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ORIGINAL ARTICLE

# Developing an evidence-based reading intervention for early brain injury rehabilitation

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## Abstract

**Introduction:** Providing evidence-based services in areas with emerging or low-level evidence is a challenge for many clinicians. The aim of the current study was to apply a newly designed novel methodology to develop and describe a new intervention for cognitive-communication reading comprehension deficits in early acquired brain injury rehabilitation.

**Methods:** An emergent multi-phase mixed methods design allowed phases of different research activity to build an evidence base of quantitative and qualitative data. A pragmatic clinical framework was developed to combine these traditional research findings with principles from knowledge translation and implementation science, evidence-based practice and intervention development models, clinical contextual practice guidelines and the Medical Research Council's guidelines for developing and evaluating complex interventions, to create an evidence-based contextually driven clinical intervention.

**Results:** The resulting reading comprehension intervention and service delivery model is presented and involves a multiple-strategy intervention across increasing level of reading comprehension complexity. In areas where traditional methodologies provide low-level evidence, this method provides an alternate way to conduct evidence-based clinical research.

**Keywords:** Cognitive communication; intervention development; reading comprehension

## Introduction

Performing clinical behavioural research in areas with an emerging evidence base presents a number of unique challenges. Often, the available evidence is varied or at low level, and typical methods (e.g. randomised control trials) are unable to be applied (Turner-Stokes, 2008). Further, when translating behavioural-intervention research findings to real-world clinical situations, their application to everyday clinical practice may be limited by contextual constraints (Douglas, Campbell & Hinckley, 2015). This article presents a methodology and framework that can be used to maximise small groups of evidence from differing research fields in behavioural clinical research to develop an evidence-based treatment protocol for clinical practice. It recognises the importance of using both qualitative and quantitative findings (Onwuegbuzie & Leech, 2005) and combines these to develop a novel, contextually relevant intervention that is based on all available evidence. This has occurred within the specific clinical context of early acquired brain injury (ABI) rehabilitation by speech–language pathologists (SLPs) for cognitive-communication reading comprehension (CCRC) deficits.

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Changes to communication skills, including reading comprehension, can occur following ABI. Reading comprehension changes that occur at a text or 'discourse' level following ABI are typically a feature of a cognitive-communication disorder (CCD) (MacDonald & Wiseman-Hakes, 2010; Togher *et al.*, 2014). The incidence of CCD following ABI has been reported as 80%–100% (MacDonald & Wiseman-Hakes, 2010; Togher *et al.*, 2014); however, the incidence of CCRC deficits following ABI is unknown. While discourse-level reading comprehension deficits have been reported to occur following aphasia (Mayer & Murray, 2002), aphasia-related reading deficits typically occur at a phoneme/grapheme, word or sentence level (Kiran & Sandberg, 2012). Discourse-level reading comprehension deficits related to CCD typically occur with intact word and at sentence-level processing; these reading changes are not considered 'aphasic' in nature.

A range of skills are required to enable reading comprehension, including intact visual and perceptual skills (Ciuffreda, Han, Kapoor & Ficarra, 2006; Pollock *et al.*, 2011), sentence processing and word comprehension (Kiran & Sandberg, 2012), discourse-level comprehension skills (Holliday, Hamilton, Luthra, Oddy & Weekes, 2005) and cognitive processes including attention, memory and executive skills (Butterfuss & Kendeou, 2018; Ferstl, Guthke & von Cramon, 2002; Sohlberg, McLaughlin, Pavese, Heidrich & Posner, 2000), metacognition and self-awareness (Baker, 1989). A direct relationship is suggested between impaired cognitive skills and reading comprehension deficits following ABI (Griffiths, Sohlberg, Kirk, Fickas, & Biancarosa, 2015). Cognitive processes following ABI associated with reading comprehension deficits include attention (Sohlberg, Griffiths & Fickas, 2014; Sohlberg *et al.*, 2000), working memory (Griffiths *et al.*, 2015; Schmitter-Edgecombe & Bales, 2005; Sohlberg *et al.*, 2014), speed of language processing (Sohlberg, Griffiths & Fickas, 2015), verbal learning (Sohlberg *et al.*, 2014) and executive processes (Ferstl *et al.*, 2002; Schmitter-Edgecombe & Bales, 2005). As such, CCRC deficits typically occur following changes to the cognitive and complex communication skills that facilitate reading (Ferstl *et al.*, 2002; Griffiths *et al.*, 2015; Schmitter-Edgecombe & Bales, 2005; Sohlberg *et al.*, 2000, 2014, 2015). For example, when an adult with ABI attempts to read discourse-level information early in recovery, attentional difficulties may disrupt information processing of written text (e.g. impacting encoding, storage and/or retrieval), which disrupts the construction of an accurate situational model and impacts overall comprehension (Kintsch & van Dijk, 1978; Sohlberg & Turkstra, 2011; Sohlberg *et al.*, 2014).

Reading comprehension changes occur across all levels of function as described in the International classification of functioning, disability and health (ICF) model (World Health Organization, 2001), from impairment to participation (Griffiths, 2012), with changes to CCRC skills identified in both early (<6 months post ABI) and chronic ABI populations. Features of impairment-level CCRC deficits early in recovery include reductions in vocabulary/written word knowledge (Kaplan, 1990), reduced comprehension of literal texts at a paragraph level and above (Hinchliffe, Murdoch & Chenery, 1998; Kaplan, 1990) and impaired complex, inferential reading comprehension (Kaplan, 1990). In chronic populations, difficulties with these skills continue, including reduced vocabulary and reduced paraphrase comprehension (Sohlberg *et al.*, 2014), reduced comprehension of discourse-level text (Ferstl *et al.*, 2002; Schmitter-Edgecombe & Bales, 2005; Sohlberg *et al.*, 2015) and reduced complex comprehension, including text coherence (Ferstl *et al.*, 2002), inferential reading and gist memory (Holliday *et al.*, 2005). Adults with ABI tend to have more difficulties with inferential comprehension than literal/verbatim comprehension (Sohlberg *et al.*, 2014).

These impairment level changes to reading comprehension impact individuals' function, activity and participation. Changes to cognition impact reading processes and ability, which impacts the success of reading for a specific purpose (i.e. reading activity) and ultimately influences global participation (Griffiths, 2012). These changes to activity and participation occur across all recovery time points, from early in recovery to long-term post-injury. Specific limitations and restrictions have been associated with CCRC deficits, in the areas of participation during rehabilitation (Malec, Smigielski, DePompolo & Thompson, 1993), independence within the home and

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community (Jacobs, 1988), participation in leisure activities and return to study/work (Laatsch & Guay, 2005), participation in vocation and education (Griffiths, 2012) and tertiary education performance (Sohlberg *et al.*, 2015). As the goal of SLP interventions following brain injury is to maximise independent function for participation in daily living (American Speech-Language-Hearing Association, 2020), providing rehabilitation of CCRC deficits, regardless of time post-injury is supported. As CCRC deficits are present from early post-injury, providing early rehabilitation for CCRC deficits may maximise participation and function during early recovery and positively influence future participation and function.

Rehabilitation and management of CCRC deficits are typically provided by SLPs and occur across the rehabilitation continuum, from early post-injury (Blake, Frymark & Venedictov, 2013; Coelho, DeRuyter & Stein, 1996; Watter, Copley & Finch, 2016) to later in recovery (Griffiths *et al.*, 2015; Harvey & Hux, 2015; Sohlberg *et al.*, 2014). However, the evidence base for managing CCRC deficits is predominantly from chronic populations (MacDonald, 2017; Watter, Copley & Finch, 2017). In a recent systematic review of discourse-level reading comprehension interventions following ABI, only 3 of 23 identified papers investigated clients in early rehabilitation (i.e. <6 months post onset) (Watter *et al.*, 2017). Identified CCRC interventions included strategy-based interventions (Griffiths *et al.*, 2015; Sohlberg *et al.*, 2014), cognitive interventions with a reading focus (Laatsch & Guay, 2005) and the use of compensatory devices (e.g. text-to-speech) (Harvey & Hux, 2015). MacDonald reports there is evidence to support the interventions of oral reading, compensatory and metacognitive strategy interventions, organisational training and gist reasoning training for CCRC deficits (MacDonald, 2017).

