Submitted in partial fulfilment of the Lancaster University Doctorate in Clinical Psychology

Doctoral Thesis

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study

Emma Fowler

Division of Health Research, Lancaster University

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Word Count

	Main Text	Appendices (inc. tables, references, abstracts, footnotes and title pages)	Total
Thesis abstract	297		297
Literature review	6995	17379	24374
Research paper	7998	6668	14666
Critical appraisal	2890	839	3729
Ethics section	5997	3468	9465
Total	24474	28354	**52828**

Thesis abstract

This thesis comprises a systematic literature review, an empirical paper and a critical appraisal. A systematic review of quantitative studies examining the efficacy of cognitive interventions to improve decision-making in people with Mild Cognitive Impairment (MIC) was conducted. Twenty-six papers were identified. Results indicate that interventions to improve decision-making in people with MCI can be effective. Most studies tested interventions designed to improve higher-order thinking skills, or executive functions, that are thought to underpin decision-making. Of these, interventions targeting logical reasoning, cognitive control and inhibition demonstrated the best results. Risk of bias arising from poor quality research design or reporting affected most studies. Consequently, it was not possible to draw clear conclusions about the efficacy of particular interventions at this time. Implications and recommendations for research are discussed.

The empirical paper explores the feasibility of using a capacity assessment tool designed to support remote working during the COVID-19 health crisis. Views were gathered from eight participants either through online focus groups or online individual interviews. Data from transcribed discussions, notes taken by a focus group assistant and notes from focus group debrief sessions between the researcher and focus group assistant were analysed using thematic analysis. Findings indicate that the tool is perceived to be feasible for use in practice and merits additional research. The assessment tool was praised for its structure and for prompts, questions and examples that enabled participants to obtain useful data in a pressurised context. Clinical implications are discussed and recommendations for research are outlined. The critical appraisal section offers reflections on the process of undertaking research into mental capacity and decision making. Ethical, philosophical and practical benefits and challenges are explored. The experience of

undertaking research during a significant health crisis is examined and recommendations made for future applied research in these areas.

Declaration

This thesis documents research undertaken between September 2019 and August 2020 in partial fulfilment of the Doctorate in Clinical Psychology at Lancaster University. The work presented is my own except where references to other authors are made. The work has not been submitted for the award of a higher degree elsewhere.

Name: Emma Fowler

Signature:

Date:

Acknowledgements

I would like to thank the participants who gave generously of their time in the context of significant professional challenges. Thank you to my supervisors, Dr Guillermo Perez Algorta, Dr Janice Mackenzie, Dr Anna Duxbury and Dr Suzanne Hodge whose advice, ideas and encouragement have been invaluable in completing this work. Finally, thank you to my friends and family for their love, wise words, practical help and their belief in both me and this project. Thank you.

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Chapter 1

Section One: Systematic Literature Review

Neuropsychological interventions to support complex decision-making in people with mild cognitive impairment: A systematic review

Word count: 6995

Emma Fowler

Doctorate in Clinical Psychology
Division of Health Research, Lancaster University

All correspondence should be addressed to:
Emma Fowler, Doctorate in Clinical Psychology, Division of Health Research, Faculty of Health and Medicine, D Floor, Health Innovation One, Sir John Fisher Drive, Lancaster University, LA1 4AT.
Email: e.l.fowler@lancaster.ac.uk
Prepared for submission to *Neuropsychology Review*[1]

[1] Please note this manuscript was prepared in line with author guidelines for *Neuropsychology Review* (See Appendix 1-I). Where these guidelines have not been followed, most notably the word count, Lancaster University thesis guidelines have.

Abstract

This systematic review evaluated interventions designed to improve complex decision-making skills. A systematic search of four databases was undertaken. Papers were included if they had a quantitative design, were published in English, peer reviewed, related to people over 18 with mild cognitive impairment and included neuropsychological interventions to improve complex decision-making or closely aligned executive functions. The Revised Cochrane Risk-of-bias tool for randomized trials (RoB 2) and the Risk of Bias in Non-randomised Studies (ROBINS-1) tools were used to assess the quality of each study with the exception of one publication for which the single-case design tool by Lobo et.al. (2017) was used. The final review included 26 studies. Limited randomization strategies, insufficient reporting of confounding variables and the exclusion of missing participant data from analyses were the most frequent quality concerns. Results indicated that using cognitive training to improve complex decision-making is effective regardless of whether it is delivered individually or in a group. Associated executive functions of logical reasoning, cognitive control and inhibition achieved the most significant results. However, there is insufficient evidence at this time to recommend a particular intervention to clinicians and health services. Directions for future research and implications for clinical practice are discussed.

Keywords: Mild cognitive impairment, decision-making, intervention, executive function, cognition, neuropsychology

Neuropsychological interventions to support complex decision-making in people with mild cognitive impairment: A systematic review

Mild cognitive impairment (MCI) is a heterogeneous condition that can represent clinically significant cognitive impairment but does meet the criteria for dementia (Morris et al., 2001; Petersen et al., 2001). There is broad consensus that there are three sub-types of MCI: a) Amnestic MCI (aMCI), defined as a clinically significant impairment in short-term memory and learning; b) Non-amnestic MCI, where deficits are observed in domains like planning, problem-solving and reasoning (usually described as executive functions) and c) multi-domain MCI that may or may not include a memory impairment (Collie & Maruff, 2000; Diamond, 2013; Grober & Kawas, 1997; Petersen, 2011).

MCI is more prevalent in older people, with estimates of six to 16% of people over 65 being affected. Prevalence rates can double in people over 80-years-old (Manly et al., 2008; Petersen et al., 2010; Plassman et al., 2009). In terms of MCI sub-types, aMCI is considered more common than non-amnestic MCI but some authors have found parity across sub-types in research samples (Busse et al., 2006; Manly et al., 2008)

Decision-making and MCI

Decision-making involves the analysis of internal and external states, evaluation of the different options available and selecting a course of action (Morgado et.al., 2015). Complex decision-making is typically defined by differing amounts of risk associated with the options or ambiguity about the consequences of choosing one option over another (Hsu & Willis, 2013). In health care, decisions that include risks or ambiguity can include choosing a course of treatment, deciding whether to have rehabilitation after an injury or whether to pay for care and support at home after leaving hospital. Whilst rational and intuitive processes may be activated when making complex decisions under risk or ambiguity, it is thought that more optimal outcomes are likely when rational processes are privileged (Evans, 2003;

Schiebener & Brand, 2015). Moreover, there is evidence to indicate that rational processing correlates with higher order skills, or executive functions, such as inhibition, cognitive flexibility, cognitive control, reasoning and working memory (Brand, 2008; Brand et al., 2014; Derbyshire et al., 2014; Earnst et al., 2001; Gupta et al., 2009; Sinz et al., 2008; Stanovich & West, 1998; West & Stanovich, 2003). Nevertheless, heterogeneity in research designs and methodology makes it difficult to compare and sythesise findings across the literature.

In relation to MCI, extant research indicates that people are more likely to use inconsistent strategies in complex decision-making, which may reflect reduced reasoning skills compared to age matched control groups (Delazer et al., 2007). There is also evidence that intuitive decision-making processes are more heavily relied on in this population (Delazer et al., 2007). This could be accounted for, in part, by reduced number processing abilities, cognitive control and inhibition, all of which can be affected in people with MCI and are considered important for complex decision-making (Delazer et al., 2007; Griffith et al., 2003; Jasper et al., 2013; Niccolai et al., 2017; Okonkwo, Griffith, Belue, et al., 2008; Okonkwo, Griffith, Copeland, et al., 2008; Okonkwo et al., 2006; Pertl et al., 2015, 2017; Zamarian et al., 2010; Zamarian et al., 2011).

