelity of SENSe therapy, a complex intervention targeting upper limb somatosensory loss post-stroke. The aim was to quantify treatment fidelity of SENSe therapy when delivered by novice clinicians and explore factors associated with high, moderate and low fidelity levels.

Methods: Data was collected from two cohorts of novice clinicians (who delivered 1-3 therapy programs) participating in two separate SENSe implementation studies. Treatment delivery was assessed via documentation audit and session observation, using checklists comprising the core intervention components.

Results: Thirty-three programs delivered across 16 clinicians were audited. Overall TF ranged from 57-100%. Eleven SENSe Implement programs were delivered with high fidelity (≥80%) compared to 15 SENSe CONNECT therapy programs (78% total with high fidelity). The remaining therapy programs were delivered with moderate fidelity (51-79%). The SENSe CONNECT therapists engaged in more frequent feedback strategies to enhance TF, compared to the Implement therapists.

Conclusion: It is feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity, when supported by documentation proformas, expert trainers and provided with regular feedback opportunities. SENSe-delivery experience and clinical years of experience were not clearly associated with treatment fidelity score.

Keywords: sensation, intervention, treatment fidelity, audit, feedback, framework

Introduction

Treatment fidelity is broadly defined as the extent to which the therapy provider delivers the intervention as per the study protocol [1,2]. Within the psychotherapy field it is widely acknowledged that the process of examining treatment fidelity is a critical element to the successful implementation of complex rehabilitation interventions [3,4]. More recently, there has been greater consideration for applying the concept within rehabilitation research [5], with monitoring and enhancing treatment fidelity forming part of the recommendations outlined in the *Template for Intervention Description and Replication (TIDieR)* reporting guidelines for intervention research [1,6].

Rehabilitation interventions are often multi-faceted, require the therapist to possess a defined level of skill and knowledge and are dependent on clinician delivery and patient interactions [5,7]. An example of a complex intervention is the *Study of the Effectiveness of Neuro-rehabilitation on Sensation (SENSe) therapy* approach developed and tested by Carey, Macdonnell and Matyas [8]. SENSe therapy is founded on theories of neuroscience and learning and targets upper limb somatosensory loss post-stroke through a core set of retraining principles. The intervention is currently at the point of implementation to practice in clinical settings in two studies – *SENSe Implement* [9] and *SENSe CONNECT* [10]. Core principles and treatment protocols for SENSe have been operationalised in treatment manuals, intervention videos, and an educational program to upskill therapists [11]. The protocol and treatment forms specify different levels of skill training aligned to the patient's level of ability/impairment. Progression through therapy is operationalised as part of the training protocol. Further, as per the SENSe protocol, standardised assessments are performed prior to intervention delivery. This enables SENSe therapy to be tailored to individual patient's needs and abilities [9]. SENSe Implement focuses on upskilling a large number of clinicians (8-12 per site) to deliver therapy to a small number of clients (n=1-3 each) across multiple sites (n=8) [9], while SENSe CONNECT is designed to upskill a small number of therapists (3-4 per centre) to

deliver therapy to a large number of stroke survivors (n=12 each) at each SENSe therapy centre [10].

In the context of implementation science, fidelity acts as a moderator between interventions and their expected treatment outcomes; for example it allows for early detection of errors during intervention delivery and prevents widespread protocol deviations [3,12]. It has been demonstrated in numerous research studies that the fidelity of an intervention at time of implementation affects how well the intervention succeeds, with higher levels of treatment fidelity associated with better treatment outcomes [3,12,13]. According to Resnick and colleagues [14], it cannot be determined whether a lack of intervention impact is due to poor intervention adherence, or that the intervention itself is ineffective, unless fidelity is frequently assessed and evaluated throughout the course of the research project. Further to this, there are specific challenges associated with the evaluation of complex interventions because of the difficulties defining, documenting, and reproducing the various components of the intervention. Often researchers have also not defined the active components of the intervention prior to evaluation [15].

Several studies strongly recommend a conceptual framework or model be applied to guide the treatment fidelity process [3,12,14]. One such framework is the *National Institutes of Health Behavioral Change Consortium (NIH BCC)* framework [16]. Review of the literature identified the (NIH BCC) conceptual framework, as the most frequently applied and referenced across treatment fidelity studies. This framework was first published by Bellg and colleagues in 2004 [16], and updated by Borelli in 2011 [12]. The framework details a collection of strategies and methods, which aim to assess, enhance, and evaluate fidelity at different stages of an intervention's implementation. Although the framework's efficacy has not been formally tested, it was applied to 15 behaviour change studies during its development through the Treatment Fidelity Workgroup of the National Institutes of Health Behavioral Change Consortium [16]. During pilot testing, the framework was shown to have good inter-rater reliability when used to evaluate levels of

treatment fidelity [12,16].

The framework categorises treatment fidelity into five specific domains: study design; training of providers; treatment delivery; treatment receipt; and treatment enactment [12,16].

The aim of the current study was to quantify the treatment fidelity of SENSe therapy when delivered by novice clinicians and explore factors associated with high, moderate and low fidelity levels. To achieve this study aim, two key strategies from 'Treatment delivery' (domain 3) of NIHBCC framework were applied. The two key strategies included 1) assessment of SENSe therapy delivery through auditing documentation of therapy programs and observing clinicians deliver individual SENSe therapy sessions, and 2) providing feedback on documentation and performance during observation sessions, with both audit and feedback guided by developed checklists.

Treatment delivery relates to processes that assess and enhance the actual delivery of the treatment so that it is delivered as intended [12,16]. This approach is consistent with recommendations from the NIH BCC framework, which highlights the importance of considering the category of treatment delivery and its strategies as mutually exclusive from prior categories [12]. This is of particular importance, given suggestions by Borelli in 2011 that *"well-trained providers may not always deliver the intervention protocol effectively, or with different participants across different contexts"* (p. S57).

As part of this study, two research questions were explored in the context of clinicians who were considered 'novice' SENSe therapists (i.e upskilled in SENSe therapy, but only have experience in delivering SENSe therapy to three or less stroke survivors). First, is it feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity in clinical practice settings? Second, which factors are associated with treatment fidelity when clinicians deliver SENSe therapy? The decision to explore individual clinician factors was based on the current fidelity literature, which

outlines that it remains unclear whether there is an association between intervention and/or clinical experience and treatment integrity. This is in comparison to other clinician factors including therapist's acceptability of the treatment and their perception of the treatment's efficacy, which is suggested by Borelli in 2011 to have already shown to influence treatment implementation [12].

Methods

Study Design

Pragmatic before-after study design, with quantitative treatment fidelity data collected across two cohorts of clinicians delivering SENSe therapy, as part of the *SENSe Implement* [9] and *SENSe CONNECT* [10] studies. These studies are part of a larger partnership program of research titled: A network of sites and 'up-skilled' therapists to deliver best-practice stroke rehabilitation of the upper limb (NHMRC grant no: 1134495) [10]. The SENSe Implement study involved clinicians from existing health services that deliver stroke rehabilitation, while the SENSe CONNECT study involved clinicians who were recruited to deliver therapy via new SENSe therapy centres, as part of the research partnership. Occupational therapists and physiotherapists delivering SENSe therapy to stroke survivors recruited, were involved in both studies. The SENSe Implement study delivered SENSe therapy to stroke survivors who were living in the community or undergoing rehabilitation in a hospital setting [9]. The SENSe CONNECT study delivered SENSe therapy to stroke survivors who were living in the community and were able to access the community-based specialist SENSe therapy centres [10]. Additional participant inclusion criteria included: stroke survivors with impaired touch sensation, limb position sense and/or tactile object recognition of the upper limb as identified by standardized testing; able to give informed consent; able to comprehend simple instructions; and willing to commit time to participate in the SENSe therapy program [10]. The SENSe therapy delivery schedule included a total of 10 individually tailored

treatment sessions, each of approximately 1 hour duration, delivered across 5-6 weeks at participating sites [10].

All therapists across both cohorts were upskilled in SENSe therapy by the same expert SENSe therapy educators. In both cohorts, therapists applied sensory discrimination principles based on the SENSe therapy approach developed and tested by Carey, Macdonnell and Matyas [8]. The core components of SENSe therapy include three sensory discrimination modules (Texture Discrimination, Limb Position Sense, and Tactile Object Recognition) and a fourth module designed to transfer sensory discrimination skills into client-selected daily activities (Occupation-based training).

This research forms part of the larger partnership study currently being undertaken, therefore this paper will only report on data sourced from novice clinicians involved in the trial from September 2019 – May 2021. The long-term findings of the overarching study will be covered in future publications. Ethics approval for the two studies included central hospital-based approval (*SENSe Implement: HREC/13/Austin/8; SENSe CONNECT: HREC/18/Austin/153)* and approval by La Trobe University *(FHEC 14/243).* At time of recruitment to the original studies, the SENSe Implement and SENSe CONNECT patients and clinician participants, consented to the use of their data for related studies and analysis by members of the research team.

Design specific to assessment and monitoring of treatment fidelity

There were key differences between how treatment delivery was monitored and assessed across the SENSe Implement and SENSe CONNECT sites. SENSe Implement therapists receive feedback on treatment fidelity at 3 time points per site due to the majority of clinicians delivering therapy to only a small number of stroke survivors (n=1-3). However, SENSe CONNECT therapists were upskilled to deliver SENSe to a larger number of stroke survivors (n=12), therefore SENSe CONNECT feedback was provided at 3 patient time points per clinician. Please see Figure 1 for a summary of the feedback

process for SENSe Implement and SENSe CONNECT therapists throughout the course of involvement in the study, in the context of the novice clinicians across both sites. This meant that for novice clinicians in SENSe Implement, receiving observation feedback was dependent on which patient they were treating i.e if they were delivering SENSe therapy to patient 2 or 3 recruited at the site, they were offered an observation session. In comparison, for the SENSe CONNECT study, each clinician was offered observation feedback for their patient 2 or 3 as part of baseline fidelity check. Thus the key difference was that SENSe Implement therapists only received observation feedback if their patient's recruitment number aligned with specified feedback time points.
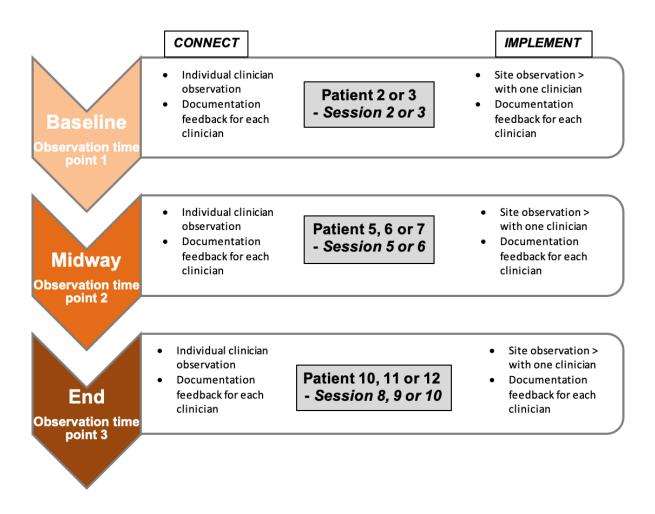
Sample selection

Occupational therapists and physiotherapists were recruited from the first three SENSe Implement sites to move to phase two of the SENSe Implement study where SENSe therapy is delivered (*n= 8 therapists, who delivered 14 patient programs*) [9]. In phase one, SENSe Implement therapists provide usual care to stroke survivors with somatosensory loss. In phase two, participating therapists are up-skilled in SENSe therapy, credentialled and then provide this therapy to stroke survivors. Therapists participating in the SENSe CONNECT study at 3 out of 4 specialist SENSe therapy centres were included in the second sample *(n = 8 clinicians, who delivered 19 patient programs)* [10]. The first 3 specialist sites were chosen to be consistent with the number of sites included from the SENSe Implement study.