Strategy use is a common rehabilitation intervention for adults with ABI (Cicerone *et al.*, 2011), including those with CCRC deficits (Watter *et al.*, 2017). Deliberate strategy use can aid reading comprehension by helping to compensate for the cognitive impairments that impact reading processes (Sohlberg & Turkstra, 2011). The use of strategy-based interventions for CCRC deficits has been supported in previous reviews (MacDonald, 2017; Watter *et al.*, 2017). Recent research into managing CCRC deficits has focused on adults undertaking post-secondary education and the use of strategy-based interventions in a chronic population. This includes investigating the cognitive and reading comprehension skills of adults with ABI and traumatic brain injury (TBI) (Sohlberg *et al.*, 2015); the effectiveness of computer-delivered reading strategies (Griffiths *et al.*, 2015; Sohlberg *et al.*, 2014) and developing new tools to assess reading comprehension and identify strategy use during reading (Kucheria, Sohlberg, Prideaux & Fickas, 2019; Kucheria, Sohlberg, Yoon, Fickas & Prideaux, 2018). While the CCRC evidence base grows for those with chronic deficits, it continues to be limited for those early post-injury, and the application of the above interventions to early recovery is unknown.

The need for early rehabilitation of CCRC deficits has previously been recognised. Adults with ABI may require functional reading skills on discharge from hospital to enable return to previous roles, including running the house, returning to work, engaging in social networks (Watter *et al.*, 2016) and to participate in meaningful activities that involve reading, including leisure and social pursuits (Cocks, Pritchard, Cornish, Johnson & Cruice, 2013). Maximising reading skills early in recovery may increase success and participation in these activities and in life roles, increasing independence in the home and community, reducing the amount of support required post-discharge and increasing the levels of social participation which may in turn impact the quality of life.

Further, CCRC deficits can impact participation in rehabilitation (Malec *et al.*, 1993; Ryan, Sautter, Capps, Meneese & Barth, 1992), including participation and success in more complex rehabilitation (e.g. vocational rehabilitation) (Ryan *et al.*, 1992). If aspects of a rehabilitation programme require comprehension of written information, then the person's ability to fully comprehend and participate in that aspect of rehabilitation may be compromised (Malec *et al.*, 1993). This may result in reduced rehabilitation progress and client outcomes. Accessing specialised, early ABI rehabilitation is considered 'best practice' (Australasian Faculty of Rehabilitation Medicine, 2011; Royal College of Physicians and British Society of Rehabilitation Medicine,

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2003). This rehabilitation maximises recovery and long-term gains and is effective and cost-efficient for adults with ABI of working age (Turner-Stokes, 2008; Turner-Stokes, Nair, Sedki, Disler & Wade, 2005; Turner-Stokes, Williams, Bill, Bassett & Sephton, 2016). However, if reading deficits interfere with rehabilitation participation, then client outcomes may be negatively impacted if reading is not addressed early in recovery. Therefore, providing early rehabilitation for CCRC deficits may maximise rehabilitation participation and gains, addressing best practice recommendations for adults with ABI.

During the period of early recovery and early rehabilitation (i.e. first 6 months post-injury), health services typically provide maximum intensity rehabilitation (Christensen *et al.*, 2008). This includes rehabilitation for cognitive deficits (Beaulieu *et al.*, 2015; Rabinowitz & Levin, 2014) and the cognitive processes associated with CCRC deficits. The recovery of cognitive functions is also accelerated during the first 5 months post-injury (Christensen *et al.*, 2008). Therefore, providing rehabilitation for CCRC deficits early in recovery takes advantage of the accelerated recovery of cognitive processes, the spontaneous recovery period and a period of increased rehabilitation intensity. This may maximise recovery and gains for these individuals and may enhance the rehabilitation potential for people with ABI and their future participation and clinical outcomes both in hospital and at home/in the community.

SLPs provide management and interventions for CCRC deficits in early ABI rehabilitation (Blake *et al.*, 2013; Coelho *et al.*, 1996; Watter *et al.*, 2016), with evidence of improved CCRC skills overall (Blake *et al.*, 2013; Coelho *et al.*, 1996). Yet the priority of providing CCRC rehabilitation is unknown. SLPs within specialised sub-acute brain injury rehabilitation units in Australia reported providing highest intensity services to clients with dysphagia and severe communication disorders (Watter, Addis, Copley & Finch, 2014b). Australian SLPs also identified that sub-acute rehabilitation for CCRC deficits may not be prioritised for all clients, given concomitant swallowing or CCDs (e.g. auditory–verbal and social communication skills) (Watter *et al.*, 2016). Reduced rehabilitation of CCRC skills in early recovery has also been demonstrated in a recent multi-site study, which reported on 'common' SLP interventions in sub-acute rehabilitation for TBI (Beaulieu *et al.*, 2015). Reading/writing skills (including paragraph, multiple paragraph, functional and advanced reading) were not reported as 'common' SLP interventions during early rehabilitation (Beaulieu *et al.*, 2015). It is possible that clients' reading comprehension needs are not being adequately prioritised or addressed early in recovery, which may negatively impact rehabilitation outcomes and individuals' function and participation. There has been limited research in this area to guide clinicians to provide evidence-based interventions for the early rehabilitation of CCRC deficits, with clinicians relying on findings from the chronic evidence base.

Providing evidence-based practice (EBP) is the cornerstone of delivering quality healthcare. The principles of EBP are used in clinical decision-making as part of regular practice by allied health clinicians, including SLPs (American Speech-Language-Hearing Association, 2005). Being an evidence-based practitioner involves integrating multiple types of information to inform decision-making in clinical practice, including research evidence, clinical experience, utilising client and consumer preferences and information on context (Hoffman, Bennett & Del Mar, 2017). These have been described as the 'external' research evidence, evidence 'internal' to clinical practice, evidence regarding the preferences of an informed client (Dollaghan, 2007) and 'context' (Hoffman *et al.*, 2017). Clinical guidelines, practice recommendations and position statements from professional bodies also inform clinicians when delivering 'best practice' services. Within clinical practice, treatment selection, timing of interventions, service delivery methods and treatment intensity are considered alongside the context of the workplace and clinical service. However, a lack of research in specific areas, poor generalisation of research to clinical practice or specific settings, and workplace and contextual factors have been identified as barriers to clinicians in providing EBP (O'Connor & Pettigrew, 2009; Reilly, 2004).

In the areas of ABI rehabilitation, a significant body of evidence exists to support early specialist multi-disciplinary rehabilitation (Turner-Stokes, 2008; Turner-Stokes *et al.*, 2005, 2016)

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including systematic reviews and evaluations, with access to early rehabilitation considered best practice for adults with ABI (Australasian Faculty of Rehabilitation Medicine, 2011; Royal College of Physicians and British Society of Rehabilitation Medicine, 2003). However, studies typically investigate the process and overall outcomes of rehabilitation, not specific interventions provided during rehabilitation (Turner-Stokes *et al.*, 2005). Similarly, a lack of published research has been identified regarding specific CCRC interventions and their effectiveness during early, sub-acute ABI rehabilitation (Watter *et al.*, 2016, 2017).