Evidence for Interventions

Research aiming to mitigate the impact of MCI has traditionally focused on compensatory strategies, such as the use of memory aids (Mewborn et.al., 2017; Davies et.al., 2019). Other studies have examined individual factors that could affect cognition, such as mood, lifestyle and sense of purpose (Davies et al., 2019; Geda et al., 2010; Larouche et al., 2015; Strough et al., 2015). As evidence emerges of preserved neuroplasticity in people with MCI, there is growing interest in developing neuropsychological interventions that can maintain or preserve cognitive function (Dinse, 2006; Fotuhi et al., 2016; Mahncke et al., 2006; Simon et

al., 2012). MCI may offer a unique window for this type of cognitive remediation as interventions seem to achieve better results in people with MCI than in people whose impairment has progressed to a dementia (Belleville et al., 2011; Requena et al., 2006; Simon et al., 2012).

Most cognitive interventions have focused on maintaining or improving short-term and working memory (Jean et al., 2010). Results indicate that memory interventions can be effective in improving day-to-day skills in all types of MCI (Gates et al., 2011; Jean et al., 2010). Moreover, interventions designed to train aspects of memory may be more effective, at least in the short-term, than memory strategies, such as mnemonics (Gates et al., 2011). In addition, there is growing evidence that improvements in function correlate with the development of neural networks, lending support for theories of neuroplasticity in people with MCI (Miotto et al., 2018).

More recent studies have provided compelling evidence that cognitive domains other than memory can be improved in for people with MCI (Barban et al., 2016; Sherman et al., 2017; Yang et al., 2020). Moreover, a number of reviews indicate that interventions facilitated by a therapist can be more likely to result in improvements in functional skills, such as complex decision-making (Basak et al., 2020; Chandler et al., 2016; Sherman et al., 2017; Zhang et al., 2019).

Mixed Findings and Areas of Limited Knowledge

Whilst interventions for people with MCI have been shown to be effective, reviews indicate that positive outcomes may only achieve statistical significance in half to three-quarters of participants (Gates et al., 2011; Jean et al., 2010) Furthermore, effect sizes for cognitive interventions have varied widely and gains have not always generalised to other functional domains (Gates et al., 2011; Jean et al., 2010; Sherman et al., 2017). Moreover, the extent to which specific cognitive skills relate to functional abilities like decision-making

in people with MCI remains an incomplete picture (Verdejo-Garcia et.al., 2009; Verdejo-Garcia et.al., 2019). Extending MCI research in this area is likely to be important for health services, given that difficulties in complex decision-making have been associated with reduced everyday functioning and poorer health outcomes (Aretouli & Brandt, 2010; Cameron et al., 2010; Gauthier et al., 2006; Marson, 2001). Accordingly, a clearer indication of the types of cognitive interventions that could support complex decision-making abilities in people with MCI may help to maintain both their independence and wellbeing.

Addressing Gaps in Research and Practice: A Health Perspective

The National Health Service (NHS) has been clear that supporting patients through effective leadership and the implementation of best evidence is a priority for the organisation (NHS Leadership framework, 2011). Clinical psychologists are well placed to support this agenda through research and the translation of research to practice (Clinical Psychology Leadership Development Framework, 2010). An examination and synthesis of the literature is timely, as the last decade has seen an increase in studies aiming to improve complex decision-making in a range of clinical populations including MCI (Boot et al., 2008; Mudar et al., 2017; Zamarian et al., 2019).

Early reviews into cognitive interventions for MCI expressed concern about the quality of research designs and found limited evidence for the generalisation of trained skills to other abilities (Boot et al., 2011; Jean et al., 2010). However, Sherman (2017) suggests that, in the last decade, many of the earlier criticisms have begun to be addressed and that the time is right to re-examine the utility of current research findings for client wellbeing.

The Aim of the Review

The review will contribute new knowledge to the field by evaluating and comparing interventions designed either to maintain or improve complex decision-making in people with MCI or the cognitive functions that support it. To help to achieve this aim, the review will

also synthesise theory and research into the cognitive correlates of complex decision-making in MCI. The initial hypothesis is that cognitive interventions specifically designed to support complex decision-making will produce the best results.

Accordingly the research question for this review will be:

What neuropsychological interventions are effective in improving or maintaining complex decision-making skills in people with Mild Cognitive Impairment?

Different language is used in the neuropsychological literature to describe similar processes relating to complex decision-making. Some descriptions are used interchangeably, however there is some consensus on definitions (Capucho & Brucki, 2011). For this review, a "complex decision" is defined as encompassing the process of choosing a course of action under risk or ambiguity and is distinguished from "reasoning", which is taken to mean the process of weighing the benefits and risks of the available options (Chapman & Mudar, 2014; Toplak et al., 2010).

Twelve reviews have been undertaken in the last decade that refer to some of the studies included in this review. These reviews reference fourteen of the twenty-six studies examined in this review. However, several related reviews either did not specify the focus of the intervention or focused exclusively on memory abilities (Chandler et al., 2016; Cooper et al., 2013; Jean et al., 2010; Jeong Hong et al., 2015; Preobrazhenskaya et al., 2019; Rodakowski et al., 2015; Sherman et al., 2017; Wang et al., 2014). Other reviews were concerned with examining or comparing intervention formats, such as computerised games, whilst others were focused on different clinical populations or outcomes other than complex decision-making abilities (Basak et al., 2020; Gates et al., 2011; Miotto et al., 2018; O'Shea et al., 2019). None of the reviews examined questions specific to interventions aimed at maintaining or improving complex decision-making or closely aligned cognitive processes.

Methods

Search Strategy

This review adheres to the principles outlined by the Centre for Reviews and Dissemination and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement for the undertaking and reporting of systematic literature reviews (a completed PRISMA checklist can be seen in Appendix A) (Liberati et al., 2009). Following scoping searches, four databases (PsychInfo, Medline, Embase and Web of Science) were searched for relevant published literature from their inception until July 2020. The PubMed database was also searched for the preceding twelve months to identify papers that might be awaiting categorisation. These databases were selected as they balanced clinical and inter-disciplinary sources and, in combination, covered the widest number of relevant publications (Falagas et al., 2008).

The search strategy, created in consultation with a specialist librarian, contained no methodological key words that might have limited results to specific designs. The approach employed thesaurus terms alongside a set of free text words and phrases, informed by relevant theory and literature (see Appendix B for the complete search syntax). For instance, the literature was synthesised to identify executive functions that are associated with complex decision-making in people with MCI. Whilst there was some heterogeneity in research designs, the synthesis established that: Cognitive flexibility, cognitive control, reasoning, monitoring of decision strategies over time, risk calculation, planning, problem-solving, cognitive fluency and working memory are associated with optimal decision-making under risk or ambiguity (Brand, 2008; Brand et al., 2014; Delazer et al., 2007; Griffith et al., 2003; Jasper et al., 2013; Schiebener & Brand, 2015; Niccolai et al., 2017; Okonkwo, Griffith, Belue, et al., 2008; Okonkwo, Griffith, Copeland, et al., 2008; Okonkwo et al., 2006; Pertl et

al., 2015, 2017; West & Stanovich, 2003; Zamarian et al., 2010; Zamarian et al., 2011). Accordingly, these abilities were included in the search.

In addition, the most commonly used outcome measures were also identified and included in the search. The way that complex decision-making is measured varies widely (Okonkwo, Griffith, Belue, et al., 2008). Nevertheless, tests like the Iowa Gambling Task, Cambridge Gambling Task and the Health Related Ratio Processing task represent some of the more common tasks employed in research (Brand et al., 2006; Jacus et al., 2018; Lipkus et al., 2001).