Only data from novice clinicians were included in the current study. Clinicians from both cohorts were classified as novice if they had delivered between $1-3$ patient programs. Data was included if the clinician had delivered a minimum of 5 therapy sessions per patient therapy program (and the stroke survivor received a minimum of 7 therapy sessions overall).

For the eight therapists included from SENSe Implement study, two worked at a metropolitan private hospital, three worked at a metropolitan public hospital and three therapists were working in a regional public hospital. For SENSe CONNECT, the therapists delivered the intervention via the SENSe therapy centres that were linked to a metropolitan hospital / rehabilitation facility and / or a metropolitan research institute.

Figure 1.

Process of Real-Time Observation and Documentation Feedback for SENSe Implement and SENSe CONNECT Sites.

Strategies to assess Treatment delivery

There were two key strategies utilised to assess treatment delivery of SENSe therapy: audit of the whole patient therapy program using a documentation audit checklist and

observation of individual therapy sessions using an observation checklist. A documentation audit checklist and observation checklist were developed to assess fidelity of treatment program delivery records and direct observation of delivery in a treatment session to objectively verify intervention delivery. This combined approach to treatment fidelity assessment is recommended within the literature [16, 17]. The documentation audit checklist was developed based on recommendations by NIH BCC framework and Burian and colleagues in 2018 [18] and described in the study submitted for publication (see Chapter 3). The same approach to checklist development was applied for the observation checklist.

Following refinement, the audit checklist for assessing documentation of complete patient treatment programs comprised of 28 items (core components) grouped as follows: documentation of the Training Schedule Overview (summarises the therapy delivered across 10 treatment sessions), the three sensory discrimination modules delivered (Texture Discrimination, Limb Position Sense, and Tactile Object Recognition), and a module designed to transfer sensory discrimination skills into client-selected daily activities. This module will be referred to as Occupation-based training throughout the paper. The Training Schedule Overview comprised of five core components. Each sensory discrimination module comprised 6-7 core components, and the Occupational-based training comprised four core components (See Appendix B for details).

The observation checklist used to assess treatment fidelity during intervention session delivery, comprised of 32 core components. Similar to the documentation audit checklist, the core components were grouped by sensory discrimination module – Texture Discrimination, Limb Position Sense, and Tactile Object Recognition, and Occupation-based training. Each module contained between 7-8 core components (See Appendix C for details). The key difference between the two checklists is the presence of the training schedule overview and its core components for the documentation audit, which assesses the fidelity of the whole SENSe therapy program (per patient). This is not required for the

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observation checklist as this is utilised during the observation of a single SENSe therapy session. There are five additional core components included in the observation checklist, which relate to collaborative discussions with the stroke survivor to determine sensory goals. Further, during the single session most of the core components observed relate directly to the stroke survivor's sensory needs and therapy delivered within that individual session.

The degree to which clinicians demonstrate the core components in the observation sessions and documentation audits, is assessed using a 3-point rating scale; where a score of 0 indicates the core component has not been documented, a score of 1 indicates the core component was documented with partial adherence or quality, and a score of 2 is awarded when the clinician documents the core component with a high degree of adherence and quality according to the criterion. This ordinal rating method is recommended by Borelli [12] instead of a Likert rating scale used in some fidelity studies, as it minimises assessor subjectivity and is consistent with strategies outlined by Burian et al. in 2018 [18]. Not Applicable (N/A) is recorded when a core component is deemed, by the assessor, not to be applicable to the particular therapy program or client. The score for each core component documented or observed is then summed to provide a total raw score for the treatment program. In order to calculate the percentage of Treatment Fidelity (TF) for each clinician, the following calculation is completed: the total raw score of all documented core components is divided by the total possible raw score if the intervention was documented with 100% fidelity (i.e. usually 56 for the documentation audit checklist and 66 for the observation session checklist; with adjustment for N/A components) and then multiplied by 100 to achieve a percentage score. For example, if the total raw score = 36 this would equate to a TF percentage of 57% (36 / 56 = 57%). The criterion of 80% is the recommended benchmark according to the study by Borelli in 2011, who reports there is a consensus amongst treatment fidelity experts that 80-100 percent integrity is indicative of high fidelity, whereas 50 percent or below demonstrates low fidelity [12].

For the observation treatment fidelity rating, clinician adherence and quality of delivering the intervention was rated by SENSe trainers via Zoom or face-to-face observation. The SENSe trainers were skilled in treatment delivery, and the more subtle aspects of the intervention and treatment manual guidelines. The observation session went for the duration of the SENSe therapy session.

Strategies to enhance Treatment delivery

The provision of feedback is an important component to helping clinicians acquire and maintain the skills required to deliver the core treatment components of SENSe therapy. For real-time observation, feedback was provided after each observed session and after the SENSe trainer had scored the clinician's performance according to the observation checklist. For the documentation audit feedback, clinicians were asked to send through a copy of the chosen therapy program to a specific member of the research team and were provided with written feedback on their documentation on the core components of SENSe therapy. The checklists outlined above guided the feedback process during both observation sessions and documentation audits.

Feedback was provided to the clinician directly on their performance and included areas for learning and improvement. Any clinician whose treatment fidelity percentage was documented below 80% adherence to core components, was offered additional training and support. Clinicians were provided with copies of both the observation and documentation checklists and encouraged to use them to evaluate their own delivery of SENSe therapy. Clinicians were encouraged to share their feedback with peers also participating in the study at their site as a way of enhancing site-specific treatment fidelity.

Data collection and analysis

All available data sets from the documentation of whole therapy programs delivered by SENSe Implement and SENSe CONNECT novice clinicians (programs 1-3) were included from the data collection period September 2019 to May 2021. The treatment fidelity percentages from observations sessions are reported in the Results (see Figure 6). Due to the small number of occasions (n=10), the observation data was not used to describe overall treatment fidelity, however, it did provide additional objective data on the accuracy of SENSe delivery and identified those clinicians requiring additional upskilling.

A single assessor from the research team audited all included whole therapy programs (n=32). The data retrieved from the documentation audit checklist was used to determine a percentage of treatment fidelity, as outlined above in the methods section. This raw data was then sorted and categorised descriptively to examine several relationships between treatment fidelity percentage and individual clinician factors specific to SENSe therapy. Relationships were identified by charting the data as outlined in Figures 2-5, with discussions held between all authors to ensure accurate interpretation. These factors included experience of SENSe delivery (based on number of treatment sessions delivered), clinical years of experience in stroke rehabilitation, and amount and type of treatment fidelity feedback received.

Results

Data from eight clinicians in SENSe Implement and eight clinicians in SENSe CONNECT studies were included in the analysis, with a total of 33 SENSe therapy programs audited. SENSe Implement therapists delivered 14 SENSe therapy programs, with 19 programs in the SENSe CONNECT group. Half of the Implement therapists delivered two SENSe therapy programs or more, compared to the CONNECT group with seven out of the eight clinicians delivering three SENSe therapy programs.

Treatment fidelity across studies

Overall treatment fidelity scores are illustrated in Figure 2 and Figure 3 for SENSe Implement and SENSe CONNECT cohorts respectively, with type and timing of documentation (D) or Observation (O) feedback indicated. The overall treatment fidelity percentage for audit of documented SENSe therapy patient records ranged from 69% to 95% in the SENSe Implement group. Ten SENSe therapy programs were delivered with high fidelity ($\geq$80%), and four delivered with moderate fidelity (51-79%). SENSe CONNECT therapists delivered SENSe therapy programs with treatment fidelity between 57% to 100%. Fifteen programs were delivered with high fidelity and four delivered with moderate fidelity. Seven of the eight SENSe Implement therapists delivered their first therapy program with high fidelity, compared to six of the eight therapists in the SENSe CONNECT group. For those clinicians across both groups who delivered two therapy programs, treatment fidelity percentage declined in close to half of the SENSe therapy programs, with two programs from each group assessed as being within moderate fidelity range (51-79%).

Factors associated with treatment fidelity when novice clinicians deliver SENSe therapy
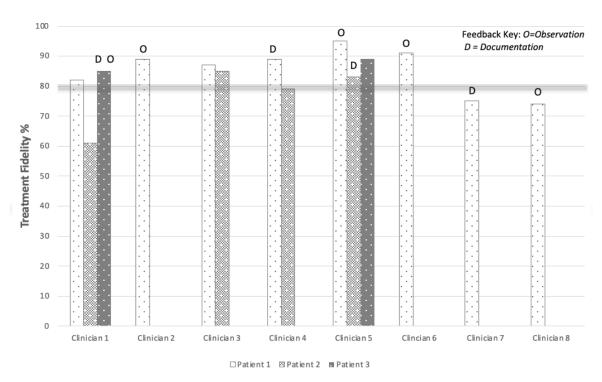
Clinical years of experience

The SENSe Implement therapists had an average of 7.6 years clinical experience, ranging between 1 – 20 years. For the eight therapists in the SENSe CONNECT study, they had an average of 8.4 years of clinical experience working with stroke patients, ranging from 1 to 15 years.

When comparing treatment fidelity scores and years of experience, three out of four SENSe CONNECT therapists who had less than 10 years of experience working in in stroke rehabilitation delivered SENSe therapy with high fidelity, consistent with the

group of clinicians who had more than 10 years of clinical experience. SENSe Implement

was similar, with four out of five clinicians with less than 10 years clinical experience

delivering at least one of their therapy programs with high fidelity. All three clinicians

with more than 10 years experience in stroke rehabilitation delivered their programs with

high fidelity. Both groups had individual clinicians who delivered one or two SENSe

therapy programs with moderate fidelity.