Conducting ABI rehabilitation research presents a number of challenges, including heterogeneity of the population, resources required for system-level interventions, ethical concerns with treatment selection, participant withdrawal and the impact of real-life clinical practice on treatment design (Turner-Stokes *et al.*, 2005). During early rehabilitation, other clinical factors may also impact ABI research, including medical stability, spontaneous recovery, service-level decisions (e.g. length of stay) and timing of interventions (Hall & Cope, 1995). Subsequently, research that also investigates practice-based evidence (alongside EBP) has been recommended (Turner-Stokes *et al.*, 2005). Practice-based evidence investigates specific clinical practice (e.g. clinical rehabilitation interventions) alongside client characteristics, deficits and outcomes (Beaulieu *et al.*, 2015) to provide detailed information on rehabilitation activities. Early interventions and outcomes for adults with brain injury in sub-acute rehabilitation have recently been investigated in a practice-based evidence study; the categories for SLP interventions investigated included cognitive and communication domains (Beaulieu *et al.*, 2015). Specific SLP interventions were not detailed; however, these studies are a positive step towards building the evidence-base for early SLP rehabilitation practice for cognitive-communication.

While the evidence supports early rehabilitation for adults with ABI and interventions for chronic CCRC deficits, there is little formal evidence to guide SLPs in managing CCRC deficits early in recovery. When attempting to provide evidence-based services for adults with CCRC deficits in early rehabilitation, SLPs face a challenging task. They must relate published evidence for interventions from a chronic, stable population to early rehabilitation; utilise clinical and professional guidelines; use clinical judgment, practitioner-based knowledge and 'expert opinion'; and consider client preferences, all within the context of their clinical service.

## Objectives

This study aims to apply a newly designed novel methodology to develop and describe a context-specific intervention and service delivery model for CCRC deficits that is evidence based and can be delivered by SLPs in sub-acute and early ABI rehabilitation (<6 months post-injury) as part of regular service delivery. The study was developed within an Australian rehabilitation context. The principles and frameworks that guide multi-disciplinary service provision in specialist sub-acute ABI rehabilitation centres in Australia have previously been presented (Watter *et al.*, 2016). To summarise, Australian SLPs provide early, sub-acute rehabilitation for adults with ABI and TBI within specialised brain injury rehabilitation centres, broader rehabilitation services and generalist health settings. Australian ABI rehabilitation facilities operate under the Australasian Faculty of Rehabilitation Medicine's Standards (2011), where services are provided in line with the World Health Organization's ICF framework (World Health Organization, 2001). As such, findings from an Australian healthcare context should translate to other healthcare settings and contexts.

## Considerations When Developing an Evidence-Based Clinical Intervention and Service Delivery Model: Using a Pragmatic Clinical Framework

A number of models and principles informed the development of the CCRC intervention and service delivery model and intervention design. These models were broadly congruent and shared

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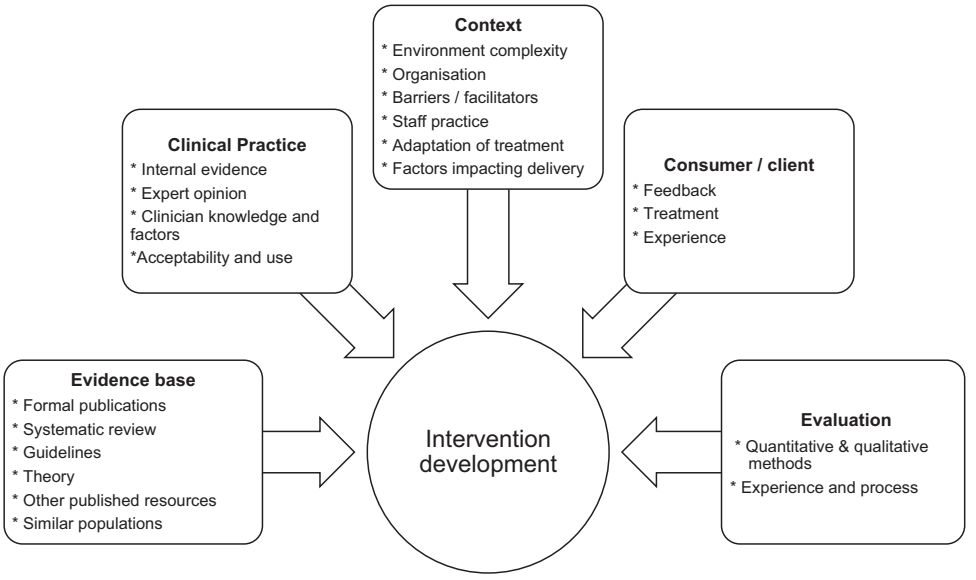



**Figure 1.** Clinical frameworks influencing intervention development: A pragmatic clinical framework.

a number of key themes and factors; an emergent multi-phase mixed-methods design (Creswell, Klassen, Plano Clark & Smith, 2011) allowed for the combination of methodologies.

The Medical Research Council's (MRC) guidelines for developing and evaluating complex interventions (Craig & Petticrew, 2013; Craig *et al.*, 2008) were utilised alongside knowledge translation and implementation science principles (Curran, Bauer, Mittman, Pyne & Stetler, 2012; Douglas *et al.*, 2015; Fixsen, Naoom, Blase, Friedman & Wallace, 2005; Olswang & Prelock, 2015), intervention development models (Curran, Mukherjee, Allee & Owen, 2008; Fraser & Galinsky, 2010; Gitlin, 2013) and EBP models and principles that guide clinical practice (American Speech-Language-Hearing Association, 2005; Dollaghan, 2007; Hoffman *et al.*, 2017; Sackett, Straus, Richardson, Rosenberg & Haynes, 2000).

Steps one, two and three of the MRC framework have been applied to this study. This includes development of the complex intervention, planning to pilot the new intervention via contextually designed *n*-of-1 trials and planning evaluation of the intervention involving a range of outcomes and measures. Step four (implementation) has not been fully executed and is an identified future direction.

From these models and frameworks, five key factors were identified that informed the treatment design: evidence base (including theoretical constructs), clinical practice, consumer and client factors, contextual factors and evaluation. These have been combined to form a pragmatic clinical framework, which is summarised in Fig. 1, and detailed below. These key features are also summarised in Appendix 1.

When developing a new intervention, a range of information should be considered (American Speech-Language-Hearing Association, 2005;Craig & Petticrew, 2013; Craig *et al.*, 2008; Curran *et al.*, 2008, 2012; Dollaghan, 2007; Douglas *et al.*, 2015; Fixsen *et al.*, 2005; Fraser & Galinsky, 2010; Gitlin, 2013; Olswang & Prelock, 2015; Sackett *et al.*, 2000). The MRC recommends identifying the evidence and knowledge base, performing a systematic review of the literature if there is little evidence (Craig *et al.*, 2008) and identifying or developing the theoretical basis for the intervention (Craig & Petticrew, 2013). In addition to utilising formal evidence from the literature (Dollaghan, 2007; Hoffman *et al.*, 2017; Sackett *et al.*, 2000), published evidence from a range of sources should be considered, including texts, web-based information, education/professional development information (American Speech-Language-Hearing Association, 2005) and theory

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and practice guidelines (Gitlin, 2013). The evidence base for similar interventions from related populations may also be useful to consider (MacDonald & Wiseman-Hakes, 2010).

Evidence 'internal' to clinical practice (Dollaghan, 2007; Sackett *et al.*, 2000), alongside clinician factors and clinical knowledge (Gitlin, 2013; Hoffman *et al.*, 2017), should also be used to inform the development of new interventions. Input from consumers should be sought (Dollaghan, 2007; Gitlin, 2013; Hoffman *et al.*, 2017; Sackett *et al.*, 2000) to identify needs and perspectives. Integrating users and stakeholders into study methodology and treatment development (Gitlin, 2013) can aid in providing information on consumer preferences. The perceptions of evidence for those involved (e.g. clinicians, clients) should also be identified and addressed in treatment development (Douglas *et al.*, 2015).