Scoping searches also indicated considerable heterogeneity in tests used to measure executive functions that are aligned to decision-making (Kortte et al., 2002; Robertson et al., 1994). For instance, there was no unified approach in the measurement of cognitive control; tests for this ability ranged from the Trails Test (version B) (TMT), The TMT Version B-A, the Stroop Colour-Word Test and the Test of Everyday Attention (TEA) (Barban et.al., 2016; Boripuntakul et al., 2012; Donnezan et.al., 2018; Gagnon et.al., 2012). Moreover, some studies examining the effect of interventions on complex functions appeared only to employ tests of simple cognitions, such as the Digit Span Forward (Ostrosky-Solís & Lozano, 2006). An Excel spreadsheet was created to capture the range of tests used.

An experienced clinical neuropsychologist was asked to review the list and revisions were made in line with their feedback to improve the relevance and accuracy of the search. Some tests of simple cognition were included to ensure a broad search. However, papers that included no tests typically understood to measure relevant executive functions were ultimately excluded. The final list was included in the search terms.

Having tested the search strategy for specificity and sensitivity, search syntax were applied to titles, abstracts and full texts within the databases. Citation chain searches included hand

searches of reference lists and forward searches in Google Scholar to identify additional papers. A final search was undertaken on 15th July 2020.

Screening and Selection

Citation results were exported to EndNote. A screening of titles and abstracts established their relevance to the review. The full texts of potentially relevant studies were obtained and reviewed. Initial and in-depth screening was undertaken against a tool developed for the study, which was informed by the Patient Intervention, Comparison and Outcome (PICO) framework (see Appendix C) (Stillwell et al., 2010). Ten percent of potentially relevant studies (six) were inter-rated against the inclusion criteria by a fellow student in the final year of a doctorate in Clinical Psychology programme. A consensus decision was taken after discussing any disagreement in detail.

Studies were included if they: a) were published in English; b) peer reviewed; c) related to adults over 18 years without a diagnosis of a mental health difficulty or neuropsychological condition other than MCI that could affect cognition; d) included interventions that aimed to maintain or improve complex decision-making skills or the executive functions that are indicated as most likely to underpin this ability; e) included any quantitative measure of complex decision-making or relevant executive function and f) had a quantitative design.

Data Extraction

A data extraction table captured methodological, demographic, outcome and quality details from the included studies. Age, gender and educational attainment were included as these variables have been identified as relevant to individual difference in cognition in people with MCI (Jasper et al., 2013; Petersen et al., 2010).

Tables were piloted with four papers to determine their utility. Uncertainty about what information to extract was resolved through discussion with supervisors where

necessary. Twenty three authors were contacted in relation to missing, or limited data, and follow-up emails written as necessary. Two authors replied and additional information was added to the findings (Burgio et al., 2018; Donnezan et al., 2018). If studies explored multiple hypotheses, only data related to the review question was extracted. Where studies applied multiple analyses, only data that related to the outcomes of interest were extracted and only data derived from the most complex models used. A narrative synthesis was undertaken as heterogeneity in study methodology meant that it was not possible to undertake a meta-analysis.

Quality Assessment

Quality was evaluated using three critical appraisal tools that best fitted the range of studies included. The majority (19) of studies had a randomised design, for which the Revised Cochrane Risk-of-bias tool for randomized trials (RoB 2) was used (Higgins et al., 2011). The tool assesses risk across five domains with each evaluated as "low risk of bias", "some concerns" or "high risk". Seven studies were of a non-randomised design, which were assessed using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-1) (Sterne et al., 2016). The ROBINS-1 evaluates studies across seven domains assessed as either "low risk of bias", "moderate risk", "serious risk", "critical risk" or "no information" on which to base a judgement. These tools were selected as they have been peer reviewed and praised for the level of detailed information they can produce (Boland et al., 2017; Higgins et al., 2020). One paper had a single case study design. The assessment tool developed by Lobo et.al. (2017) was used to assess this study. Each tool provides scope for an overall quality rating and a rating in each domain of potential bias, judged to be effective for comparing studies in detail (Boland et al., 2017). For randomised studies, quality was

assessed against intention-to-treat principles in order to generate the most robust evidence (Ranganathan et al., 2016).

Results

Studies Identified and Included

The search strategy identified 4105 records[2]. From these, 112 full text articles were reviewed and 26 publications included in the review. Information relating to the selection and inclusion of records is summarised in Figure 1.

Study Characteristics

Table 1 provides an overview of the characteristics of included studies and a summary of the results. Of the 26 studies included, four studies used the same, or a subset of the same, participant group, resulting in 24 samples used across the review (Mudar et al., 2017; Mudar et al., 2019; Oskoei et al., 2016; Oskoei et al., 2013).

Eighteen studies employed a randomised design of which five were single blind (typically blinding the outcome assessors to information about the group to which the participant had been allocated) and two were double blind. Two studies incorporated a cross-over design and two used matched pairs of participants. Half of these studies included an active control group and, in two instances, this was achieved using a cross-over design. The remainder employed a passive control group, commonly clients on a waiting list or those receiving standard care.

Of the eight studies that employed a non-randomised design, one used a single case study approach, one a within-participant cohort design, one a passive comparator group, another a cross-over design and four used comparator groups from different clinical

[2] Scoping searches indicated that the MCI population was sometimes imprecisely defined; referred to as, for example, “at risk of dementia” or “pre-Alzheimer’s” in the title and abstract. As such, a broad search was used for the population. Accordingly, this resulted in a large number of search results.

populations. Seven studies described themselves as either a pilot or feasibility study and all included studies employed a convenience sampling strategy (see appendix D for a detailed summary of included studies).

Research contexts varied in terms of nationality, comprising nine European regions, three American, three Iranian, two Chinese, two Thai, two Canadian, one Taiwanese and two Australian samples. The majority of participants were female (71%). Nineteen studies reported the average age of participants, which ranged between 68 and 74-years-old. Across the 14 studies reporting on educational attainment, the average number of years in education was 11. However, there was a considerable range from 3 to 18 years in education across studies, with the lowest level of educational attainment reported in a sample of Iranian women (Damirchi et al., 2018) (see Appendix 1-E for summary of participant characteristics).

Intervention Characteristics, Measures and Analysis

Complex decision-making was directly targeted and measured in one study (Burgio et al., 2018). Beyond this, there were a broad range of foci for interventions and outcomes. Reasoning or cognitive control (typically conceptualised as a combination of attentional switching, inhibition and divided attention) were the main foci in seven studies. The remaining 18 studies targeted multiple executive functions relevant to complex decision-making, including problem-solving, working memory, planning, goal management, verbal or semantic fluency, and calculation.

Cognitive training (CT) comprises guided practice of standardised tasks intended to improve cognitive skills through repetitious training (Clare & Woods, 2004). The study that directly targeted complex decision-making used a computerised cognitive training (CCT) intervention that trained number processing and executive fluency skills to improve complex decision making under risk (Burgio et al., 2018). Of the remaining studies, the majority

employed CT to enhance relevant executive functions (*n* = 17), of which 13 were delivered on a computer. Four of the studies included in the review used cognitive stimulation (CS) interventions involving a range of activities, such as reminiscence work and discussions of current affairs (Da Cruz et al., 2015). The remaining study employed cognitive rehabilitation, which involved input from a range of allied health professionals such as clinical psychologists and occupational therapists (Clare & Woods, 2004).

Outcome tasks in the study using a complex decision-making intervention included the Game of Dice Task and the Probability Associated Gambling Task (Brand et al., 2005; Brand et al., 2006). Where executive functions were the focus of the intervention, the most commonly used measures were the Trail Making Test parts A and B (TMT) (*n* = 13) (Kortte et al., 2002). After this, semantic fluency tests, digit span backwards task and tests based on cognitive interference were the most commonly employed (Delis et al., 2001; Ostrosky-Solís & Lozano, 2006; Strauss et al., 2006). Overall, a broad range of tests were used with few being employed more than twice.