Figure 2.

Overall Treatment Fidelity Percentage Based on Documentation of SENSe Therapy by
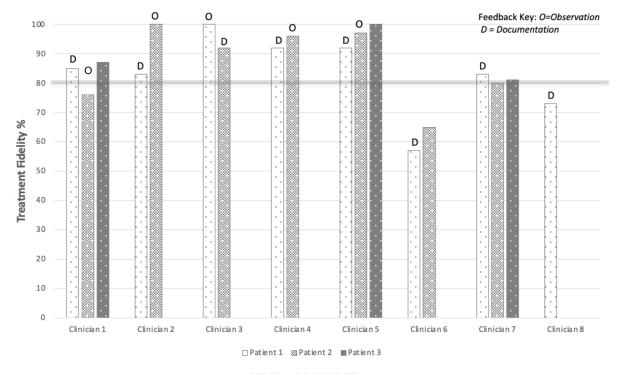
SENSe Implement Therapists.

Feedback Key: Observation (O) and Documentation (D) indicates therapist received this type of feedback during specified patient therapy program

Figure 3.

Overall Treatment Fidelity Percentage Based on Documentation of SENSe Therapy by SENSe CONNECT Therapists.
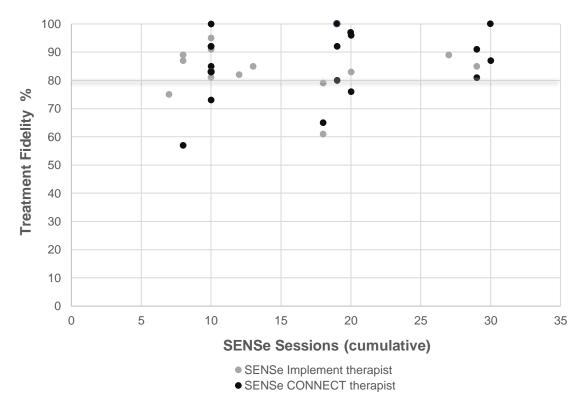

Feedback Key: Observation (O) and Documentation (D) indicates therapist received this type of feedback during specified patient therapy program

Experience based on number of sessions delivered

Experience in SENSe delivery in the SENSe Implement therapist group ranged from 7 to 29 sessions, and 10 to 30 sessions in the SENSe CONNECT therapist group. Four of the SENSe Implement therapists delivered two or more patient programs (at least five sessions per program). In comparison to seven SENSe CONNECT therapists who delivered two or more patient therapy programs during the trial. Figure 4 maps the number of sessions delivered and percentage of treatment fidelity of associated therapy program for each clinician. Six SENSe Implement therapists and SENSe CONNECT therapists delivered their first treatment program with high fidelity (≥80%).

Figure 4.

SENSe Experience and Associated Treatment Fidelity Percentage.

● SENSe Implement therapist
● SENSe CONNECT therapist

Note: SENSe experience refers to number of therapy sessions delivered per individual SENSe Implement and SENSe CONNECT therapist.

Treatment Fidelity percentage is based on assessment of SENSe therapy documentation per whole therapy record.
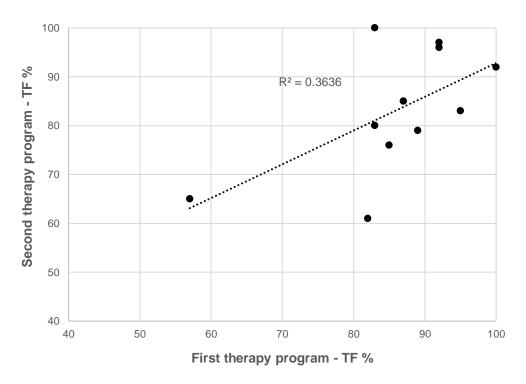
There were 11 clinicians across both groups who delivered 2 or more therapy programs. TF percentage of first and second therapy program were explored for correlation, as depicted in Figure 5. Treatment fidelity percentage increased in four SENSe CONNECT therapists' second therapy programs and decreased in three. In comparison, treatment fidelity decreased for all of the SENSe Implement therapists delivering a second program.

Figure 5.

Relationship Between Treatment Fidelity Percentage (TF %) of First and Second Therapy

Programs.

Note: Treatment Fidelity percentage is based on assessment of SENSe therapy documentation per whole therapy record.
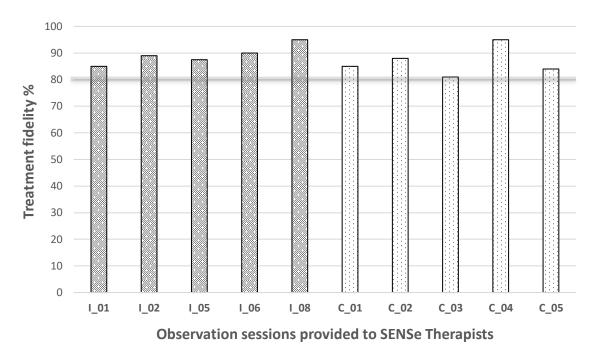
Amount and type of feedback

There were nine occasions of feedback provided for the SENSe Implement group and 13 for the SENSe CONNECT therapists (documentation and direct observation occasions combined). Five SENSe Implement and five SENSe CONNECT therapists received observation feedback. Total treatment fidelity percentage across the 10 observation sessions ranged from 80 – 95%, within the high treatment fidelity range (Figure 6). Four SENSe Implement therapists received documentation audit feedback, in comparison to SENSe CONNECT, where every therapist received documentation feedback. Only two SENSe Implement therapists received both Documentation and Observation feedback, compared to five out of eight therapists in the SENSe CONNECT group. Overall, seven out of eight therapists in the SENSe Implement group received at least one type of

feedback. Feedback was provided on three occasions to Implement therapists who had scored below 80% treatment fidelity on either a documented therapy program or during an observation session. In comparison, all CONNECT therapists received at least one type of feedback, with this feedback being provided on four occasions to a therapist who had performed below 80% fidelity. See Figure 2 and Figure 3 for full details.

Figure 6.

Treatment Fidelity Percentage of Observed SENSe Therapy Sessions

Key for Therapist label: I = Implement, C= CONNECT.

Therapists are labelled according to which study they participated in (Implement or CONNECT) and numbered in the order in which they were recruited to study.

Discussion

This study of treatment fidelity applied strategies from the National Institutes of Health Behavioral Change Consortium (NIH BCC) framework to assess and monitor treatment fidelity of SENSe therapy being delivered by novice clinicians (first 1-3 therapy programs) in SENSe Implement and SENSe CONNECT cohorts. The purpose was to test

the feasibility of delivering SENSe therapy with moderate to high fidelity when delivered by novice clinicians, and explore factors associated with treatment fidelity percentage. The NIH BCC strategies, which included assessment using treatment fidelity checklists for documentation audits and observations, coupled with structured feedback opportunities, enabled the research team to identify if SENSe had been delivered with moderate to high fidelity. The results of this study will be discussed in the context of the two research questions.

Is it feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity in clinical practice settings?

The results of this study demonstrated that it was feasible for the majority of novice clinicians across both cohorts to deliver SENSe therapy, a complex rehabilitation intervention, within the moderate to high fidelity range. It is important to note that clinicians across both groups were provided with copies of the fidelity checklists and were made aware of the fidelity monitoring processes used throughout both studies. By applying the fidelity assessment tools (documentation audit and observation checklist), the research team were able to identify which clinicians required additional upskilling and support as indicated by their treatment fidelity score. This allowed for the early detection of errors in intervention delivery and enabled the research team to offer timely feedback and additional upskilling opportunities. The availability of structured documentation proformas and criterion checklists likely contributed to the accuracy with which SENSe therapy was delivered across both SENSe Implement and SENSe CONNECT groups. The documentation proformas provide a session by session guide and examples of how the core components of SENSe therapy should be delivered and documented. These observation and documentation checklists were provided to clinicians during their initial training, and copies with individualised feedback were provided as part of the feedback processes.

When interpreting the study findings, it is important to acknowledge that overall fidelity was assessed based on clinician's documentation of whole SENSe therapy programs. As mentioned earlier, it was not feasible to utilise the treatment fidelity percentages from the observation sessions due to only a small number of clinicians receiving this type of fidelity assessment and subsequent feedback. Therefore, it is important to acknowledge that although similar core delivery elements are being assessed by each fidelity tool, there is the potential for discrepancies between the information clinicians documented versus the intervention delivered within observed therapy sessions. It may be beneficial to explore this further in a future study, with a comparison made between the level of treatment fidelity within documented therapy sessions and observation sessions.

Are experience-related factors associated with delivery of treatment fidelity when novice clinicians deliver SENSe therapy?

In this study, experience was explored in two ways – years of clinical experience working with stroke patients, and SENSe delivery experience (based on number of treatment sessions delivered). Clinicians who had more than 10 years experience did not deliver SENSe therapy with a higher treatment fidelity percentage compared to those with less than 10 years experience. This may suggest that the TF checklists and feedback opportunities enabled clinicians of varying years of clinical experience to deliver SENSe therapy with similar levels of fidelity (i.e moderate to high). These findings align with the current treatment fidelity literature, which advises that there is insufficient evidence that more experienced clinicians have higher levels of treatment fidelity when delivering complex interventions [12]. It is important to acknowledge that majority of clinicians had more than 4 years of clinical experience. Therefore, it may be beneficial to consider a future study which examines the feasibility of SENSe therapy being delivered by

clinicians who have less than 1-2 years' experience or are considered entry-level therapists.

Treatment fidelity scores did not consistently increase with delivery of more SENSe therapy programs or sessions, rather they fluctuated between high ($\geq$80%) to moderate (51-79%), or moderate to high on clinicians second or third patient therapy program. Although the SENSe CONNECT therapists delivered a higher number of therapy sessions, only three therapists in this group increased their treatment fidelity percentage during the second therapy program. For the majority of the SENSe Implement therapists, treatment fidelity percentage was higher during the first patient program, and decreased on the second, at times falling below the 80% benchmark. However, in the SENSe CONNECT therapists, there was no clear pattern. Exploration of an association between TF percentage during the first therapy programs and second therapy programs suggested a weak correlation [19]. SENSe patient presentation and complexity may have impacted on ability for some clinicians to maintain or increase the accuracy with which SENSe was delivered. For example, stroke survivors with very severe somatosensory impairment may have experienced difficulties with progression through treatment levels, and clinicians may have had difficulty recording this accurately. This may be expected for novice clinicians who are still learning the core intervention components.

It is important to acknowledge that the differences between SENSe Implement and SENSe CONNECT study designs could have also influenced some of these outcomes. The SENSe CONNECT study is designed to upskill a small number of therapists to deliver SENSe therapy to a large number of stroke survivors, therefore enabling the first 1-3 SENSe therapy programs to be delivered in a shorter time frame compared to the SENSe Implement group.