Contextual factors (Hoffman *et al.*, 2017) should be considered in the design and development of a new implementation intervention (Curran *et al.*, 2008; Olswang & Prelock, 2015). These include knowledge of the site, setting and service for future implementation (Douglas *et al.*, 2015; Fixsen *et al.*, 2005; Gitlin, 2013), complexity of the practice environment and organisational factors and barriers (Gitlin, 2013). Specific intervention characteristics, including the ability to apply the intervention in practice (i.e. being manageable and acceptable) should also be considered (Douglas *et al.*, 2015). Identifying barriers and facilitators to practice and assisting staff to implement and contextualise interventions to their local service influence the likelihood of interventions being successfully adopted (Curran *et al.*, 2008).

Evaluating the feasibility of a potential intervention requires knowledge and acknowledgement of the context, including factors impacting delivery, acceptability and use of the intervention in the target setting (Craig *et al.*, 2008). Investigating the intervention's acceptance and use via qualitative research is recommended (Gitlin, 2013). Curran and colleagues (2012) support the use of a mixed-methods hybrid design to investigate the effectiveness of interventions via quantitative methods, plus investigating aspects relevant to implementation success (e.g. barriers, facilitators, feasibility and acceptability).

The translation of the pragmatic clinical framework to the target population (SLP management of sub-acute CCRC deficits) is detailed in the Methods section.

## Methods

This study has ethical clearance from the University of Queensland Medical Research Ethics Committee (# 2013000489; #2014000755) and the Metro South Human Research Ethics Committee (HREC/11/QPAH/533; HREC/13/QPAH/094). The Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guidelines (CReDICI 2) have been applied to this study (Mohler, Kopke & Meyer, 2015); specifically, all four steps in the first stage, which relate to the development of a complex healthcare intervention.

A mixed-methods approach using an emergent multi-phase mixed-methods design (Creswell *et al.*, 2011) allowed for the translation of factors identified from the pragmatic clinical framework to the target population (SLP management of sub-acute and early CCRC deficits). This process is described in detail in the procedure below and summarised here to aid the reader. The evidence base for discourse-level reading comprehension deficits following ABI needed to be identified, which involved conducting a systematic review (Watter *et al.*, 2017), identifying other sources of published evidence and investigating the evidence from other populations for discourse-level reading comprehension deficits. Clinical guidelines and practice recommendations for SLP service provision for ABI and CCD rehabilitation were also reviewed. The clinical practice of sub-acute SLPs for CCRC management and service delivery was investigated (Watter *et al.*, 2016), and contextual factors including practice patterns and service delivery of SLPs in specific brain injury sub-acute rehabilitation facilities were identified (Watter, Addis, Copley & Finch, 2014a; Watter *et al.*, 2014b). Consumer preferences for sub-acute rehabilitation of CCRC deficits were also sought.

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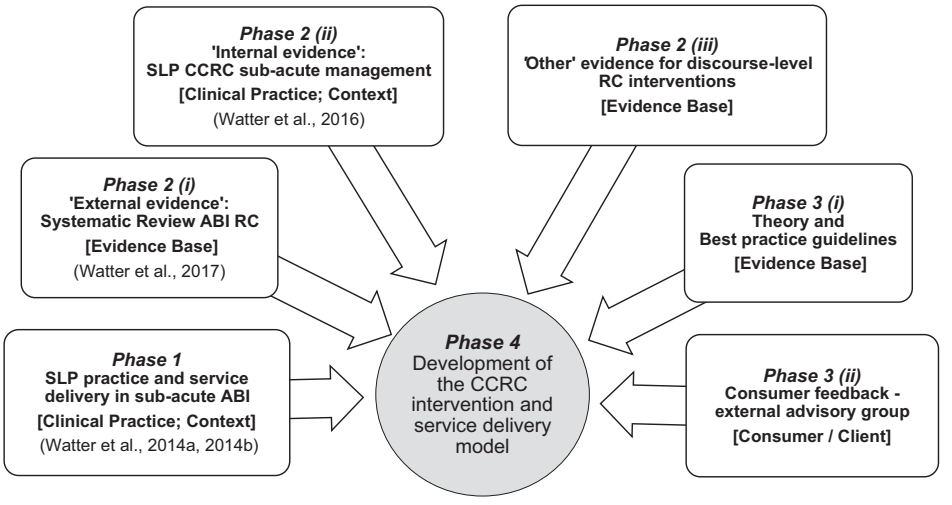



**Figure 2.** Developing the CCRC intervention and service delivery model.
ABI: acquired brain injury; CCRC: cognitive-communication reading comprehension; RC: reading comprehension; SLP: speech–language pathology.

Lastly, when developing the intervention, the theoretical constructs that underpin the intervention were explored, and future evaluation measures were considered.

## Procedure

The emergent multi-phase mixed-methods design (Creswell *et al.*, 2011) allowed for multiple phases of activity; each phase was separate and possessed its own methodology. Earlier phases of the study informed and guided the following phases, and qualitative information informed the development of quantitative interventions (Creswell *et al.*, 2011). Within the study, three phases of research activity led to the development of a CCRC intervention and service delivery model for SLPs in sub-acute brain injury rehabilitation (phase four of this study). These phases are described below. A fifth and future phase involved implementing the developed intervention and service delivery model with adults with ABI and CCRC deficits during early rehabilitation (Watter, Copley & Finch, 2020). These phases are presented alongside the clinical framework factors in Fig. 2.

### *Study phases*

*Phase 1: SLP service delivery and practice in sub-acute ABI rehabilitation – identifying clinical practice and context*

The clinical practice and service delivery methods of SLPs working in specialised sub-acute brain injury rehabilitation centres across Australia were investigated (Watter *et al.*, 2014a, 2014b) to provide information on 'context' and clinical practice (Hoffman *et al.*, 2017). The areas investigated involved staffing, prioritisation, intervention, frequency, mode, education provision and family/consumer involvement (Watter *et al.*, 2014a, 2014b). The key findings from phase one that influenced the development of the CCRC intervention are presented in the Results section (see Table 1).

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**Table 1.** Phase 1 Findings used in CCRC Development

| Phase 1: SLP service delivery in specialist sub-acute ABI centres (Watter *et al.*, 2014a, 2014b) | |
|---|---|
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Variation across SLP services: staffing, support (e.g. assistants), prioritisation, service delivery, consumer engagement | Unable to provide daily intensive therapy for CCRC: maximum frequency of 3 sessions per week; sessions 30–60 min duration<br>Supplement therapy with independent practice and practice support from others (e.g. family) |
| SLPs manage a range of communication disorders and dysphagia; client need and severity impacts service delivery | |
| Trend for less severe patients (e.g. CCD) to receive lower intensity services (1–3 per week), plus group therapy, independent practice tasks | |
| Some SLP services identified wanting to provide 'more' services: education, involving families in sessions, functional therapy activities | Intervention to include education to client and family, family involvement and functional tasks |

ABI, acquired brain injury; CCD, cognitive-communication disorder; CCRC, cognitive-communication reading comprehension; SLP, speech–language pathologist.

*Phase 2: Identifying the evidence base*

The evidence base for CCRC interventions following ABI was investigated in this phase. The 'external' research evidence and 'internal' clinical practice evidence (Dollaghan, 2007) for CCRC sub-acute interventions were investigated via (i) a systematic review (Watter *et al.*, 2017), (ii) investigation of SLP clinical practice (Watter *et al.*, 2016) and (iii) identification of 'other' research evidence for discourse-level reading interventions from related populations and research fields via a literature review.

(i) Systematic review findings (Watter *et al.*, 2017): A systematic review of the literature was conducted and reported according to PRISMA guidelines (Moher, Liberati, Tetzlaff, Altman & Group, 2009) and logged with PROSPERO (http://www.crd.york.ac.uk/PROSPERO) to identify the evidence for discourse-level reading comprehension interventions following ABI (Watter *et al.*, 2017). Twenty-three papers were identified for review, with six different groups of interventions. This study also identified intervention outcomes, assessment methods, intervention features including treatment duration, trends and future directions for CCRC research.