Analysis of variance (ANOVA) (*n* = 8), *t*-tests (*n* = 12) or equivalent non-parametric tests were the most frequently used method of analysis. Five studies reported effect sizes, and it was possible to calculate effect sizes for a further 11 studies included in the review. Of the twenty authors contacted, three provided responses in request for additional information and extraction tables were updated accordingly.

Study Quality

Tables 2, 3 and 4 provide an overview of quality ratings across domains of bias for randomised and non-randomised studies. One study was rated as low risk for all domains of potential bias (Yang et al., 2020). Nineteen of the remaining studies were considered to be at high risk of bias overall and six were assessed as being of some concern.

Limited rigour in either the randomisation of participants or the controlling of confounding variables proved relevant for 19 of the studies reviewed and includes all of the non-randomised studies. A common protocol violation in the randomised studies was the exclusion of participants from analyses who were unavailable at follow-up (n = 11). Only two studies used an intention-to-treat (ITT) analysis (Sandeep, 2011). Missing data was managed similarly across studies, in that it was typically excluded from analyses (n = 14). Risk arising from the validity of the outcome measures used affected ten studies. Few studies reported psychometric data relating to the validity or reliability of tests. Five studies used only one or two measures to capture a range of complex executive functions (Barban et al., 2016; Boripuntakul et al., 2012; Das et al., 2019; Oskoei et al., 2016; Oskoei et al., 2013).

Further, some studies used tests that may not have measured the target construct. For instance, Boripuntal et.al. (2012) used a composite score of the Trail Making Test (TMT) (B-A) to measure executive function but some authors have suggested that this might only be measuring processing speed (Salthouse, 2011). The same authors used the Digit Span Backwards (DSB) test to measure simple attention when this test might be more validly considered a test of working memory (Ostrosky-Solís & Lozano, 2006).

Most studies did not report either the outcomes of power analyses or whether assumptions for parametric tests had been met to justify their analytic strategy. Convenience sampling was used across all studies. Ten studies employed a longitudinal design, retesting participants on average six- months after training. Several studies employed computerized interventions and were provided with software for use in the research (see appendices G and H for supplementary tables assessing quality and describing supporting evidence for each domain of bias).

Study Outcomes

Fifteen studies resulted in statistically significant improvements for most, or all, the outcomes measured, favouring the intervention (see Appendix 1-F for a breakdown of results including effect sizes). When analysed, three of these studies had delivered interventions in a group format, seven had undertaken the intervention individually with support from a facilitator, one had asked people to complete training independently at home, one included a mix of groups and individual work and three did not report the intervention context. Nine studies delivered training across six or eight weeks, which was the average for the review. Four of the studies that achieved significant positive results delivered the intervention over a relatively small number of sessions (between five and ten sessions), whilst only two provided a substantial number of sessions of between two and four sessions a week for up-to six months. Most of the studies reporting improvements in cognitive function had used cognitive training as their intervention strategy (n = 13). Three quarters of these studies used a passive control group.

One of 15 studies achieving positive results, one used a decision-making intervention in which participants achieved gains in the Probability Associated Gambling Task, used as a proxy measure for complex decisions made under risk. Two studies focused on logical reasoning abilities and achieved medium to large effect sizes (d = .57, d = 2.74) (Nousia et al., 2019; Unverzagt et al., 2007). Of these two studies, one measured outcomes after two years and found that improvements had been sustained (d = .27) (Unverzagt et al., 2007). Both used a passive control group as a comparison. Five studies aimed to improve cognitive control and achieved small to medium effect sizes (R^2 = .16 - η^2 = .63) (Finn & McDonald, 2011, 2014; Gagnon & Belleville, 2012; Oskoei et al., 2016; Oskoei et al., 2013). The remaining studies that reported positive results trained a mixture of executive functions including planning, problem solving, working memory and semantic categorization (Boripuntakul et al., 2012; Damirchi et al., 2018; Donnezan et al., 2018; Li et al., 2019;

Manera et al., 2015; Moro et al., 2015; Silivaikul & Munkhetvit, 2019). Whilst effect sizes varied, most effects were large and favoured the intervention group (η^2 = .14 - *d* = 1.72). The extent to which effects were sustained varied. One study, for example, reported greater improvements than the comparator group after three months, whilst another observed no sustained effects when measured at 18 months (Damirchi et al., 2018; Li, He & Qiao, 2019).

Six studies had mixed outcomes, three of which aimed to improve gist reasoning (Das et al., 2019; Mudar et al., 2017; Mudar et al., 2019). Of these three studies, some improvements were made in abilities thought to make up gist reasoning, such as strategic attention and innovative thinking, albeit effect sizes were small (*d* = -.05 - *d* = .12). Of the other three studies achieving mixed results, one study found that positive outcomes were not sustained (Barekatain et al., 2016). Another study did not obtain positive outcomes on tests of executive function but achieved positive results on proximal measures that mirrored the tasks trained in the intervention (*d* = .42, *d* = 1.84) (Cipriani et al., 2006). The remaining study achieved positive results in tests of verbal fluency but did not find improvements in tasks of working memory or cognitive flexibility (Djabelkhir-Jemmi et al., 2018)

Five studies reported no statistically significant improvements (Barban et al., 2016; Djabelkhir et al., 2017; Matías-Guiu et al., 2016; Yang et al., 2020; Zhang et al., 2019). These studies were of mixed design and the measures used were heterogenous, making them difficult to compare.

Discussion

This review aimed to examine the effectiveness of interventions to improve complex decision-making in people with MCI. Methodological limitations constrain the extent to which conclusions can be drawn about the usefulness of one intervention over another to support complex decision-making.

Some findings indicate that interventions characterised by cognitive training techniques, targeting either complex decision-making directly or the aligned skills of logical reasoning and cognitive control can improve complex decision-making abilities in this population (Brand et. al., 2006; Brand et. al., 2014; Griffiths et. al., 2003; Pertl et.al., 2017; Sherod et. al., 2008). However, whilst studies with these characteristics demonstrated strong outcomes they only represent 30% (n = 8) of the total sample (Burgio et al., 2018; Finn & McDonald, 2011, 2014; Gagnon & Belleville, 2012; Nousia et al., 2019; Oskoei, Nejati & Ajilchi, 2013; Oskoei, Ajilchi & Geranmayepour, 2016; Unverzagt et al., 2007). Six of the remaining studies also achieved positive results and, whilst heterogeneity in targeted abilities (including planning, problem solving, divided attention and calculation) limited comparisons, four of them employed cognitive training methods. Of the best performing studies, therefore, over three quarters employed cognitive training, which is convergent with the literature (Liang et al., 2019).

Consistent with the literature, longitudinal studies demonstrated variation in the extent to which improvements were maintained (Barban et al., 2016; Barekatain et al., 2016; Damirchi et al., 2018; Das et al., 2019; Djabelkhir-Jemmi et al., 2018; Donnezan et al., 2018; Gates et al., 2011; Hertzog et al., 2008; Jean et al., 2010; Sherman et al., 2017; Li et al., 2019; Moro et al., 2015; Unverzagt et al., 2007; Yang et al., 2015). Nevertheless, half of these studies reported at least partially sustained improvements up-to 18-months after the intervention. Moreover, positive outcomes appear not to be contingent on whether interventions are delivered on an individual or group basis. Furthermore, the number or frequency of sessions did not seem to correlate significantly with better client outcomes. These findings are encouraging for professionals in health services, for whom time and resources are often limited (Robertson et al., 2017). Further, in relation to longitudinal outcomes, short-term benefits from interventions could still offer utility to practitioners if

improvements in cognition support clients to make important one-off decisions, such as deciding whether to accept a course of treatment.