When exploring clinician access to amount and type of feedback, the results identified that SENSe CONNECT therapists received more observation and documentation feedback than the SENSe Implement group. It is important to

acknowledge that although clinicians were offered these feedback opportunities, they were still required to pro-actively engage in several steps of the process themselves for the feedback to occur. Using observation feedback as an example, the clinician needed to schedule a time where both the patient and the SENSe trainer were available and gain consent from the patient for the observation to occur. Therefore, the results may suggest that SENSe CONNECT therapists were more invested in, or accepting, of the treatment fidelity processes and feedback strategies throughout the study. All SENSe CONNECT therapists were employed through research centres linked to a metropolitan hospital / rehabilitation facility and / or a metropolitan research institute, demonstrating a fundamental investment in research outcomes. This is consistent with findings in the literature, which highlight how treatment implementation is influenced by provider factors such as therapist's acceptability of the treatment and their perception of the treatment's efficacy [12].

Additionally, it was reassuring to see that the majority of SENSe Implement clinicians (n=7) still received one type of feedback to guide their clinical skill development, and were able to deliver their first 1-3 SENSe therapy programs with moderate to high fidelity. SENSe Implement therapists were given the option of sharing their observation and/or documentation feedback with other therapists at their site, therefore it is possible this enabled a wide group of SENSe clinicians to be upskilled through feedback provided to their peers.

Limitations

Only one assessor analysed all 33 therapy programs for scoring of treatment fidelity percentage and data analysis. The same assessor was involved in providing documentation feedback, and therefore unable to be blinded during data analysis. Due to the Covid-19 pandemic there were pauses in study recruitment, which impacted on ability to provide clinicians with regular observation and documentation feedback. This also

limited the author's ability to accurately determine the relationship between the timing at which clinicians received feedback and impact on treatment fidelity for the next SENSe therapy program delivered. The pause in data collection due to pandemic restrictions also led to only a relatively small number of novice clinicians being able to be included in the sample, and within the required timeframes (September 2019 – May 2021). As a result of the small sample size, there was limited ability to complete inferential statistics and therefore, the majority of the data has been summarised descriptively.

Conclusion

This study demonstrates the feasibility of applying selected strategies from the NIH BCC framework to assess and monitor the treatment fidelity of a complex rehabilitation intervention – SENSe therapy. Years of clinical experience and number of SENSe therapy sessions delivered did not consistently influence treatment fidelity outcomes at a novice therapy level, however clinicians who had experience and /or interest in research engaged more frequently in upskilling opportunities. Overall, this study demonstrates it is feasible for novice clinicians to deliver SENSe therapy – a complex rehabilitation intervention – with moderate to high fidelity when supported by documentation proformas, expert trainers and when provided with regular feedback opportunities guided by intervention checklists.

Abbreviations

SENSe: <u>S</u>tudy of the <u>E</u>ffectiveness of <u>N</u>eurorehabilitation on <u>Se</u>nsation

NIHBCC: National Institutes of Health (NIH) Behavior Change Consortium (BCC)

TF: Treatment Fidelity

Declaration of Interest

The authors declare that they have no competing interests.

Data Availability Statement

The data that support the findings of this study are available on reasonable request
from Principal Investigator of the SENSe Implement and SENSe CONNECT
studies (LMC).

References

[1]   Carragher M, Ryan B, Worrall L, et al. Fidelity protocol for the Action Success Knowledge (ASK) trial: A psychosocial intervention administered by speech and language therapists to prevent depression in people with post-stroke aphasia. BMJ Open. 2019;9:e023560.

[2]   Persch AC, Page SJ. Protocol development, treatment fidelity, adherence to treatment, and quality control. Am J Occup Ther. 2013; 67(2):146–53.

[3]   Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. Implement Sci. 2007;2(40):1-9.

[4]   O'Shea O, McCormick R, Bradley JM, et al. Fidelity review: A scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions. Phys Ther Rev. 2016;21(3-6):207-14.

[5]   Gearing, RE, El-Bassel N, Ghesquiere A, et al. Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. Clin Psychol Rev. 2011;31:79–88.

[6]   Hoffman TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: Template for Intervention Description and Replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687

[7]   Hildebrand MW, Host HH, Binder EF, et al. Measuring treatment fidelity in a rehabilitation intervention study. Am J Phys Med Rehabil. 2012;91(8):715 –24.

[8]   Carey LM, Macdonell R, Matyas TA. SENSe: Study of the effectiveness of neurorehabilitation on sensation: A randomized controlled trial. Neurorehabil Neural Repair. 2011;25(4):304-1.

[9]   Cahill LS, Lannin NA, Mak-Yuen Y, et al. Changing practice in the assessment and treatment of somatosensory loss in stroke survivors: protocol for a knowledge translation study. BMC Health Serv Res. 2018;18(1):34.

[10]   Carey, L. M (2018). Network of sites and 'upskilled' therapists to deliver best-practice stroke rehabilitation of the upper limb. Australian New Zealand Clinical Trials Registry [Internet]. Available from: https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375706&isReview=true (accessed 19 September 2020)

[11]   SENSe: Helping stroke survivors regain a sense of touch: A manual for therapists (with DVD). Melbourne, Australia: The Florey Institute of Neuroscience and Mental Health and La trobe University. 2012. Available from: https://sensetherapy.net.au/resources/sense-manual-and-dvd/

[12]   Borelli B. The assessment, monitoring, and enhancement of treatment fidelity In public health Clinical trials. J Public Health Dent. 2011;71(s1):S52–63.

[13]   Durlak JA, DuPreEP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol. 2008;41(3-4):327-50.

[14]   Resnick B, Galik E, Pretzer-Aboff I, et al. Treatment fidelity in nursing home research: The Res-Care Intervention Study. Res Gerontol Nurs. 2009;2(1):30-8.

[15]   Cahill LS, Carey LM, Lannin NA, et al. Implementation interventions to promote the uptake of evidence-based practices in stroke rehabilitation. Cochrane Database Syst Rev. 2017;(10). Art. No.:CD012575.

[16]   Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. Health Psychol. 2004;23(5):443–51.

[17]   Toomey E, Matthews J, Guerin S, et al. Development of a feasible implementation fidelity protocol within a complex physical therapy-led self-management intervention. Phys Ther. 2016; 96:1287-98.

[18]   Burian BK, Clebone A, Dismukes K, et al. More than a tick box: Medical checklist development, design, and use. Aneth Analg. 2018;126(1):223-32.

[19]   Hoffman T, Bennett S, Del Mar CB. Evidence-based practice across the health professions, 3rd ed. Elsevier; 2017. p.28-30.

4.3 Summary and Conclusion – Chapter 4

This Chapter builds on findings from previous chapters and describes the implementation of several strategies from the NIH BCC framework. Strategies to assess and measure treatment fidelity of SENSe therapy included the documentation audit checklist developed in Study 2, and use of the observation checklist in observed therapy sessions. Strategies to enhance treatment fidelity of SENSe therapy being delivered by clinicians across SENSe Implement and SENSe CONNECT, included the written feedback on audited treatment programs and feedback on observed therapy session provided by a SENSe trainer at scheduled time points.

An additional strategy to support clinicians was the introduction of documentation proformas for the occupation-based training unit following findings outlined in Study 2. This was introduced prior to commencement of this study and it was pleasing to see that this unit of training was documented with higher levels of in response to the introduction of the formalized documentation proforma.

Findings from the current study demonstrated that it is feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity when supported by documentation proformas, expert trainers and when provided with regular feedback opportunities guided by treatment fidelity checklists.

CHAPTER 5

GENERAL DISCUSSION & CONCLUSION

In this Chapter, the main findings of the research project are summarised in the context of several key themes that have emerged from this thesis. These themes are identified and integrated within the current state of the literature pertaining to treatment fidelity. The aim of this research project was to demonstrate the application of several methods for assessing and monitoring the treatment fidelity of a complex rehabilitation intervention – SENSe therapy. This included identifying available frameworks and tools to enhance the assessment and monitoring process in the delivery of complex interventions; developing and trialing a treatment fidelity checklist for SENSe therapy; and systematically applying the chosen framework, its strategies and the newly developed treatment fidelity checklists (documentation audit and observation) to enhance the implementation of SENSe therapy.

Three main findings emerged from this research to address this aim. First the *National Institutes of Health Behavior Change Consortium* (NIH BCC) framework was identified as an available and commonly used framework with strategies to enhance the assessment and monitoring process in the delivery of complex interventions. Second, a treatment fidelity checklist was developed for SENSe therapy and refined based on findings from an existing data set. Third, guided by the NIH BCC framework and strategies and application of newly developed treatment fidelity checklists (documentation audit and observation), it was demonstrated that moderate to high treatment fidelity can be achieved by novice clinicians in the implementation of SENSe therapy.

5.1 Intervention fidelity of a complex rehabilitation intervention can be enhanced by using components of a framework's strategies; however, these must be systematically applied

Highlighted in the introduction of this thesis is the inherent complexity of rehabilitation interventions provided by occupational therapists and other allied health professionals. Rehabilitation interventions are often multi-faceted, require the therapist to possess a defined level of skill and knowledge, and are dependent on clinician delivery and patient interactions. This creates several challenges for therapy providers trying to implement evidence-based interventions in research studies and 'real world' clinical practice settings, where in the latter there is greater likelihood of inconsistencies in intervention implementation (Carroll et al., 2007).

For SENSe therapy to demonstrate its effectiveness in research and clinical practice across the two implementation studies – SENSe Implement and SENSe CONNECT, it was acknowledged that the therapy must be implemented as intended. The evidence review outlined in the first chapter, identified the conceptual framework by the *National Institutes of Health Behavior Change Consortium* (NIH BCC) as the most commonly used and suitable framework available to examine and enhance treatment fidelity in the context of complex interventions. Specific recommendations and strategies developed by the expert panel from Treatment Fidelity Workgroup as part of the NIH BCC, were chosen to be applied in the development of a treatment fidelity checklist (Study 2) and application of specific strategies to enhance treatment fidelity of SENSe across the two implementation studies (Study 3).