(ii) Clinical practice findings (Watter *et al.*, 2016): The clinical practice of Australian SLPs and how they provided sub-acute CCRC rehabilitation for adults with ABI was investigated via an online national survey (Watter *et al.*, 2016). The mixed-methods study identified SLP service delivery for CCRC in sub-acute rehabilitation, including assessment practices, intervention frequency and types of interventions provided (including impairment and functional/participation-level intervention activities and reading strategy interventions).

(iii) 'Other' discourse-level reading comprehension evidence: The evidence base for other discourse-level reading comprehension interventions was investigated via a literature review and involved research and literature from the fields of education, learning disability and adult literacy. This literature base was large and included government reports, systematic reviews and meta-analyses. It provided high levels of evidence for a range of strategy-based reading interventions, with key papers referenced in the Results section (see Table 2).

The key findings from phase two that influenced the development of the CCRC intervention are presented in the Results section (see Table 2).

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**Table 2.** Phase 2 Findings Used in CCRC Development

| Phase 2: Evidence Base for CCRC interventions | |
|---|---|
| (i) Systematic Review Findings (Watter *et al.*, 2017) | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Strategy-based reading interventions were the most common intervention identified. | Using reading strategies for discourse-level RC deficits is supported |
| Visual, content, cognitive and metacognitive strategies were used in discourse RC rehabilitation | Multiple-strategy use is supported |
| Use of multiple-strategy interventions was supported | |
| The three most common reading strategies identified from the systematic review were:<br>– Identifying key ideas or points,<br>– Summarising<br>– Re-reading/reviewing information | Strategies to be used in new intervention:<br>– identifying key ideas or points<br>– summarising |
| A growing trend in strategy-based reading research was noted, and strategy-based interventions for CCRC deficits were identified as a future research priority | Research involving strategy-based CCRC interventions is supported |
| Strategy-based interventions identified as relatively cost-effective, with shorter duration interventions and positive trends in reading comprehension | Cost-effective and shorter duration interventions suited to sub-acute rehabilitation and healthcare settings |
| Thirteen studies used interventions and activities that assisted in complex processing and comprehension of written information, 11 of these studies demonstrated a positive change in reading comprehension. These included discussion, questioning, problem-solving, drawing conclusions, generate opinions, foreshadow/predicting, using abstract/complex information.<br>These were often used alongside reading strategies. | Utilise supporting cognitive-communication activities to aid complex comprehension and inferencing (as required) alongside strategies |
| Ten studies reported using hierarchical reading stimulus; eight of the studies reported improved RC for at least one participant group. These studies involved adults with severe to high-level RC deficits.<br>Hierarchies were based on increasing complexity of written information (e.g. reading level, text length, complexity/ abstractedness of information). | Hierarchical progression of reading comprehension tasks and stimulus is supported for clients with different levels of RC severity. |
| (ii) SLP management of CCRC deficits in sub-acute rehabilitation (Watter *et al.*, 2016) | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| 100% of SLPs reported using reading strategies in sub-acute CCRC clinical practice<br>SLPs used visual, content, cognitive and metacognitive reading strategies<br>SLPs may use multiple strategies with one client | SLPs commonly use reading strategies for sub-acute CCRC deficits<br>Multiple-strategy use is supported |
| The most common strategies (used by 95%–100% of SLPs) were:<br>– Underlining key words<br>– Identify main point/questioning/Wh information<br>– Summarising<br>– Re-reading<br>– Reducing visual load | Strategies for intervention:<br>– Underlining key words<br>– Identify main point/questioning/wh information<br>– Summarising |

(*Continued*)

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**Table 2.** (*Continued*)

| Phase 2: Evidence Base for CCRC interventions | |
|---|---|
| (i) Systematic Review Findings (Watter *et al.*, 2017) | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Majority of SLPs used both impairment and activity-based/ functional CCRC interventions | Use impairment-based therapy tasks alongside reading strategies to aid complex comprehension and inferencing skills if required. These activities are similar to those identified in the systematic review above. |
| High-use (>60% SLPs) impairment-based reading comprehension tasks involved: answering open-ended factual questions; predicting and problem-solving; retelling information; forming conclusions and opinions; inferencing and reasoning | |
| Functional reading stimuli used by 100% of SLPs as a common or regular activity.<br>High-use activity/functional reading tasks involved activities related to work/study, self-management, home/community/ family, and used functional stimuli | Incorporate functional RC stimulus in reading tasks and activities, individualise and relate stimulus to client's discharge needs and goals |
| SLPs manipulated RC stimulus features to increase complexity/difficulty:<br>– Concrete vs abstract items (100% SLPs)<br>– Length (impairment tasks: 97.4% SLPs; functional tasks: 84.2% SLPs)<br>– Linguistic and grammatical complexity (78.9% SLPs) | Hierarchical progression of reading stimulus is supported. Text features to manipulate include length, linguistic/grammatical complexity, and level of abstractedness. |
| CCRC therapy involved individual therapy, independent practice, groups, using others (e.g. therapy assistants) | Use individual face-to-face sessions plus independent practice tasks<br>Involve others in therapy/with practice/for support – e.g. family |
| Majority of SLPs were able to provide 3–4 sessions per week, with CCRC rehabilitation often provided as part of a therapy session | Service delivery: 3–4 sessions per week |
| (iii) 'Other' evidence base for discourse RC interventions (Berkeley, Mastropieri & Scruggs, 2011; Crowe, 2003; Ehren, 2005; Gajria, Jitendra, Sood & Sacks, 2007; Guthrie *et al.*, 2009; Kim, Vaughn, Wanzek & Wei, 2004; Lovett, Lacerenza, Palma & Frijters, 2011; Mellard, Fall & Woods, 2010; National Reading Panel, 2000; Robinson, 1970; Snow, 2002) | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| High-level evidence was identified from education, learning disability and adult literacy fields, for the use of reading strategies in discourse-level reading | Reading strategies supported in other populations by high-level evidence |
| Evidence-based strategies included visual, content, cognitive and metacognitive strategies<br>Multiple-strategy use, including strategy plus a metacognitive strategy was promoted | Similar to SLP practice and systematic review findings;<br>Metacognitive strategy use is supported; also supported in ABI rehabilitation (Kennedy *et al.*, 2008)<br>Reading strategies of *Identifying main points*, using *wh questions* and *summarising* identified as RC instruction methods with a firm scientific basis (National Reading Panel, 2000) and evidence-based interventions with large effect sizes for students with learning difficulties (Gajria *et al.*, 2007). |
| Strategies were effective for at-risk and poor readers, as well as achieving readers, and were used across the age spectrum from children to adults. | Using reading strategies for varying level of reading skill, and with adults is supported |
| Similarities identified between this evidence base and ABI CCRC populations, in regards to reading and cognitive skills (Watter *et al.*, 2017) | Supports the application of reading strategies with people with ABI. |
| Using parts of this evidence-base and applying it to ABI CCD rehabilitation has previously been recommended (MacDonald & Wiseman-Hakes, 2010) | |

ABI, acquired brain injury; CCD, cognitive-communication disorder; CCRC, cognitive-communication reading comprehension; RC, reading comprehension; SLP, speech–language pathologist.

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*Phase 3: Theory, practice guidelines and consumer feedback*

Additional information was investigated to inform the intervention development, regarding (i) theory, (ii) practice guidelines and (iii) information from consumers.

(i) Theory: The broad construct of cognitive rehabilitation theory underpins the development of the CCRC intervention and service delivery model. Specific theories influencing treatment development included systematic instructional theory (Sohlberg & Turkstra, 2011), contextual cognitive rehabilitation paradigms (Ylvisaker, 2003) and neuroplasticity (Kleim & Jones, 2008). These theories are congruent with recommendations contained in the practice guidelines and learning principles detailed below. As it is beyond the scope of this paper to explain these theories in-depth, readers are referred to the specific papers referenced for further information. The specific concepts of these rehabilitation theories that influenced the treatment and service delivery design are outlined in the Results section (see Table 3).