The majority of studies used a heterogenous sample of MCI subtypes and varied in how MCI was defined and diagnosed. Whilst this presents challenges for research designs it affords some ecological validity as it mirrors the challenges of differentiating MCI from other clinical populations and indicates that positive outcomes may benefit a range of MCI subtypes (Petersen, 2011; Ritchie et al., 2001).

Just under half of the studies included (n = 12) reported either mixed findings or did not achieve any significant change as a result of an intervention. Mixed findings identified could reflect the complex and dynamic nature of MCI (Collie & Maruff, 2000; Petersen, 2011). For example, experimental groups in some study samples achieved similar scores before and after the intervention, whilst cognitive outcomes in control groups, particularly passive groups such as those on a waitlist, worsened over the course of the research (Moro et al., 2015; Silivaikul & Munkhetvit, 2019). Intervention effects for some participants therefore, appear to reflect the maintenance, rather than improvement in cognitive abilities. Moreover, some participants' conditions might have progressed to a dementia during the course of the research, reducing the likelihood of beneficial effects from interventions (Peterson, 2011).

The findings of the review, therefore, lend some support for the hypothesis that people with MCI can, and do, benefit from neuropsychological interventions designed to improve complex decision-making.

Methodological Explanations for Mixed Findings

Variation in outcomes within this review could be, in part, accounted for by the different comparator groups used across studies. For instance, larger effect sizes were

typically observed in studies where a passive control group, such as those retained on a waiting list, was used.

In most studies, researchers measuring intervention outcomes were blind to group allocation. However, only two studies used a double-blind design to disguise the aim of the intervention, or of the study as a whole, to participants or facilitators (Gagnon & Belleville, 2012; Yang et al., 2020). Not using a double-blind design increases the risk of outcomes being influenced by factors other than the intervention, such as an awareness of being observed on the part of participants (the Hawthorne effect) or positive therapeutic effects from receiving attention and support (Sedgwick & Greenwood, 2015; Nousia et.al., 2019). Indeed, Daly et.al. (2000) suggest that improvements in mood or stress levels could account for some of the spontaneous improvements in function observed in people with MCI in the community.

Most randomised studies violated the intention to treat (ITT) principle, excluding people who did not complete an intervention from the analysis. This is likely to have reduced comparability between group outcomes, particularly in instances where the reasons cited for attrition included the perception that training was too difficult or time consuming (Ranganathan et al., 2016). This approach could also have resulted in exaggerated treatment effects or reduced statistical power (Ranganathan et al., 2016). However, academic positions on ITT analysis vary with some authors criticising ITT principles on the basis that they are too conservative and can result in type II error (Sandeep, 2011). Moreover, the exclusion of missing data was an issue for most studies and could limit the extent to which results can be said to reflect the true value of the intervention (Fleming, 2011). Nevertheless, this information could still be of value to clinicians if they know that an intervention is more likely to be successful if people complete all the sessions or actively engage in activities.

Some studies used small sample sizes, with six describing their study as a pilot or feasibility research (Boripuntakul et al., 2012; Das et al., 2019; Finn & McDonald, 2011; Manera et al., 2015; Matías-Guiu et al., 2016; Mudar et al., 2017). As a consequence, analyses were sometimes under-powered, reducing the reliability, and replicability, of the results.

The extent to which the difficulty of tasks could be personalised for participants varied in across the studies in this review. This could be because, as yet, there is an inadequate body of evidence to indicate how best to manage task difficulty in cognitive intervention research (Li et al., 2011; Liang et al., 2019). Lovden (2010) suggests that this issue is important, as interventions must be sufficiently difficult to effect cognitive change. Nevertheless, this reviewed did not establish a link between difficulty level and participant outcomes (Sherman et al., 2017). Moreover, there was considerable heterogeneity in the tests used to measure executive function and heterogeneity in how tests were used or combined to measure specific abilities. For instance, planning skills were measured in one paper using the Digit symbol Coding Task, in another using the Tower of London Task and in a third using a picture completion test designed specifically for the study (Baraketain et. al., 2016; Damirchi et.al., 2018; Massimo et. al., 2011; Tulsky, 2003; Zhang et. al., 2019). Accordingly, it was difficult to accurately compare results across studies.

Accordingly, whilst several studies reported positive findings it is important to consider them in the context of the design quality issues observed and the impact this might have had on the validity and reliability of results. However, some studies may have been disadvantaged as a result of journal word count restrictions (Sterne et al., 2019). This was especially true for non-randomised studies, none of which reported potential confounding variables or how they might have been controlled for. It was possible, for example, to rate one paper as lower risk in relation to randomisation after receiving additional information from the author (personal communication with Dr. L. Zamarian, May, 2020).

Clinical Implications

Whilst other reviews have explored complex decision-making interventions in clinical populations, this is, to our knowledge, the first review to examine cognitive remediation in complex decision-making for people with MCI (Verdejo-García et al., 2019). Moreover, the results of this review have direct relevance for clinical psychology in practice.

Adults with reduced cognition can experience problems with everyday life and, understandably, low mood and anxiety as a result (Health equity in England: The Marmot review 10 years on, 2020). Accordingly, in terms of improving the overall psychological health of older people, addressing complex decision-making deficits has clear benefits. Clinical psychologists are often required to undertake complex capacity assessments or to advise on how best to support someone to make their own decision (Mental Capacity Act 2005: Code of Practice, 2007). Knowledge of how to improve cognitions that underpin complex decision-making abilities could enable professionals to provide interventions that might enable clients with MCI to retain autonomy over their affairs for longer.

Inferring suitability of an intervention for an individual client when it has been trialled with a population can be problematic and this review does not take the position that one approach will suit everyone (Darby & Dickerson, 2017). However, the review indicates that cognitive training for skills such as reasoning and cognitive control could offer utility to clinicians. Moreover, some studies that achieved positive results employed methods that might be more easily replicated in practice than those requiring complex technology, such as written articles, short stories and health literature (Das et al., 2019; Mudar et al., 2017; Mudar et al., 2019).

Strengths and Limitations of the Review

The review adhered to PRISMA guidelines in order to achieve a high level of rigour and transparency and to enable replication. The review was comprehensive; four databases

were searched and a broad range of search terms were used. The study was intentionally broad in scope to capture relevant research, encompassing international literature and including any type of cognitive remediation targeted at either complex decision-making or relevant higher-order cognitive skills. However, this breadth may have limited the extent to which findings could be synthesised. The exclusion criteria applied, such as excluding papers published in languages other than English, might have limited the reliability of findings.

This review necessitated reviewer judgement and interpretations, which may have biased results. For instance, a judgement was made about executive functions that are relevant to complex decision-making and the measures that are most likely to capture these functions after reviewing the literature in this area. However, decisions taken were done in consultation with supervisors and experts in the field to ensure they were well-informed. Reduced cognitive ability, as an aspect of in individual difference, is unlikely to fully account for all the variation in functional decision-making competence (Han et al., 2015). Other factors are also likely to be important, including low mood, anxiety and stress (De Visser et al., 2011; Miu et al., 2008; Morgado et al., 2015). Moreover, environmental factors in health care settings, including the quality of the relationship between clients and professionals, can influence client decision-making competence (Series, 2015). Nevertheless, cognitive deficits have consistently been shown to play an important role in complex decision-making and therefore justifies academic and clinical attention.

Conclusions and Recommendations

This review has explored emerging findings for complex decision-making interventions for people with MCI. Results indicate that cognitive training in decision-making and the associated skills of reasoning and cognitive control, and to an extent abilities such as ratio-processing, planning, cognitive flexibility and numerical calculation, offer

potential directions for the improvement of complex decision-making skills for this population. This area of research is growing and it is hoped that design issues that might limit the quality of findings in future studies will reduce, creating a more coherent literature and increased confidence in interventions.