The importance of systematically applying the key elements of a conceptual framework is recognised as an important consideration when examining treatment fidelity in the context of implementation studies. The focus of this research project has been

primarily on the implementation of strategies to achieve treatment fidelity through the 'treatment delivery' domain from NIH BCC framework. However, it is important to note that recommendations from the first two domains of the framework – '*Study design'* and '*Training of providers'*, were already incorporated as part of the two implementation studies prior to this research project commencing. Treatment fidelity as part of 'Study design' was achieved through the operationalisation of the SENSe protocol and intervention manual and training procedures based on the treatment protocol developed (Carey et al. 2011, SENSe manual and DVD). When considering processes for 'training of providers', the content of upskilling workshops and competency assessments reflected the theory-based active ingredients of the intervention as recommended by the NIH BCC framework. Additionally, competency assessments were completed with expert trainers prior to clinicians commencing intervention delivery, consistent with strategies suggested in the training of providers section of the framework (Borelli, 2011). According to the NIH BCC framework, *Treatment receipt* and *Treatment enactment* uses strategies to enhance and assess recipient knowledge. These domains were considered beyond the scope of this thesis and the research project, however the patient's perspective of being involved in SENSe therapy has been considered as part of previous SENSe research (Turville et al.,2019) and continues to be considered as part of the wider research project.

The evidence review completed as part of this thesis, highlighted the importance of using pre-defined performance checklists which map to all core components and active ingredients of the complex intervention under testing. The development of pre-defined performance checklists for treatment fidelity assessment across both SENSe therapy documentation, and later observed intervention delivery, became a significant focus for Study 2 included in this thesis. Further to this, the NIH BCC framework recommends that treatment fidelity should be measured using a tool that can rate the occurrence or non-

occurrence, quality, and frequency of core components that are key to an intervention's delivery (Borelli, 2011).

This recommendation was achieved in Study 2 through use of a systematic approach to developing the documentation audit checklist. Firstly, the core components were identified for both SENSe therapy documentation (n=29) and SENSe therapy observation sessions (n=32). This was then followed by the development of a 3-point rating scale which identified the degree to which clinicians adhered to each of the core component; 0 = absent, 1 = partially competently performed, 2 = high degree of adherence and quality according to the criterion. The score for each core component was then summed to provide a total raw score and treatment fidelity percentage. An important component of the documentation audit checklist was its ability to rate adherence based on both the quantity of SENSe therapy delivered but also the quality with which the core components are delivered across a 3-point rating scale, rather than just the presence or absence of an intervention component. Poltawski et al. (2014) acknowledged the importance of considering how core components related to dosage impact on the therapeutic effect of rehabilitation interventions. They advised that factors such as number of repetitions, duration and intensity should be included in fidelity rating forms when defining the active ingredients of a rehabilitation intervention; highlighting the importance of detailed quantity and quality ratings.

Another recommendation that came from the evidence review, which was consistent with NIH BCC framework recommendations, was the importance of treatment fidelity measures being developed with defined parameters and thresholds, which can clearly indicate when an intervention's core components have been delivered accurately. This was achieved through the introduction of treatment fidelity percentage threshold which indicated when a SENSe therapy record or intervention session, had been delivered with high, moderate or low fidelity. As outlined above, when determining overall

treatment fidelity, the score for each core component was summed to provide a total raw score which was turned into a treatment fidelity percentage. The percentage indicates overall level of adherence and quality and according to the NIH BCC framework, the majority of treatment fidelity literature advises that 80-100% adherence/quality indicates high fidelity, 51-79% is moderate fidelity and 50% or below constitutes low fidelity (Borelli, 2011).

The final recommendation from the evidence review was the importance of ensuring the reliability of the fidelity tool is tested and clearly reported on. This was achieved in Study 2 through testing rater agreement using a sub-set of 10 SENSe therapy records. The use of rater agreement testing to identify areas for refinement was particularly important within the context of SENSe, as it identified the need for more structured documentation guidelines and a proforma for therapists to use when recording intervention sessions, particularly within the occupation-based training unit. Testing of rater agreement in Study 2 also highlighted the importance of ensuring there were individual definitions available for scoring each core component as either absent, partially performed or competently performed. For example, several of the core components with the preliminary checklist only had individualised definitions for 1 or 2 items of the 3-point rating scale. It was anticipated that this may have led to subjective interpretation by the assessors to determine what constituted the core component as partially performed versus competently performed.

In summary, findings from Study 2 demonstrated that it was feasible to develop a documentation checklist that could be used as one strategy to assess and evaluate treatment fidelity of complex rehabilitation interventions. The checklist was able to identify a small number of files (n=6) that were documented with high overall fidelity (≥80%), with the remaining 32 files documented with moderate fidelity (51 – 79%). As part of this process, an observation checklist was also developed to address a key

recommendation from the NIH BCC framework. The use of direct observation or video-taping is recommended for assessing how accurately clinicians are delivering the core components of an intervention (Borelli, 2011). However, as highlighted throughout this thesis, it should be used in conjunction with clinician reporting methods to ensure treatment fidelity has been comprehensively examined.

Although the development of the observation checklist is not reported in detail, the same systematic approach was applied as is reported for the documentation audit checklist. As a result of this systematic process undertaken during measurement tool development, both the documentation and observation fidelity assessment tools were chosen to evaluate the treatment fidelity of SENSe therapy being delivered as part of SENSe Implement and SENSe CONNECT studies (outlined in Study 3).

As stated by Borelli in 2011, "*competence or quality of delivery is distinct from provider adherence to treatment components, and both are predictive of treatment outcome*" (p. S58). During development of both checklists with the panel of SENSe experts, it was acknowledged that there were core components included that required clinician adherence or quality, however the majority required both elements for SENSe to be performed competently (a score of 2). Therefore, it was decided that it was important to have a score of 1, which indicated partial adherence or quality, and then a score of 2 which indicated that both adherence and quality had been met for the majority of core components. A consideration for future research may be to more clearly label the core components of the checklist as adherence, quality or both. This would enable researchers to determine clinicians which deliver the intervention with good quality but poor adherence or good adherence but poor quality.

5.2 Importance of considering clinician needs and perspective during the tailoring of framework strategies to enhance treatment fidelity

Borelli (2011) highlights the importance of choosing specific strategies from the NIH BCC framework to suit the needs of key stakeholders i.e. therapy providers and therapy recipients. It is recommended that the treatment fidelity model not be a series of rigid steps but a set of guidelines, with flexible adaptation across each of the domains. Borelli (2011) provides the example *"training needs to be standardized but also flexibly adapted to different provider learning styles and levels of experience; treatment delivery needs to take into account different patient types and levels of motivation for change"* (p. 10).

During the development of the treatment fidelity assessments tools, it was recognised that the documentation audit checklist and observation checklist had been developed as strategies to support clinicians to acquire and maintain the skills they needed to deliver SENSe therapy. As part of Study 3, research questions were explored in the context of clinicians who were considered 'novice' SENSe therapists (i.e. upskilled but only have experience in delivering SENSe therapy to three or less stroke survivors) and factors associated with moderate and high treatment fidelity. Study 3 highlighted the importance of considering the learning needs of the therapy provider (referred to as clinician or SENSe therapist) throughout the process of examining and enhancing treatment fidelity of complex rehabilitation interventions.

According to the NIH BCC framework, monitoring treatment fidelity during treatment delivery is of particular importance, based on evidence that well-trained providers do not always deliver the treatment protocol accurately, or with various patients across different sites (Borelli, 2011). The importance of frequent monitoring and feedback is justified by the findings outlined in Study 3, which demonstrated that increasing levels of therapist experience did not relate to higher levels of documented adherence to the core components. The results suggested that treatment fidelity levels can fluctuate despite an

increase in clinical experience, further supporting the NIH BCC recommendation to closely monitor fidelity of treatment delivery at regular time points throughout the course of a study. This allows for expert trainers to identify when booster training sessions and feedback is required to return intervention delivery to a level of high fidelity ($\geq$80%). These findings are confirmed on review of a previous rehabilitation intervention study by Hildebrand et al. (2012), which demonstrated that videotaping and observation alone was insufficient to improve therapist's adherence to a usual-care intervention. In comparison, the therapists trained in the experimental intervention who received regular feedback and supervision strategies based on the NIH BCC conceptual framework, achieved greater adherence (Hildebrand et al., 2012).

Study 3 demonstrated it was feasible for novice clinicians to deliver SENSe therapy with moderate to high fidelity, and there were several strategies implemented which supported clinician learning. These strategies included documentation proformas, observation sessions with expert trainers, and regular feedback opportunities guided by intervention checklists. Checklist testing during Study 2 identified the need for more structured documentation proformas for therapists to use when recording intervention sessions, particularly within the occupation-based training unit. As a result, documentation proformas for the occupation-based training unit were introduced prior to commencement of Study 3. On review of the core components delivered by SENSe CONNECT therapists in this study, 89% of the components from the occupation-based training unit had been documented competently (compared to 23% in the checklist development study, outlined in Chapter 3). Therefore, it was pleasing to see the improvement in treatment fidelity for this unit of training following the introduction of a formalised proforma to guide clinicians' documentation procedures.

In Study 3, years of clinical experience and number of SENSe therapy sessions delivered did not consistently influence treatment fidelity outcomes at a novice therapy level. This was firstly highlighted in Study 2, where an increase in the number of whole

SENSe therapy programs delivered did not lead to consistently higher levels of treatment fidelity, according to clinician documentation. However, clinicians in Study 3 who had experience and /or interest in research engaged more frequently in upskilling opportunities. The SENSe CONNECT therapists engaged in more frequent feedback strategies to enhance treatment fidelity, compared to the SENSe Implement group. This finding is supported by Taylor et al. (2019), who identified that when allied health clinicians with some interest in research were given access to clinical research support and resources, there was an increase in research experience. This was in contrast to the majority of the allied health clinicians at the same health service, who reported limited research experience or interest in research despite the introduction of the clinical research office (Taylor et al., 2019).

The findings from Study 2 and 3 align with current treatment fidelity literature, which suggests there is no clear relationship between intervention experience and higher treatment integrity. However, Borelli (2011) does state that *"other provider factors, such as acceptability of the treatment to the provider and providers' perceived effectiveness of the treatment, have shown to influence treatment implementation"* (p. 6). Therefore, these provider factors are important to address as part of the treatment fidelity assessment monitoring process. Feedback strategies should be offered consistently to all clinicians implementing complex rehabilitation interventions, irrespective of clinical years of experience or familiarity with the complex rehabilitation intervention.