(ii) Practice guidelines: Recommendations on SLP practice in brain injury (American Speech-Language-Hearing Association, n.d.), guidelines for the management of CCDs (Togher *et al.*, 2014) and for ABI rehabilitation of cognitive and executive skills (Ehlhardt *et al.*, 2008; Kennedy *et al.*, 2008; Ownsworth, Quinn, Fleming, Kendall & Shum, 2010; Sohlberg & Turkstra, 2011) were reviewed to inform the CCRC intervention. Key adult learning principles and motivators (Knowles, Holton & Swanson, 1998) were also reviewed and applied to the development of the intervention (see Results, Table 3).

(iii) Consumer feedback: Consumer and client views were investigated via a consumer advisory group, with feedback from the group incorporated into the development of the new CCRC intervention. The group comprised four consumers – an adult with ABI and their partner and two experienced ABI SLP clinicians. The group met twice to provide information and feedback on this study; communication with the group occurred via email and telephone.

Prior to the meetings, the information to be discussed was emailed to the group. The information provided was written for a lay audience, and phone support was offered to the consumer with ABI and their family member prior to the meetings to go through the information. During the meetings, communication strategies were used to maximise the participation of the consumer with ABI. These included the use of written and verbal information, repetition of information, rephrasing, summarising the discussion and giving increased time for discussion and responses.

In the first meeting, the group provided feedback and information on their perspectives of participating in sub-acute ABI rehabilitation, barriers and facilitators to rehabilitation, CCRC interventions, involvement of family in therapy and the overall study design. In the second meeting, the group provided feedback on the newly developed CCRC intervention and service delivery model.

The key findings from phase 3 that influenced the development of the CCRC intervention are presented in the Results section (see Table 3).

*Phase 4: Intervention development*

Findings from phases 1–3 were combined to form an intervention and service delivery model for sub-acute SLP management of CCRC deficits that was evidence based and able to be delivered under current clinical service models and caseload constraints (see Fig. 2). The resulting CCRC intervention and service delivery model are presented in the Results section, with the components described according to the Rehabilitation Treatment Specification System (Hart *et al.*, 2019; Turkstra, Norman, Whyte, Dijkers & Hart, 2016; Van Stan *et al.*, 2019), see Appendix 2.

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**Table 3.** Phase 3 Findings used in CCRC Development

| Phase 3: Evidence base (theory, guidelines, principles) and consumer/client views | |
|---|---|
| (i) Cognitive rehabilitation theories | |
| **Key findings influencing CCRC development and applied to CCRC intervention** | |
| Systematic instruction (Sohlberg & Turkstra, 2011)<br>– Uses explicit instruction and error minimisation to aid acquisition<br>– Practice to mastery; engage the learner<br>– Combined approach: direct instruction plus strategy-based instruction<br>– Metacognitive strategy training supported for cognitive rehabilitation | |
| Contextualised cognitive rehabilitation (Ylvisaker, 2003)<br>– Client goal-directed therapy<br>– Impairment and functional activities using personally relevant stimulus<br>– Task-specific training plus strategies<br>– Generalisation of skills from the commencement of treatment | |
| Principles of experience-dependent neuroplasticity in ABI rehabilitation (Kleim & Jones, 2008; Sohlberg & Turkstra, 2011)<br>– Minimise interference by training new skills individually and consecutively<br>– Use stimuli that are specific, mirror the task and context, are meaningful and personally relevant (i.e. salient activities)<br>– Address repetition, intensity and transference of new skills by frequent and intensive practice with generalisation tasks included in the intervention | |
| (ii) Practice guidelines and adult learning principles | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Facilitate learning via self-evaluation and awareness (Ehlhardt *et al.*, 2008; Kennedy *et al.*, 2008; Knowles *et al.*, 1998) | Incorporate self-evaluation into treatment: via questioning, self-reflection and use of a metacognitive self-checking strategy *'have I understood it?'* |
| Person centred intervention that uses individualised items and recognises previous literacy skills (Togher *et al.*, 2014) | Acknowledge previous reading skills in treatment planning and stimulus selection; individualise reading tasks and stimulus |
| Use of direct instruction methods plus strategies (American Speech-Language-Hearing Association, n.d.; Togher *et al.*, 2014) | Explicit teaching of reading strategies, with massed practice to mastery |
| Use of compensatory strategies and metacognitive skills (American Speech-Language-Hearing Association, n.d.; Kennedy *et al.*, 2008; Ownsworth *et al.*, 2010; Sohlberg & Turkstra, 2011; Togher *et al.*, 2014) | Strategy use is supported; use metacognitive self-checking strategy plus reading strategies |
| Use family members and independent practice tasks to aid generalisation (American Speech-Language-Hearing Association, n.d.; Togher *et al.*, 2014) | Involve family in therapy and independent practice |
| Use adult learning principles and motivators (Knowles *et al.*, 1998) | Incorporate principles and motivators into intervention design: Identify and acknowledge previous reading skill and experiences; select practical, relevant reading materials that are related to reading goals, interesting and motivating; encourage self-directed practice via individualised tasks and materials; structure treatment to result in client independence / autonomy with reading strategy use; use a collaborative approach to ensure mutual respect |
| (iii) Consumer feedback (external advisory group) | |
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Involve family/significant others in all aspects (e.g. assessment, therapy) | Request family involvement in all aspects of intervention and service delivery: assessment, goal setting, therapy, practice |

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**Table 3.** (*Continued*)

| (iii) Consumer feedback (external advisory group) | |
|---|---|
| **Key findings influencing CCRC development** | **Application to CCRC intervention** |
| Consider needs at home, and link reading goals to discharge goals | Individualise treatment stimulus to address identified needs at home/for discharge |
| Provide written information about: the treatment, goals, future therapy times/sessions, success with therapy tasks | Provide written information for client and family about the entire intervention process, ensure good communication and regular updates |
| 'More' therapy, want 3–5 sessions per week | Service delivery intensity: 3+ sessions per week; intensive therapy programme |
| Better environment (on ward) to complete independent practice | Identify suitable, quiet areas for practice tasks |

ABI, acquired brain injury; CCRC, cognitive-communication reading comprehension.

## Results

### *Developing the CCRC intervention (phases 1–3)*

Key findings from phases 1–3 that influenced the development of the CCRC intervention are presented in Tables 1–3.

### *Developing the CCRC intervention (phase 4)*

The methodology was successfully applied to develop a new CCRC intervention that aims to improve discourse-level reading comprehension for texts of increasing complexity and length, using a service delivery model and treatment schedule that can be implemented by SLP clinicians as part of their rehabilitation practice in early or sub-acute rehabilitation (i.e. <6 months post onset).

### *Description of the CCRC intervention components*

The intervention is a multiple-strategy reading intervention. It uses content, visual and metacognitive strategies: identifying key points/wh strategy (strategy identifying who, what, where, when, why and how); summarising information; underlining/highlighting key information and self-checking – asking 'Have I understood it?'.

The intervention involves three hierarchical reading levels: basic functional reading, longer factual reading, and inferential reading, with hierarchical progression of reading complexity and text length between levels. Stimulus materials are personalised, address functional tasks and activities for the home and community and relate to client goals.

### *Treatment process*

*Level 1: Basic, functional reading comprehension*

Strategies are taught individually and sequentially commencing with identifying key ideas/identifying wh information, underlining, summarising and lastly self-checking. Strategies are taught via direct, explicit instruction and practiced on basic factual reading materials, with massed practice occurring in 1:1 sessions and via independent practice tasks. Each strategy is practiced to emerging mastery and client confidence with the strategy. Fading cues, client self-reflection and self-rating of confidence, massed practice in therapy activities and independent practice tasks and talk-aloud procedures when applying the strategies are used to aid strategy acquisition, future mastery and generalisation. Once all strategies have been learned and practiced, and comprehension accuracy for basic factual reading stimulus is high (≈80%), and the intervention progresses onto the next level of reading (i.e. longer, factual reading).