Many of the studies reviewed were pilot or feasibility studies and it is recommended that these are up-scaled to larger research projects. It is acknowledged, however, that recruiting large numbers of participants in a short-space of time can be challenging (Finn & McDonald, 2014). An alternative approach could be to extend the use of single-case designs (SCD) in this area of research (Lobo et al., 2017). Authors such as Dallery and Raiff (2014) discuss how SCDs offer both a practical and flexible approach for scientist-practioners in that one or more people can be included in a sample, units of analysis (or "case") can be settings such as hospitals as well as people and they are not limited to detecting large changes in wellbeing. Whilst generalisability of results can be limited this can be increased by choosing people that are representative of the type of person for which the intervention would be used or undertaking replication studies (Barlow & Hersen, 1984; Franklin et. al., 1996). Moreover, the requirement to assess individuals at multiple time points in SCDs is arguably more feasible given developments in technology, providing scope for the use of smart phones and webpages in gathering data (Lobo et al., 2017).

More studies that concurrently examine neurophysiological as well as neuropsychological changes would help to establish the extent to which underlying physiological processes influence functional change (Gaitán et al., 2013). More research employing a longitudinal design would clarify the extent to which cognitive interventions help over time. Furthermore, increased use of functional tests of complex decision-making could increase the ecological validity, and therefore usefulness, of findings; reducing reliance on proxy measures of executive function (Gaitán et al., 2013).

Improving complex decision-making skills for people with cognitive impairments can help to maintain independence and increases the scope for Clinical Psychologists to provide effective psychological care to clients and their families across all settings. It is hoped that this review offers a useful synthesis and analysis of the current literature in relation to cognitive interventions for decision-making that can support these goals. The results highlighted in this review point to promising avenues for future applied research that could promote improved understanding of what works and what might practicable in services.

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Figures and Tables

Figure 1

Search Results Flow Diagram

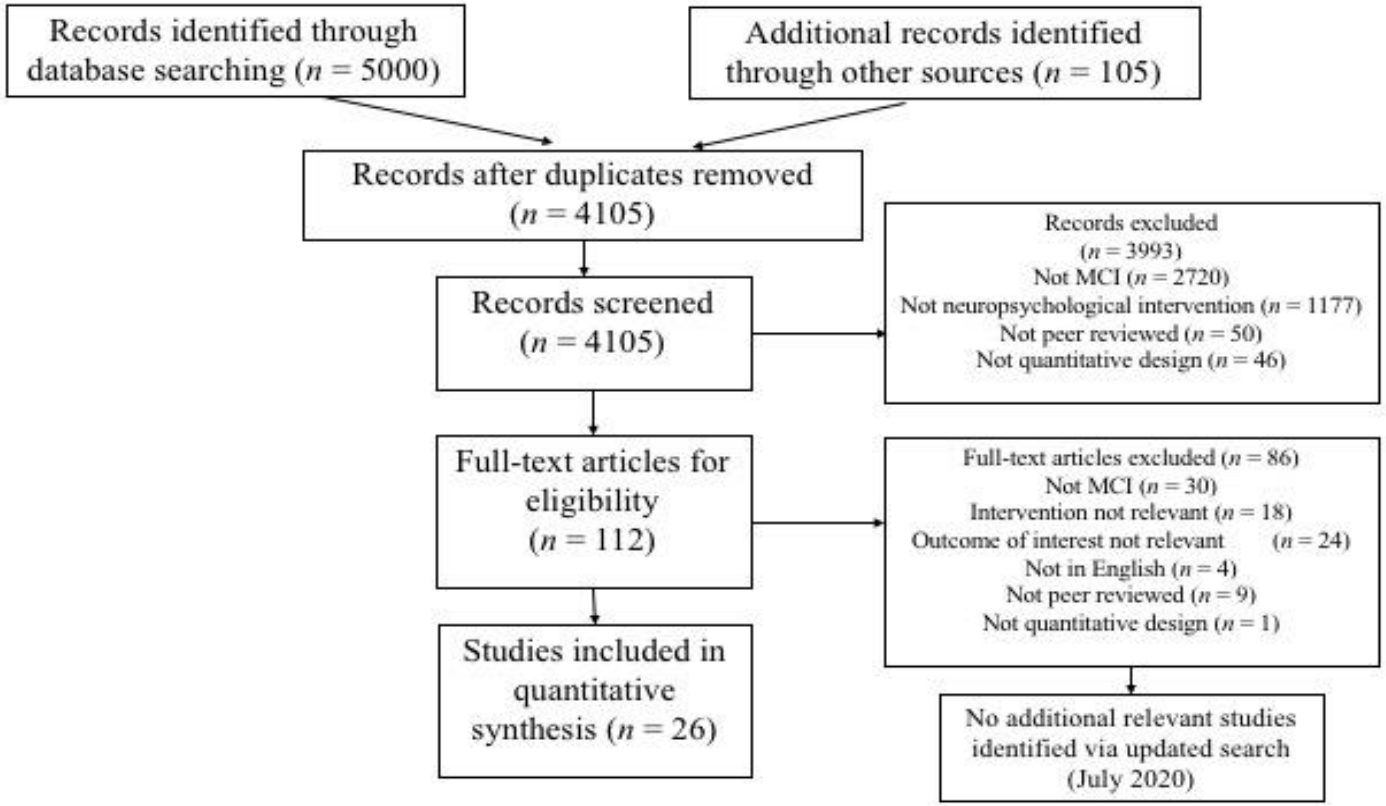

Table 1

Summary of Study Characteristics and Results

Author (yr.)	Study Design	Location	Focus of intervention	Comparator(s)	Primary outcome(s) of interest	Results
Barban et al. (2016)	Randomised (multi-centre) controlled cross-over design.	Italy, Greece, Norway and Spain.	CCT: Selective attention, abstraction, logical reasoning and visuo-spatial skills.	Two arms. Arm A (CCT then rest *n* = 12) and arm B = reverse order.	Outcomes of psychometric tests designed to tap the EFs trained.	The intervention did not result in significant gains after training or over time and there were no significant differences between the scores across training arms.
Barekatain et al. (2016)	Randomised, single-blind design.	Isfahan, Iran.	CR: Strategies to improve EFs.	Passive control group (waiting list).	Outcomes of psychometric tests designed to tap the EFs trained.	Training group showed significant improvements in planning skills compared to control participants. No significant results achieved for other EFs tested.
Boripuntakul et al. (2012)	Randomised, matched pairs pilot study.	Chiang Mai, Thailand.	CT: Tasks that target EFs including: Auditory and visual selective attention, planning, organising, problem solving and abstract reasoning that were intended to simulate activities of daily life.	Passive control group (waiting list).	Outcomes of psychometric tests designed to tap the EFs trained.	Significant improvements were observed for attention and EF in the intervention group.
Burgio et al. (2018)	Randomised controlled cross-over design.	Venice, Italy.	CT: Numerical v. EF training.	Two arms. Arm A (numerical then EF training *n* = 12) and arm B = reverse order.	Decision-making under risk and ratio processing.	Group A showed a steady increase in decision-making scores over time. Ratio-processing improved at all time points for group A and at T2 and T3 for group B.
Cipriani et al. (2006)	Between-subject design.	Brescia, Italy.	CCT: Tasks training non-verbal intelligence which comprised reasoning skills.	Comparison group comprising people with multiple system atrophy (MSA) who received the same training.	Non-verbal intelligence: Pre-post cognitive scores on seven psychometric tests.	There were no significant differences achieved after training in either group. Mean scores suggest some improvement in semantic fluency and inhibition for the MCI group.
Damirchi et al. (2017)	Randomised controlled matched pairs design.	Aliabad-e Katul, Iran.	CCT: Tasks training EFs that included working memory, reasoning, spatial ability.	Passive control group.	Cognitive performance on the trained abilities as well as processing speed, planning and problem solving.	Significant differences between groups in all scores after training favouring the intervention group, except in measures of reaction time. Differences in inhibition increased (favouring experimental group) after six months.