The clinician perspective was an important consideration when applying the NIH BCC framework and its strategies to enhance treatment delivery of SENSe therapy. The main findings highlighted in Study 2 and 3, have strengthened the understanding that for complex rehabilitation interventions to be delivered as intended, it is imperative clinicians have access to feedback through multiple methods, such as clinical observation and feedback, written feedback on documentation, access to intervention checklists for self-reflection and peer support. From anecdotal feedback provided by SENSe Implement and

SENSe CONNECT clinicians, it was clear they appreciated the specific documentation audit feedback provided to them by the research team, stating *"...it is very useful to get some very specific comments like this. I will have a detailed read and reflection before my next client."*

The use of videotaping or direct observation is recommended for assessing how accurately clinicians are delivering the core components of an intervention (Borelli, 2011). Toomey et al. (2016) acknowledged that videotaping and real-time observation approaches can be time-consuming, resource-intensive and at times considered intrusive for some therapy providers. It was a strategy offered to clinicians throughout both the SENSe Implement and SENSe CONNECT studies and clinicians recognised its value stating, *"Thank you for the feedback. This cleared up a few questions I had about how to move through and use the different textures and levels properly. The feedback that comes with the training is very helpful."* Clinicians also reported an increased confidence following observation sessions with SENSe trainers *"I just had another session with him this morning and it went really well. I've got much more confidence and gave clearer instructions, and allowed lots of time for breaks."*

The findings from this research project are consistent with the clinician perspective highlighted in a recent treatment fidelity study by Toglia et al. (2020), where the intervention checklist developed for treatment fidelity assessment was also used to promote discussions and supervision post video recordings. Therapists in the study advised *"video reviews were a critical component in training, learning and skill development"* and the study concluded that the treatment fidelity measure could *"provide a useful clinical tool for therapist supervision, training and self-reflection"* (Toglia et al., 2020, p. 372*).*

Although real-time observation, or video, with feedback is not regularly used as a standard supervision tool for allied health professionals in clinical practice or research trials, it is frequently utilised in the psychotherapy field to upskill clinicians (Hildebrand,

2012). Based on the clinician feedback provided anecdotally during Study 3 and findings from Toglia et al. (2020), there is preliminary evidence to support the use of video or observation feedback to improve the delivery of evidence-based interventions in daily clinical practice, outside of research studies alone. It is important to reiterate that clinicians in both SENSe CONNECT and SENSe Implement studies were provided with multiple strategies to enable them to acquire and maintain the skills required to deliver the complex rehabilitation intervention as intended. Therefore, video and real-time observation feedback is a strategy that may be of benefit alongside clear documentation proformas and procedures for recording, documentation audit feedback, and access to intervention checklists which outline the core components of the complex intervention. In summary, clinician engagement throughout the fidelity process is imperative to the success of feedback and monitoring strategies used to enhance the treatment fidelity of complex rehabilitation interventions.

5.3 Treatment fidelity tools, such as checklists for documentation audit and observation sessions, provide both outcome data and a means to enhance the intervention in an implementation study

When reflecting on the clinician perspective as part of the treatment fidelity process, it highlights the benefits of using these developed intervention checklists as tools to facilitate clinician learning and upskilling in daily clinical practice. The process of defining an intervention's core components and enabling clinicians to access resources such as treatment fidelity intervention checklists, is a valuable learning experience in itself. Intervention checklists provide clinicians with clear expectations of their role in delivering evidence-based interventions, and enables immediate feedback on their performance either through self-reflection or through support of a supervisor and clinical

expert. This enables clinicians to quickly identify areas for further skill development and support required from expert trainers and key champions within the clinical area.
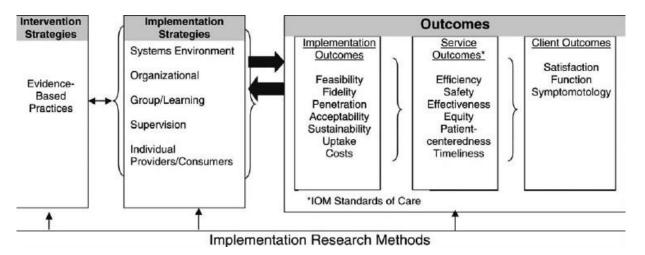
Additional to the use of pre-defined intervention checklists, is the importance of frequent monitoring and feedback opportunities. As demonstrated throughout this thesis, clinicians with varying levels of clinical experience benefit from repeated opportunities to receive feedback on therapy documentation and intervention delivery in real-time. Treatment fidelity has been shown to fluctuate despite an increase in clinical experience related to the intervention itself due to multiple factors at a patient, clinician and organisational level (Borelli 2011, Toglia et al., 2020).

It is important to acknowledge that the process of achieving treatment fidelity is considered an outcome in the wider context of implementation science. As stated by Carroll et al. (2007) "*Successful evidence-based practice is governed by many things, and implementation fidelity is one of them*" (p. 7). Glisson and Schoenwald (2005) strengthen this perspective further, advising successful implementation requires that specified treatments are delivered in ways that ensure their success in the field, that is: *"feasibly and with fidelity, responsiveness, and sustainability"*.

Proctor et al. (2009) developed a model for implementation research which illustrates three related types of outcomes, referred to as implementation, service and client outcomes (Figure 1). Fidelity is listed under "Implementation Outcomes" however, the relationship between fidelity and implementation strategies such as group learning and supervision, is clearly linked and presented as a cyclical process as indicated by the arrows in both directions.

Figure 1.

Conceptual Model of Implementation Research.

Implementation strategies can be defined as specified activities put into practice to improve the sustainability of treatment interventions (Proctor et al. 2009). Therefore, when reflecting on the process undertaken to achieve treatment fidelity of SENSe therapy, it is clear the NIH BCC framework and its individual strategies were embedded within an implementation model. This has resulted in the feasible development of fidelity measurement tools (i.e. intervention checklists for audit and observation) and fidelity monitoring strategies that can be considered for implementation in evidence-based practices within real-world clinical settings. The clinician remains the centre of this strategy implementation, with treatment fidelity assessment and associated feedback strategies on therapy documentation and real-time therapy observation, required to be completed in consultation with clinicians. Feedback provided should be adapted to their needs to ensure these strategies utilised to achieve treatment fidelity continue to align with implementation science approaches outlined above. SENSe therapy has been used as an exemplar to demonstrate how chosen strategies from the NIH BCC framework can be systematically applied to support existing clinical supervision models used in both

research and everyday clinical practice to enable complex rehabilitation interventions to be delivered as intended.

Through using SENSe therapy as an exemplar, this thesis provides considerations for how the application of fidelity measures can be beneficial to the wider rehabilitation community. Firstly, it demonstrates the importance of understanding the theoretical concepts which define complex rehabilitation interventions, and supports the intervention designer, researcher and therapy provider to consider the core components which define an intervention's delivery (Toomey, 2020). Through systematically defining complex rehabilitation interventions, treatment protocols can be more accurately developed to guide clinician practice, alongside upskilling and training programs. Additionally, this enables greater access of complex rehabilitation interventions to health service managers and clinicians, in turn leading to greater outcomes for patient's accessing those health services.

5.4 Thesis Limitations

The body of literature pertaining to treatment fidelity is a relatively new and an emerging area of implementation science. Consequently, the findings reported and discussed throughout this thesis must be considered in the context of limitations pertaining to available evidence, methodology and study design applied.

Firstly, there were a limited number of high-quality articles and quantitative in study design available for the evidence review. This led to inconclusive findings regarding the efficacy of the NIH BCC framework and the need to review additional literature, prior to recommending the frameworks application to the SENSe implementation studies.

Methodology across Study 2 and 3 was influenced by several factors. With a focus on determining the feasibility of the treatment fidelity assessment tools, only one assessor was available to complete documentation audits of all included SENSe therapy records in

Study 2 and Study 3. Therefore, inter-rater reliability of both intervention checklists (documentation audit and observation) requires further examination through future research.

During Study 3, the Covid-19 pandemic led to pauses in study recruitment and impacted on the ability to provide clinicians with regular observation and documentation feedback. Therefore, only a small number of clinicians were able to be included in the sample to meet expected time frames for the submission of this thesis. Due to limitations in sample size, formal statistical analyses were not able to be performed across the studies, and specifically for rater agreement testing in Study 2. As a result, the majority of the data has needed to be summarised descriptively throughout this thesis.

Due to the above limitations, this research thesis focuses on the feasibility of applying selected strategies from the NIH BCC framework to monitor and enhance treatment fidelity. However, further longitudinal data is required to accurately determine the framework's efficacy and impact on treatment fidelity outcomes throughout the duration of the SENSe implementation studies.

Conclusion

The aim of this research was to first identify, and then demonstrate, the systematic application of a framework and its related strategies, for assessing and enhancing the treatment fidelity of SENSe therapy. The fidelity of a complex rehabilitation intervention at time of implementation affects how well it succeeds, with higher levels of treatment fidelity associated with better treatment outcomes and successful intervention implementation. This research project demonstrates the importance of using a treatment fidelity framework to improve the accuracy with which rehabilitation interventions such as SENSe therapy, are delivered for stroke survivors.

The process of examining and enhancing treatment fidelity is an iterative process,

with benefits both for assessing fidelity of treatment delivery as well as enhancing the skills of the clinician to deliver the therapy with high fidelity and success. For complex rehabilitation interventions to be delivered with fidelity, the core intervention components must be included in the assessment criteria, and clinicians given the opportunity for continued monitoring and feedback opportunities adapted to their individual learning style. Although not routine in clinical supervision of allied health professionals, the use of intervention checklists to both assess and provide feedback to clinicians on therapy documentation and observation of real-time therapy sessions may improve the implementation of evidence-based practices. Further to this, sustainable adherence to core components and quality of intervention delivery can be achieved through regular, structured monitoring and feedback processes.

The findings presented in this thesis provide a strong foundation for the continued application of these strategies to monitor and enhance the treatment fidelity throughout the duration of the SENSe Implement and SENSe CONNECT implementation studies. It is hoped that these combined strategies will enable the early detection of protocol deviations, and prevent long-lasting and wide-spread inaccuracies in the delivery of the core components of SENSe therapy, across participating research sites. Future recommendations include the need to ensure feedback and monitoring strategies continue to be offered consistently to all clinicians implementing SENSe therapy, irrespective of clinical years of experience or familiarity with the intervention itself. Further research is needed to formally examine the validity (i.e. inter-rater reliability) of both the documentation and observation intervention checklists developed to assess the treatment fidelity of SENSe therapy.

In conclusion, it is feasible to apply components of the NIH BCC framework and its strategies systematically to help clinicians acquire, and maintain the skills required, to deliver the core components of complex rehabilitation interventions in both research and real-world clinical settings.