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*Level 2: Longer, factual reading comprehension*

This stage of the intervention aims to increase participants' independence and confidence in strategy application, for longer factual information. The clinician continues to use fading cues, client self-reflection and self-rating, and massed practice to aid accurate strategy application and mastery. Additional self-cues (e.g. written prompts, internal rehearsal) can be utilised as required. Progression to level 3 occurs when reading comprehension accuracy is ≈80% for the stimulus, and increased independence, accuracy and confidence with strategy application are demonstrated.

*Level 3: Inferential reading comprehension*

The final stage of the intervention involves inferential reading of complex, lengthy text. Ideally, the client will be generalising strategy use and require minimal prompts and cues to accurately apply the strategies. If specific difficulties in inferencing are identified, cognitive-communication strategies and activities that promote complex processing, problem-solving, reasoning and comprehension will be utilised during the intervention (e.g. discussion, how and why questions, identifying themes and argument structures).

### Service delivery model

The intervention will be provided via 1:1 sessions with an SLP, use independent practice tasks and involve family members where possible. The proposed intervention dosage is 3–4 sessions per week, over 4–6 weeks.

### Participant characteristics

The intervention is designed for clients with CCRC deficits at a paragraph level or above, who have: functional pre-morbid literacy skills; functional visual and visual processing skills; the ability to learn and apply strategies and modify their behaviour; access to a longer period of intensive, early rehabilitation and use English as a primary means for communication or vocation. Exclusion criteria include a diagnosis of aphasia, an active psychiatric illness, severe cognitive impairment or a post-traumatic amnestic state impacting their ability to participate in the rehabilitation program.

### Intervention description via the rehabilitation treatment specification system

The Rehabilitation Treatment Specification System (Hart *et al.*, 2019; Turkstra *et al.*, 2016; Van Stan *et al.*, 2019) has been applied to further describe and categorise the components of the intervention and service delivery model, and aid specificity of reporting. This involved identifying the intervention targets, active ingredients, dosage, group and relevant treatment theory. This is presented in Appendix 2.

### Outcome measures

Both core and supplemental outcome measures are planned as part of the intervention evaluation. Core outcome measures will be used to identify changes in reading comprehension across different levels of text and involve both formal and informal measures of reading comprehension. Formal assessment of discourse-level reading comprehension occurs pre-/post-intervention and at follow-up (3+ months) to objectively identify and monitor changes to reading comprehension skills. The Gray Oral Reading Test (Wiederholt & Bryant, 2012) was chosen as it assesses reading skills from primary to tertiary-level readers and accommodates short time frames for test/retest; other assessments used in this population include the Nelson Denny Reading Test (Brown, Fishco & Hanna, 1993) and the Discourse Comprehension Test (Brookshire & Nicholas, 1997). Informal comprehension assessment occurs continuously during the intervention, with the dual purpose of identifying clients' performance on therapy stimuli tasks (i.e. percentage correct on comprehension questions) and identifying amount of support required to apply strategies

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(i.e. level of strategy mastery). Outcome measures have been designed specifically for the *n*-of-1 pilot study (multiple-baseline single-case experimental design), which involve the use of 'probe' reading comprehension assessments at each level of the reading intervention. Supplemental outcome measures include formal assessment of CCD function across the ICF via the Australian Therapy Outcome Measures for Speech Pathology (Perry & Skeat, 2004); a measure of reading comprehension activity from the Rehabilitation Institute of Chicago's Functional Assessment Scale (Heinemann, 1993); and self-perceived overall communicative functioning through the Latrobe Communication Questionnaire (Douglas, O'Flaherty & Snow, 2000).

## Discussion

This study has utilised a novel approach to identify and develop contextually relevant evidence by combining qualitative and quantitative data with information from clinical frameworks. This pragmatic approach has resulted in the development of an intervention that is evidence based (utilising available evidence) and designed for a specific early rehabilitation context. Given the emerging nature of the evidence for CCRC interventions, multiple models and systems have been utilised to guide intervention development directly facilitated by the methodology.

A multiple-strategy intervention was developed. Multiple-strategy-based CCRC interventions have only been investigated in chronic ABI populations; however, their use in early ABI rehabilitation is supported. Findings from phase 2 of this study identified that strategy use for CCRC deficits during sub-acute rehabilitation is high (100% SLPs) and is clinically higher than reported in the literature (Watter *et al.*, 2016). Strategy-based interventions are regularly provided in ABI rehabilitation, and reading-strategy interventions have been reported in the literature for over 30 years (Watter *et al.*, 2017). The developed intervention and service delivery model may be suitable for clients with specific CCRC goals for discharge, who have the ability to learn and apply strategies and moderate their own behaviour and have access to a longer period of early rehabilitation (e.g. 4–6 weeks).

The intervention has a focus on deliberate strategy instruction and strategy acquisition to mastery, across increasingly difficult levels of text. Within the systematic review (Watter *et al.*, 2017), non-significant gains in reading comprehension were reported in four of the five solely strategy-based studies identified. The study where reading comprehension gains were not identified for people with ABI occurred over a sole session and did not explicitly focus on strategy learning and acquisition/mastery (Sohlberg *et al.*, 2014). The paper's authors identified the lack of systematic training of strategies as a potential factor impacting performance and reading comprehension; other studies have also highlighted the need and importance of systematic strategy instruction for CCRC rehabilitation (Griffiths *et al.*, 2015). As such, the use of explicit strategy instruction (for acquisition to mastery) is supported. Massed practice of strategies to mastery should provide the best chance of generalisation and future (post-hospital) use, as compared with only providing education or limited practice for strategies. It is anticipated that the final level of reading in this treatment may require increased time and practice for inferencing skills.

It is hypothesised that this intervention will also be applicable to different CCRC severities and presentations during early rehabilitation. Strategy-based interventions have been used with chronic individuals with significant (i.e. paragraph level) reading deficits to mild, high-level CCRC deficits (i.e. inferencing deficits, difficulties with university-level reading); reading stimuli have ranged from functional phrase reading to chapter-level reading of academic texts (Watter *et al.*, 2017). In applying this intervention, clients with more severe CCRC deficits (e.g. reading comprehension at a primary school level) or more severe cognitive deficits may benefit from the use of errorless learning in strategy teaching and may not progress to lengthy or more complex texts. Clients with higher level CCRC deficits (e.g. difficulties with complex, lengthy text) may progress quicker through the reading hierarchy or may not require progression through all three levels of the intervention. These clients should still learn strategies on a simpler level of reading

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before applying them to more complex materials, to reduce the overall cognitive load for the task. Providing specific intervention details via the Rehabilitation Treatment Specification System (Hart *et al.*, 2019; Turkstra *et al.*, 2016; Van Stan *et al.*, 2019) may aid in increasing the applicability of this intervention outside of early rehabilitation. This intervention may also translate outside of Australian rehabilitation contexts to countries where rehabilitation is provided according to similar rehabilitation structures and principles, including longer periods of early rehabilitation. This is an identified future direction of this study.

This methodological approach may be useful in other clinical areas with varied levels of evidence and contextual constraints, and in areas where typical quantitative research paradigms are difficult to implement. Utilising data gathered from clinicians and consumers regarding treatment and context for intervention development increases the likelihood of translation from theory to clinical practice. A limitation of this study is the small number of consumers and stakeholders involved. Additional or different feedback may have been gained if more consumers had been included in the study. Currently, consumer feedback on participation and experience with the developed intervention is not available; however, this is included in a future phase of this study. A limitation of this methodology is its novel approach; its actual translation and application to other contexts of populations are unknown.