Author (yr.)	Study Design	Location	Focus of intervention	Comparator(s)	Primary outcome(s) of interest	Results
Das et al. (2019)	Randomised, single-blind pilot trial.	Texas, U.S.	Gist reasoning training to improve a combination of: Strategic attention, integrated reasoning and innovative thinking.	Training + tDCS	Cognitive performance on psychometric tests intended to capture gist reasoning.	Significant gains in strategic attention and innovative thinking in the group that received reasoning training only but these results were not sustained over time.
Djabelkhir et al. (2017)	Randomised feasibility design.	Paris, France.	CCS: Tasks stimulating EFs.	Active control: Computerised cognitive engagement.	Cognitive performance in psychometric tests of EF.	Cognitive stimulation group improved in some aspects of executive function.
Djabelkhir-Jemmi et al. (2018)	Between-subject, single-blind, parallel group design.	Paris, France.	CCT: Tasks training EFs.	Participants with MCI and with high levels of white matter hyperintensities (WMH) were compared with participants without WMH.	Performance in psychometric tests designed to tap EFs (planning, inhibition and flexibility).	Both groups demonstrated improvements in sustained attention over time. Participants with high levels of WMH failed to improve on all but one test of EF whilst those without WMH improved on a range of EF measures.
Donnezan et al. (2018)	Randomised controlled design.	Montreal, Canada (memory clinic).	CCT: 33 different games designed to improve EFs.	Passive control group asked to maintain existing lifestyle and routine.	EFs: Working memory, inhibition, flexibility and reasoning.	After training there was a significant main effect of training (group x time) for reasoning. No main effect for training on other measures. *T*-tests indicated significant pre-post effects for reasoning and working memory in the CCT group.
Finn et al. (2011)	Rondomised, controlled pilot design.	New South Wales, Australia.	CCT: Tasks designed to improve cognitive control.	Waitlist control group	Performance on tests intended to tap sustained Cognitive control including: Working memory and set shifting	After training there was a significant main effect of training (group x time) on attention and cognitive control.
Finn et al. (2014)	Multiple baseline single-case design.	New South Wales, Australia.	CCT: First phase of training designed to target sustained and divided attention and cognitive control.	NA	Cognitive control (cognitive set-shifting and working memory)	Fluctuations across sessions but a positive trend over training for divided attention and cognitive control. Regression analysis showed significant change in sustained attention and executive function for one participant.
Gagnon et al. (2012)	Randomised, double-blind controlled design.	Montreal, Canada.	CCT: Training on cognitive control (dual-tasks) where participants were asked to vary the priority they gave to each aspect. Supplemented with tasks of meta-cognition.	Active control group receiving same dual-task training but without being asked to vary the priority given to different tasks	Cognitive control	Significant effects of intervention across most measures in both groups indicating that fixed or variable dual task training could improve attentional control.

Author (yr.)	Study Design	Location	Focus of intervention	Comparator(s)	Primary outcome(s) of interest	Results
Li et al. (2019)	Randomised controlled trial.	Shanghai, China.	CCT: Tasks designed to improve EFs including: Visual working memory; speed of calculation; visual search; alertness, mental rotation and the rearrangement of images.	Passive control group.	Psychometric tests designed to tap the trained EFs.	Significant effects of intervention were observed across several measures of EF immediately after training but only some improvements sustained at 18mths.
Manera et al. (2015)	Between-subject parallel group pilot design.	Nice, France.	CCS: Computerised games designed to simulate everyday tasks requiring EFs including inhibition.	Group of participants diagnosed with dementia.	Outcomes of psychometric tests designed to tap the EFs stimulated.	Improvements observed in the MCI group.
Matias-Guiu et al. (2016)	Between subject parallel groups pilot study.	Madrid, Spain.	CS: Based on abacus arithmetic to improve EFs.	Results were compared with two other groups: One comprising healthy older adults and another with suspected dementia.	EF: problem solving and spatial thinking.	Scores improved in one measure of EF in the MCI group but this was statistically insignificant.
Moro et al. (2015)	Cross-over design.	Verona, Italy.	CS: Aimed at improving and maintaining decision making and EFs.	Active control group as part of the cross-over design.	Decision making and EFs.	Improvements in most domains after training that were partially maintained over time. Set-shifting skills achieved the highest scores and these were maintained. Group B showed significant decline whilst waiting to begin training. Participants and carers reported benefits.
Mudar et al. (2017)	Randomised Single-blind controlled pilot trial.	Texas, U.S.	Gist reasoning training to improve: Strategic attention; integrated reasoning and innovative thinking.	Active control employed in gaining new learning about brain health.	Cognitive performance on psychometric tests intended to tap gist reasoning skills.	Training group improved in strategic attention and concept abstraction but no significant gains observed in complex gist abstraction compared to control participants.
Mudar et al. (2019)[a]	Randomised single-blind controlled trial.	Texas, U.S.	Gist reasoning training.	Active control employed in gaining new learning about brain health.	Cognitive inhibition.	Some improvements were observed.
Nousia et al. (2019)	Randomised controlled design.	Ioannina, Greece.	CCT: Tasks designed to train EF (logical thinking)	Passive control: Standard clinical care including medication management	Psychometric tests designed to tap aspects of logical thinking.	Improvements in the experimental group in all domains with the biggest gains observed in tests of attention and verbal fluency.
Oskoei [b] et al. (2013) & Oskoei et al. (2017)	Randomised design.	Tehran, Iran.	CCT: Tasks designed to train cognitive control and set-shifting.	Passive control receiving standard care.	Performance on psychometric tests of flexibility (set-shifting).	Experimental group improved significantly in all tests compared to the control group with group differences accounting for approximately 25% of the variation in post-test scores.

Author (yr.)	Study Design	Location	Focus of intervention	Comparator(s)	Primary outcome(s) of interest	Results
Silivaikul et al. (2019)	Between-subject, single-blind study.	Chiang, Mai Provence, Thailand.	CT: Strategies and education-based activities deigned to promote EFs.	Passive control.	Executive functions.	Training group maintained, or improved their scores on tests of attention and EF, whilst the control group, in the main, worsened.
Unverzagt, et.al. (2007)	Randomised single-blind controlled trial.	Five centres across the U.S.	CT: Reasoning training.	Passive control.	Reasoning ability.	Reasoning ability improved compared to control group and results were sustained over two years.
Yang et al. (2020)	Randomised, double blind, two-arm parallel group controlled design.	Taipei, Taiwan.	CCT: Sustained attention; attentional control and visuospatial attentional tasks.	Active control using computerized cognitive games.	Aspects of attention including attentional control.	Mean scores improved for participants in the training group but differences in scores between groups were not significant.
Zhang et al. (2019)	Within-subject cohort design using a convenience sampling approach.	Beijing, China.	CCT: Tasks training EFs focused on reasoning, calculation, attention, .	No comparator.	Psychometric tests of EFs.	No significant gains were observed for any measure.