References

Borelli, B. (2011). The assessment, monitoring, and enhancement of treatment
fidelity in public health clinical trials. *Journal of Public Health Dentistry, 71*(s1): S52–
S63. https://doi.org/10.1111/j.1752-7325.2011.00233

Bellg, A., Borrelli, B., Resnick B, Hecht J, Minicucci, D., & Ory, M. (2004). Enhancing
treatment fidelity in health behavior change studies: Best practices and
recommendations from the NIH Behavior Change Consortium. *Health
Psychology*, *23,* 443–451. https://doi.org/10.1037/0278-6133.23.5.443

Bragstad, L.K., Bronken, B.A., Sveen, U., Hjelle, E.G., Kitzmullers, 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 Med Res Methodol, 19*(59), .
https://doi.org/10.1186/s12874-019-0694-z

Campbell, M., Fitzpatrick, R., Haines, A., Kinmoth, A., Sanderock, P., Spiegelhalter, D.,
& Tyrer, P. (2000). Framework for design and evaluation of complex
interventions to improve health. *British Medical Journal, 321*(7262), 694–696.
https:// doi.org/10.1136/bmj.321.7262.694

Cahill, L.S., Carey, L.M., Lannin, N.A., Tuville, M. & O'Conner, D. (2017).
Implementation interventions to promote the uptake of evidence-based practices in
stroke rehabilitation. *Cochrane Database of Systematic Reviews*, 3. Art. No.:
CD012575. https://doi.org/ 10.1002/14651858.CD012575

Cahill, L.S., Lannin, N.A., Mak-Yuen, Y. (2018). Changing practice in the assessment and treatment of somatosensory loss in stroke survivors: protocol for a knowledge translation study. *BMC Health Serv Res*.*18*(34).

Carey, L.M., Macdonell, R., Matyas, T.A. (2011). SENSe: Study of the effectiveness of neurorehabilitation on sensation: A randomized controlled trial. *Neurorehabilitation and Neural Repair, 25,* 304-13. https://doi.org/ 10.1177/1545968310397705

Carey, L.M. (2012) Touch and body sensations. In: Carey, L.M, editor. Stroke rehabilitation: insights from neuroscience and imaging. *New York: Oxford University* Press; p. 157–72

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

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

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

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

Gearing, R.E., El-Bassel, N., Ghesquiere, A., Baldwin, S., Gillies, J., & Ngeow, E. (2011). Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. *Clinical Psychology Review*, *31*(1), 79-88. https://doi.org/10.1016/j.cpr.2010.09.007

Ginsburg, L., Hoben, M., Easterbrook, A., Anderson, R., Estabrooks, C.A., & Norton, P.G. (2021) Fidelity is not easy! Challenges and guidelines for assessing fidelity in complex interventions. *Trials, 22* (1). https://doi.org/10.1186/s13063-021-05322-5

Glisson, C. & Schoenwald, S.K. (2005). The ARC organizational and community intervention strategy for implementing evidence-based children's mental health treatments. *Mental Health Services Research, 7*(4), 243-259. https://doi.org/ 10.1007/s11020-005-7456-1

Hoffman, 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., and Michie, S. (2014). Better reporting of interventions: Template for Intervention Description and Replication (TIDieR) checklist and guide. *British Medical Journal*, 348:g1687. https://doi.org/10.1136/bmj.g1687

Holmes, J.A., Logan, P., Morris, R. & Radford, K. (2020). Factors affecting the delivery of complex rehabilitation interventions in research with neurologically impaired

adults: a systematic review. *Systematic Reviews, 9*(1), 268.

https://doi.org/10.1186/s13643-020-01508-1

Masterson-Algar, P., R. 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:10.1111/jep.12174

Moncher, F., & Prinz, R. (1991). Treatment fidelity in outcome studies. *Clinical
Psychology Review, 11*(3), 247-266. https://doi.org/10.1016/0272-7358(91)90103-
2

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:
10.1080/10833196.2016.1261237

Pérez, D., Van der Stuyft, P., Zabala, M. (2015) A modified theoretical framework to assess
implementation fidelity of adaptive public health interventions. *Implementation Sci 11*
(91). https://doi.org/10.1186/s13012-016-0457-8

Poltawski, L., Norris, M., Dean, S. (2014). Intervention fidelity: developing an
experience-based model for rehabilitation research. *Journal of Rehabilitation
Medicine, 46*(7), 609-615. https://doi.org/10.2340/16501977-1848

Pumpa, L.U., Cahill, L.S., Carey, L.M. (2015). Somatosensory assessment and treatment after stroke: An evidence-practice gap. *Australian Occupational Therapy Journal*, *62*(2), 93-104. https://doi.org/ 10.1111/1440-1630.12170

Proctor, E.K., Landsverk, J., Aarons, G.A., Chambers, D.A., Glisson, C., Mittman, B.S. (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*(1), 24–34. https://doi: 10.1007/s10488-008-0197-4

Resnick, B., Galik, E., Pretzer-Aboff, I., Gruber-Baldini, A.L., Russ, K., Cayo, J., Zimmerman, S. (2009). Treatment fidelity in nursing home research: The Res-Care intervention study. *Research in Gerontological Nursing, 2*(1), 30-38. https://doi.org/10.3928/19404921-20090101-09

Taylor, N. F., Porter, J., Lynch, L., Horne-Thompson, A., Wallis, J., Kerridge, G. & Wilson, E. (2019). Evaluating the introduction of an allied health clinical research office at a health service: Effects on research participation, interest, and experience of allied health professionals. *Journal of Allied Health, 48*(1), 46-53. https://pubmed.ncbi.nlm.nih.gov/30826830/

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

Toomey E, Matthews J, Guerin S, Hurley, D.A. (2016). Development of a feasible

    implementation fidelity protocol within a complex physical therapy-led self-

    management intervention. *Physical Therapy, 96*(8), 1287-1298. https://doi.org/

    10.2522/ptj.20150446

Toomey, E., Hardeman, W., Hankonen, N., Byrne, M., et al. (2020). Focusing on fidelity:

    narrative review and recommendations for improving intervention fidelity within

    trials of health behaviour change interventions. *Health Psychology and Behavioral*

    Medicine, 8:1, 132-151, DOI: 10.1080/21642850.2020.1738935

Turville, M.L., Walker, J., Blennerhassett, J.M., & Carey, L.M. (2019). Experiences of

    upper limb somatosensory retraining in persons with stroke: An interpretative

    phenomenological analysis. *Frontiers of Neuroscience, 13*, 12. https://doi:

    10.3389/fnins.2019.00756

Appendix A

LA TROBE UNIVERSITY

Research Office

From	SHE Low Risk Human Ethics Committee
HEC Number	HEC20301
Project title	Development of a checklist to evaluate treatment fidelity in the delivery of SENSe therapy
Principal Investigator	Leeanne Carey
Co-Investigators	Brittni Nielsen Tamara Tse Brendon Haslam
Approval Period	12 August 2020 to 12 August 2025
Date	12 August 2020

I am pleased to advise you that the SHE Low Risk Human Ethics Committee has granted ethical approval of the project listed above, subject to the following conditions being met:

Conditions of Approval – All projects

- This research project was approved during COVID-19 restrictions. The conduct of the research during this period should reflect any changes in relation to COVID-19 mandates in the relevant jurisdictions. To accommodate these mandates a modification request must be submitted for any changes prior to their implementation.

- Approval is limited to the research project and associated documents as outlined in this ethics approval letter.

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.

- **Modifications to an Approved Project:** Any changes to the project application, project description/protocol and/or other project documents must be submitted for review and approval in accordance with the instructions outlined on the Human Research Ethics website. Modifications can be implemented once written approval has been received.

- **Annual Report:** If your project continues for more than 12 months, you are required to submit an Annual Report by the due date outlined in the annual report reminder. The form is available on the Human Research Ethics website. Failure to submit a Progress Report will mean approval for this project will be suspended and no further research activities can be carried out until the annual report is received.

- **Final Report or Withdrawal of Project:** At the conclusion of your project you must submit a final report within 6 months via the process outlined on the Human Research Ethics website.

- **Safety Reporting:** If a significant safety issue arises from the conduct of the project, it must be reported via the process outlined on the Human Research Ethics website.
- **Monitoring:** All projects are subject to monitoring at any time and will be monitored in accordance with the University's Research Monitoring Policy.

The Human Research Ethics Committee (HREC) Terms of Reference, membership and standard forms are available from http://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics.

Should you require any further information, please contact the Human Research Ethics Team on: T: +61 3 9479 1443| E: humanethics@latrobe.edu.au.

Warm regards,

Agnes Hazi
Co-chair, SHE Low Risk Human Ethics Committee

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Appendix B – Checklist for assessing fidelity of documentation of SENSe therapy record

Checklist for assessing fidelity of SENSe Documentation

Date:_____ Patient ID:_____ Therapist (site):_____ Study (circle): CONNECT / Implement

Core components of documented Session	Component absent from session (Score 0 = core treatment component has not been documented)	Partially performed (Score 1= the core component was documented with partial adherence or quality)	Competently performed (Score 2 = clinician documents the core component with a high degree of adherence and quality according to the criterion)	Comments / Additional information
TRAINING SCHEDULE OVERVIEW				
2 - 3 training elements per session i.e. Texture component, Object recognition, Proprioception component, and /or Occupation component.	*Only documented 1 element and / or no explanation given. Documented on 50% or less of training schedule (i.e level, component details – texture, joint, object)*	*Insufficient detail of components specified, (i.e. Tick but no level documented) and / or documented on less than 75%.*	Component details and level documented 100%.	
Evidence of grading within and across units of training, and across sessions.	*no evidence of grading and / or no explanation for limited grading.*	*Insufficient explanation and / or grading not consistent with SENSe framework.*		
2 x Occupations to be trained clearly documented on	*<2 sessions in total or no explanation as to why occupations not trained.*	*Evidence of only 2 -3 sessions in total or only 1 x occupation trained*		

schedule, at least 4-6 sessions in total.					
Evidence of occupations selected and plan documented.		*Insufficient evidence or only 1 occupation documented*	*Documented on COPM, planning form, or training overview*		
Therapist initials and date on training schedule.	*Date or initials only*				

Component Training – TEXTURE & GRID DISCRIMINATION					
Training Level attempted (tick under those which apply, * for those levels where 75% criterion is achieved)					
Wheels	**Level 1 (largest texture differences)**	**Level 2 (medium texture differences)**	**Level 3 (finest texture differences)**	**Level 4**	**Additional comments**
Rubber					
Glass					
Sandpaper					
Wallpaper I					
Wallpaper II					
Leather					
Grids	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Additional comments**
300					
260					
210					
170					
Core Components of Texture & Grid discrimination	**Component absent from session (Score 0)**	**Partially performed (Score 1)**	**Competently performed (Score 2)**	**Additional comments**	
Training forms dated and / or session no. documented	*No*		*Yes*		
Evidence of response recorded i.e. same or	*Limited or no evidence of response recorded*	*Limited evidence of response recorded*			

different, texture surface identified.				
Number of trials consistent with training protocol and / or documented abilities i.e. atleast 75% correct before progressing to next level.	*Frequently number of trials not consistent in context of progression - no explanation for early / delayed progression*	*Occasionally number of trials not consistent in context of progression and no explanation.*		
Documentation of sessions trained.	*No*		*Yes- 100% of training sessions recorded and located*	
Evidence of progression across levels for unit of training e.g. comments on no. of attempts, client confidence with performance, method of exploration, calibration strategies and feedback provided, transition across levels appears appropriate to documented abilities.	*Nil evidence of progression across unit or comments on factors impacting progression.*	*Some evidence of progression across texture levels or limited comment on factors impacting progression. Or, skips level and progresses to higher level without explanation i.e. level 1-3.*		
Commences at appropriate level i.e level 1 or modified level supported by clinical reasoning / assessment results.	*Commences at higher level (i.e 3,4) with no explanation and not consistent with abilities (i.e appears very difficult). Does not introduce at level 1.*	*Commences at higher level with insufficient explanation, however appears consistent with abilities.*		