## Conclusions

The MRC's guidelines for developing and evaluating complex interventions, plus principles from knowledge translation and implementation science, have been applied alongside the best available evidence in a pragmatic clinical framework to develop an intervention and service delivery model for sub-acute CCRC deficits, for a specific, contextualised clinical setting (i.e. Australian sub-acute ABI rehabilitation). This method may be applied in other clinical areas with varied levels of evidence and contextual constraints and in areas where typical quantitative research paradigms are difficult to implement.

The next step of this research is to investigate the treatment during early rehabilitation via a series of experimental single-case (*n*-of-1) studies with consumer feedback and interviews (Watter, Copley & Finch, 2020). Following this, step four of the MRC's guidelines (Craig & Petticrew, 2013) (implementation) can commence, via disseminating intervention findings, conducting longer monitoring and conducting future research to replicate findings across populations and settings. Future directions also include formally evaluating the subsequent implementation of the complex intervention by applying stages 2 (feasibility and piloting) and 3 (evaluation) of the CReDICI 2 guidelines (Mohler *et al.*, 2015); and implementing the intervention outside the context of Australian rehabilitation services.

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**Conflict of interest.** None.

**Ethical standards.** The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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## Appendix 1: Key Models and Principles Underpinning the Pragmatic Clinical Framework

| Models and principles | Key features utilised to inform intervention development |
|---|---|
| Medical Research Council's (MRC) guidelines for developing and evaluating complex interventions:<br>• Craig *et al.* (2008)<br>• Craig & Petticrew (2013) | Four key phases: development, feasibility/piloting, evaluation and implementation<br>• Development: identify evidence and knowledge base; conduct systematic review if minimal evidence; identify/develop theoretical basis for intervention; recognise importance of context in intervention design<br>• Feasibility/Pilot: identify and acknowledge context and factors that may impact intervention in the target setting (delivery, acceptability, use); support RCT alternatives including pilot studies, *n*-of-1 trials<br>• Evaluation: Use a range of measures to assess multiple outcomes, including intervention effectiveness and effectiveness in everyday practice, to identify 'active ingredients' of the intervention and to understand change processes<br>• Implementation: dissemination of findings, monitoring/surveillance/long-term follow-up and replication across populations/settings |

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Appendix 1: (*Continued*)

| Models and principles | Key features utilised to inform intervention development |
|---|---|
| Knowledge Translation and Implementation Science principles<br>• Curran *et al.* (2012)<br>• Douglas *et al.* (2015)<br>• Fixsen *et al.* (2005)<br>• Olswang & Prelock (2015) | • Evidence base: Identify and address perceptions of evidence of those involved in intervention development (e.g. clinicians, clients)<br>• Intervention design and development: considerations for new interventions<br>○ contextual factors: knowledge of site, setting and service<br>○ intervention characteristics: ability to apply intervention in practice (manageable, acceptable)<br>• Evaluation: mixed-methods hybrid design – investigate intervention effectiveness via quantitative methods; also investigate aspects relevant to implementation success (barriers, facilitators, feasibility and acceptability). |
| Intervention development models<br>• Curran *et al.* (2008)<br>• Fraser & Galinsky (2010)<br>• Gitlin (2013) | • Evidence base: also consider theory and practice guidelines; clinician factors and clinical knowledge; consumer input<br>• Integrate users and stakeholders into the treatment development (methodology) for information on consumer preferences<br>• Intervention design and development: considerations for new interventions<br>○ context – knowledge of site, setting and service, complexity of environment, organisational factors and barriers<br>○ influence success of intervention adoption (to practice) – identify barriers and facilitators to practice and assist staff to implement and contextualise interventions to the local service<br>• Evaluation: Investigate intervention acceptance and use via qualitative research |
| Evidence-based practice models<br>• American Speech-Language-Hearing Association (2005)<br>• Dollaghan (2007)<br>• Hoffman *et al.* (2017)<br>• Sackett *et al.* (2000) | Consider evidence across a range of domains to inform clinical decisions and management when providing services to clients; four types of evidence to consider:<br>• Research evidence, including formal published literature ('external evidence'); consider published evidence from a range of sources including texts, web-based information, education/professional development information<br>• Clinical reasoning and expertise and evidence from clinical practice ('internal evidence')<br>• Patient values, preferences and circumstances, including family wishes and needs from informed clients/families ('client preferences')<br>• Context – can include clinical context, service delivery context, context of client/family situation and future situation |

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## Appendix 2: Applying the Rehabilitation Treatment Specification System (Van Stan et al., 2019) to the CCRC Intervention and Service Delivery Model

| Treatment theory | Targets: What/in what way | Group | Active ingredients | Dosage |
|---|---|---|---|---|
| Cognitive rehabilitation theory<br>Reading comprehension theory<br>Behaviour change and adult learning theory | • Knowledge of CCRC, reading strategies and their use | Representation | • Client education and information (verbal and written) | • At the start of program<br>• Ongoing education in sessions |
| | • Independently apply reading strategies to written information at different levels of complexity<br><br>(Strategies: identify main ideas; identify wh information; highlight/underline key information; summarise; self-check: 'have I understood') | Skills and habits | • Manualised treatment<br>• Hierarchical strategy acquisition, with practice (minimum two texts) and accuracy targets (80%) for future strategy introduction | 3–4 sessions per week; 4–6 weeks. Minimum 5 sessions per reading level; additional sessions as required. |
| | | | • Explicit, direct instruction<br>• Massed practice with talk-aloud procedures (verbalise strategy use) + home practice tasks to aid generalisation with personalised stimulus | • Program start + ongoing<br>• Each session + homework post session |
| | | | • Initial immediate and specific feedback on task performance; reducing feedback as accuracy and self-monitoring increases | • Each session, reduce dependent on performance |
| | | | • Use of verbal and visual prompts, with fading cues | • As above |
| | | | • Activities and cues to aid self-awareness and self-checking | • Each session |
| | | | • Discussion, questioning, self-reflection and self-rating | • As above, increases during Tx |
| | | | • Accuracy targets for comprehension (80%) for hierarchical treatment (moving between three levels of reading complexity: functional, factual and inferential reading) | • Throughout Tx |
| | | | • Use of cognitive-communication strategies and activities that facilitate complex comprehension and processing, if required | • As required, likely towards the end of program |

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Appendix 2: (*Continued*)

| Treatment theory | Targets: What/in what way | Group | Active ingredients | Dosage |
|---|---|---|---|---|
| | • Family support for CCRC intervention application/ practice | Skills and habits | • Client and family education and information (verbal and written)<br>• Family participation in therapy and practice tasks where possible – observation of intervention sessions and feedback; involved via phone calls, meetings, written feedback/ information | • At the start of program + ongoing<br>Family involvement as able in sessions + as able for home practice tasks |
| | • Self-awareness of RC and strategy use, and confidence with strategy use<br>• Use recommended strategies outside of therapy to read identified written information | Representation | • Client and family education and information (verbal and written)<br>• Activities and cues to aid self-awareness and self-checking<br>• Discussion, questioning, self-reflection and self-rating<br>• Explicit, direct instruction<br>• Initial immediate and specific feedback on task performance; reducing feedback as accuracy and self-monitoring increases<br>• Use of verbal and visual prompts, with fading cues<br>• Massed practice with talk-aloud procedures (verbalise strategy use) + home practice tasks to aid generalisation, with personalised stimulus | • Program start + ongoing<br>• Each session<br>• As above, increases during Tx<br>• Program start + ongoing<br>• Each session, reduce dependent on performance<br>• As above<br>• Each session + homework post session |
| | • Family knowledge of intervention and strategies | Representation | • Client and family education and information (verbal and written)<br>• Family observation of intervention sessions and feedback; family involvement via phone calls, meetings, written feedback/information | • At the start of program + ongoing<br>• Family involvement as able in sessions + as able for home practice tasks |

Key: ABI: acquired brain injury; CCRC: cognitive-communication reading comprehension; RC: reading comprehension; Tx: therapy

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