Component Training - LIMB POSITION SENSE
<u>Training Level attempted</u> (tick under those which apply, * for those levels where 75% criterion is achieved)

Individual joint	Level 1	Level 2	Level 3	Level 4	Additional comments
Finger					
Wrist					
Elbow					
Multi joint	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Additional comments**
Elbow / wrist / finger					

Core components of Limb Position Sense	Component absent from session (Score 0)	Partially performed (Score 1)	Competently performed (Score 2)	Additional comments	
Training forms dated and / or session no. documented.	*No*		*Yes*		
Evidence of response recorded (degrees of position)	*no evidence of response recorded*	*Limited evidence of response recorded*			
Number of trials consistent with training protocol and / or documented abilities i.e. atleast 75% correct before progressing to next level	*Frequently number of trials not consistent in context of progression and no explanation for early or delayed progression*	*Occasionally number of trials not consistent in context of progression and no explanation.*			
Documentation of Levels trained.	*No*		*Yes- 100% of training sessions recorded and located*		
Evidence of progression across levels for unit of training e.g. comments on no. of attempts, client confidence with performance, method of exploration, calibration strategies and feedback provided, transition across levels appears	*Nil evidence of progression across unit or comments on factors impacting progression.*	*Some evidence of progression across texture levels or limited comment on factors impacting progression. Or, skips level and progresses to higher level without explanation i.e. level 1-3.*			

appropriate to documented abilities.				
Commences at appropriate level. i.e level 1 or modified level supported by assessment results.	*Commences at higher level (i.e 3,4) with no explanation and not consistent with abilities (i.e appears very difficult). Does not introduce at level 1.*	*Commences at higher level with insufficient explanation, however appears consistent with abilities.*		

Component Training - TACTILE OBJECT RECOGNITION
 Training Level attempted (tick under those which apply, * for those levels where 75% criterion is achieved)

Diagnostic attribute	*Level 1 (large differences)*	*Level 2 (medium differences)*	*Level 3 (small differences)*	*Additional comments*
Weight				
Crushability		Cups, food	Cups, food	
Functional motion				
Shape			Plastic shapes, cutlery	
Temperature				
Size			Coins, Keys	
Texture				
Core Components of Tactile Object Recognition	**Component absent from session (Score 0)**	**Partially performed (Score 1)**	**Competently performed (Score 2)**	**Additional comments**
Training forms dated and / or session number documented	*No*		*Yes*	
Evidence of response recorded	*no evidence of response recorded*	*Limited evidence of response recorded*		
Number of trials consistent with training protocol and / or documented abilities i.e. atleast 75% correct	*Frequently number of trials not consistent in context of progression and no explanation for*	*Occasionally number of trials not consistent in context of progression and no explanation.*		

before progressing to next level.	*early or delayed progression*			
Documentation of all sessions trained.	*No*		*Yes- 100% of training sessions recorded and located*	
Evidence of progression across levels for unit of training e.g. comments on no. of attempts, client confidence with performance, method of exploration, calibration strategies and feedback provided, transition across levels appears appropriate to documented abilities.	*Nil evidence of progression across unit or comments on factors impacting progression.*	*Some evidence of progression across texture levels or limited comment on factors impacting progression. Or, skips level and progresses to higher level without explanation i.e. level 1-3.*		
Commences at appropriate level. i.e level 1 or modified level supported by assessment results.	*Commences at higher level (i.e 3,4) with no explanation and not consistent with abilities (i.e appears very difficult). Does not introduce at level 1.*	*Commences at higher level with insufficient explanation, however appears consistent with abilities.*		
Trains across a range of diagnostic attributes	*Trains across only 1 attribute and / or no explanation.*	*Trains across <3 attributes and insufficient explanation*		
OCCUPATION BASED TRAINING				
Core components of Occupation based training	***Component absent from session (Score 0)***	***Partially performed (Score 1)***	***Competently performed (Score 2)***	***Additional comments***

2 x Occupations identified to be trained are documented	*Nil documented*	*1 occupation documented*		
Occupation based training delivered in line with sensory and / or activity goal.	*No evidence*			
Commences at appropriate level	*Nil explanation for commencing at higher level / greater task complexity*		*Considers task complexity, encourages part practice in line with documented abilities*	
Grades sensory demands of task e.g. sensory challenges, discrimination difficulty, presence of other cues/feedback.	*Nil documentation of how sensory demands have been graded*	*Limited documentation of how sensory demands have been graded*		
FIDELITY SCORING				
Total Raw Scores for each column	*Absent =*	*Partially performed =*	*Competently performed =*	
Total Fidelity Raw Score **(*sum of score for each core component observed during single session*)**				
Total Fidelity % **Percentage = Total Raw Score divided by Total Score Possible (e.g. 56*) and x 100.** ***i.e. 56 if all items applicable, or adjust for items not applicable** **(aiming 80% and above= high fidelity)**				

Documentation checklist designed by Brittni Nielsen, research Master student, under supervision of Prof Leeanne Carey. Revised 2019/2020.
Administration & Scoring guidelines adapted from original Performance Criterion for Treatment Fidelity Checklist developed for observation sessions

Appendix C – Checklist for assessing treatment fidelity during observation of SENSe therapy delivery

Checklist for assessing treatment fidelity during SENSe Therapy delivery
Please see final page for further administration and scoring guidelines.

Date:_____ **Patient ID:**_____ **Therapist (site):**_____ **Study (circle): CONNECT / Implement**

Context of the review: Self-reflective practice   Observed by SENSe Trainer   Therapist and peer-therapist observation

Content of Session (in order of occurrence)	Component absent from session (Score 0 = core treatment component has not been observed)	Partially competently performed (Score 1= the core component was observed with partial adherence or quality)	Competently performed (Score 2 = clinician delivers the core component with a high degree of adherence and quality according to the criterion)	Not Applicable e.g. specific component / occupation based training not scheduled for the session. e.g. Guidance of exploratory movement not required.	SENSe trainer feedback / comments
General introduction and explanation of therapy with reference to specific tasks					
Sets up and uses equipment appropriately					

Component Training – TEXTURE & GRID DISCRIMINATION					
Sensory goal defined by therapist as appropriate and discussed with client					
Commences at appropriate Texture Grid level					
Commences at appropriate texture wheel level					
Follows texture discrimination training form					
Facilitates attentive exploration, provides feedback on accuracy, optimal exploratory procedure					
Calibration facilitated with other hand and / or vision					
Uses anticipation trials and repetition as appropriate					
Grading – progresses patient to next level once achieved 75% correct					
Records responses appropriately on the form					
Component Training – LIMB POSITION SENSE					
Sensory goal defined by therapist as appropriate and discussed with client					
Commences with appropriate Individual Joint training level					
Introduces multi-joint training as appropriate					

Facilitates attentive exploration, provides feedback on accuracy, optimal exploratory procedure				
Calibration facilitated with training device, other hand and / or vision				
Uses anticipation trials and repetition as appropriate				
Grading – progresses patient to next level once achieved 75% correct (as appropriate)				
Records responses appropriately on the form				
Component Training - TACTILE OBJECT RECOGNITION				
Sensory goal defined by therapist as appropriate and discussed with client				
Commences at appropriate level and diagnostic attribute				
Follows diagnostic attribute training procedure: - guides patient to identify same / different - identifies exploratory procedures				
Feedback provided on accuracy, critical differences, method of exploration				
Calibration facilitated with other hand and / or vision				

Uses anticipation trials and repetition as appropriate				
Grading – progresses patient to next level once achieved 75% correct				
Records responses appropriately on the form				
OCCUPATION BASED TRAINING				
Activity goal for occupational task training reviewed and discussed with client				
Occupation based training delivered in line with sensory and / or activity goal				
Applies SENSe principles to sensory attributes to be trained, e.g. attentive exploration, feedback, calibration, anticipation				
Grades sensory demands of task and feedback given, e.g. sensory challenges, discrimination difficulty required, presence of other cues/feedback.				
Provides strategies and opportunities to enhance the client's transfer of the treatment skills and knowledge in daily life				

Records training of occupational task appropriately					

Home Practice *not assessed					
Therapist sets up opportunities and schedule for home practice for the client.					

FIDELITY SCORING				
Total Raw Score for each column	Absent =	Partially performed =	Competently performed =	
Total Fidelity Raw Score (*sum of score for each core component observed during single session*)				
Total Fidelity % *Percentage = Total Raw Score divided by Total Score Possible (e.g. 66*) and x 100.* **i.e. 66 if all items applicable, or adjust for items not applicable* (*aiming 80% and above = high fidelity*)				

Framework designed by Brittni Nielsen, research Master student, under supervision of Prof Leeanne Carey in 2018

Administration & Scoring

The checklist is to be used as a means of assessing the fidelity of treatment delivery and provide an opportunity for clinical education following the scoring. The degree of adherence to deliver the core components, and quality SENSe Therapy will be assessed using a 3-point rating scale (i.e. 0 = absent; 1 = criterion partially met; 2 = criterion met). This method of treatment fidelity assessment is recommended by Borelli (2011) and is consistent with the *National Institutes of Health Behavior Change Consortium (NIHBCC)* conceptual framework being employed throughout this study.

Item Scores:

0 = the core treatment element was not observed,

1 = the core element was observed with partial adherence or quality, and

2 = the core element was delivered with a high degree of adherence and quality according to the criterion.

N/A = it was not applicable for this core element to be observed.

Summary score:

Total Raw Score = Sum of individual items (core components) observed during session.

Total Score Possible = Sum of maximum score (i.e. 2) times number of items that are applicable. If all items are applicable then the total score possible would be 2 x 33 = 66. If all items are not applicable, adjust the total possible score accordingly.

Treatment Fidelity (as a percentage) = (Total Raw Score/ Total Score Possible*) x 100.

(*i.e. 66 if all applicable or adjust for number of items that are applicable). The goal is to deliver intervention that is ≥80% Treatment Fidelity.

List Key areas for development. (For use in self-reflection and tuition in consultation with SENSe Trainer)

1.
2.
3.