[a]This study used a subset of the sample obtained by Mudar et.al. (2017b)

[b] These two publications reported on different outcomes for the same sample and have therefore been combined in line with best practice (Boland, Cherry, & Dickson, 2017)

Acronyms and definitions: CS: Cognitive stimulation; CCS: Computerised cognitive stimulation; CR: Cognitive rehabilitation; CT: Cognitive training; CCT: Computerised cognitive training; EF: Executive function; tDCS: Transcranial Direct Current Stimulation

Table 2

Assessment of quality summary table: Randomised studies

	Risk of bias per domain (Risk of Bias Tool ROB-2)						
Author (yr.)	Randomisation (selection and performance)	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Judgement overall (Deviation from algorithm? y/n)	Abridged evidence for judgement
Barban et al. (2016)	Some concerns	Some concerns	High	Low	Low	High (n)	"Randomisation.... was carried out by centre and sample with a block size of four to prevent imbalance. The allocation procedure was concealed from the raters" No reported information about whether participant allocation was concealed from researchers or the extent to which participants were aware of their group allocation. 47 people dropped out from the wider sample of 348. It is not clear how many of these had been allocated to the MCI group (106), or the reasons for attrition and so it was difficult to estimate the potential impact on the outcome other than to assume there might have been one.
Barekatain et al. (2016)	Some concerns	Low	High	Low	Low	High (n)	"Participants were assigned using block-design randomisation" "participants in each group were unaware of the existence of other groups". No other information about the randomisation process provided. This was one of only a few studies that employed an intention to treat analysis. Nevertheless, this was a small sample of which 58% of participants dropped out of the treatment group and reasons for attrition were not provided. Multiple valid and reliable tests of EF were used.
Boripuntakul et al. (2012)	Low	Low	Low	High	Low	High (n)	"Randomisation was performed by opening an opaque sealed envelope" This was a pilot study and so a small sample is to be expected and non-parametric tests were used. However no justification for the sample size reported in relation to recommended guidance for pilot studies. Data for all participants randomised was included. The biggest concern in this study was the use of inadequate and possible inappropriate measures for the target cognitive constructs. Only one measure – Trail Making Test (TMT) (B-A) as a sole measure of EF. Using just one measure is sub-optimal for a broad and complex

Risk of bias per domain (Risk of Bias Tool ROB-2)							
Author (yr.)	Randomisation (selection and performance)	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Judgement overall (Deviation from algorithm? y/n)	Abridged evidence for judgement
							construct. Moreover, there is evidence that TMT B-A may only measure speed across age ranges.
Burgio et al. (2018)	Some concerns	Low	Low	Low	Low	Some concerns (n)	"patients were randomly assigned to either training order A or B" No information provided about sequence allocation. Other than limited information about the randomization process there was good evidence about quality in all other domains.
Damirchi et al. (2017)	Some concerns	Low	High	High	Low	High (n)	Insufficient information reported to draw conclusions in several areas. Inappropriate/ insufficient measurement and missing data were the biggest threats to the reliability of results. Only one test was used to measure each type of cognition including complex functions. Some tests may have been appropriate. For example, a digit span forward test is typically considered to be a test of short-term verbal memory but in this instance it was used to measure working memory. A large portion of participants dropped out of the study and there was no reported indication of the reasons for this. Implication in the published article is missing participants and their data was excluded and that a per-protocol approach was taken. Unclear if participants knew the differences between groups.
Das et al. (2019)	Low	High	High	High	Low	High (n)	"A research assistant who was blinded to participant information and cognitive behaviour, randomised the participants into one of two groups...using random function on Microsoft Excel after baseline training". Valid and reliable measures used to test changes in EFs albeit a small range of tests. The gist training group alone received "sham" tDCS to blind participants from their group allocation. There was 32% attrition by the third assessment time point with reasons predominantly relating to demands on participants' time. Implication in the published article is that missing participants and their data was excluded and a per-protocol approach to analysis was taken.

Risk of bias per domain (Risk of Bias Tool ROB-2)

Author (yr.)	Randomisation (selection and performance)	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Judgement overall (Deviation from algorithm? y/n)	Abridged evidence for judgement
Djabelkhir et al. (2017)	Some concerns	High	Low	Low	Low	High (n)	"patients were assigned to...group using a simple computerised randomisation procedure" Whilst there was only one person who dropped out, the sample was small and already under-powered.
Donnezan et al. (2018)	High	High	High	Some concerns	Low	High (n)	Clear rationale for planned tests based on hypothesised results. Detailed tables of results and explicit reporting on non-significant findings. The unit of randomization is group. It is unclear how this was achieved but the implication is that it was to create as much similarity between groups given the small sample size. This approach to randomization may have introduced bias in the results. Analysis excluded participants post-randomisation and a naive "per-protocol" analysis was adopted. Reasons cited to account for a 26% attrition rate indicated that the reliability of the results might have been affected by attrition. For instances, reasons included "too difficult" or "too time consuming". No analysis or procedure reported to correct for bias. Awareness of intervention may have effected results through expectation (Hawthorne) effects (Sedgwick & Greenwood, 2015). However, this was an issue for the majority of studies reviewed and it is admittedly difficult to overcome in designs where the intervention includes behavioural changes.
Finn et al. (2011)	Low	Some concerns	High	Low	Low	High (n)	"Independent person placed slips of paper with either "treatment" or "waitlist" written on them into opaque envelopes that were sealed". After baseline training participants were asked to select an envelope at random. Whilst otherwise of good quality, missing data that was not handled in line with any analytic strategy was of concern in an already under-powered sample.

Risk of bias per domain (Risk of Bias Tool ROB-2)

Author (yr.)	Randomisation (selection and performance)	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Judgement overall (Deviation from algorithm? y/n)	Abridged evidence for judgement
Gagnon et al. (2012)	High	Some concerns	Low	Low	Low	High (n)	"This study was a double-blind design: Participants were unaware of the training strategies and pre/post assessments were carried out by different assistants who were blinded to assignment intervention and hypotheses" Good use of measurement. Use of proximal measurement of a similar design to the training task and multiple distal measures related to broader function. Importantly for clinical contexts, effect sizes were reported. "Randomisation was stratified for education and age in order to equate groups on those dimensions". Semi-random design. No analytic strategy for dealing with deviations from intention to treat. One person dropped-out in each group and reasons were only known for one person. The potential impact has been assessed as minimal in the circumstances.
Li et al. (2019)	Some concerns	Some concerns	High	Low	Low	High (n)	Limited information obtained about the randomization process. "They were randomised to the training or control group". Moreover, there was considerable attrition (mainly observed in the control group) which could have introduced bias. "the main reason was that participants contacted physicians for medication". A per-protocol analysis was used. "...to minimise Hawthorne effect both groups were told that the study purpose was observation, follow-up and early diagnosis"
Mudar et al. (2017)	Some concerns	Some concerns	Low	Low	Low	Some concerns (n)	Limited information about the randomization process: "after baseline scores were established they were randomised to two training groups" Limited information available in some domains reduced the extent to which the review could be confident in conclusions.
Mudar et al. (2019)[a]	Some concerns	Some concerns	Low	Low	Low	Some concerns (n)	As above[a]

Risk of bias per domain (Risk of Bias Tool ROB-2)							
Author (yr.)	Randomisation (selection and performance)	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Judgement overall (Deviation from algorithm? y/n)	Abridged evidence for judgement
Nousia et al. (2019)	Some concerns	Some concerns	Low	Low	Low	Some concerns (n)	Limited information about the randomization process: "patients were randomly divided into two groups". All statistics were reported fully regardless of whether statistical significance was achieved. Multiple measures used to assess complex processes that have good validity and reliability for the specific cognition or skill. No drop-outs in the study and no deviations in treatment allocation. Authors state that the presence of the Hawthorne effect cannot be ruled out.
Oskoei et al. (2013) & Oskoei et al. (2017)	Some concerns	High	High	High	Low	High (n)	"(Patients)...randomly divided into experimental and control groups". Only one measure used but it was appropriate for the construct under consideration. 25% attrition in an already small sample. No reasons reported that could indicate minimal impact on results and no information as to how this was managed in the analysis.
Unverzagt et.al. (2007)	Low	High	High	Some concerns	Low	High (n)	The parent study from which the data was extracted reported an appropriate analytic technique to calculate the effect of assignment to intervention. Authors, however, do not report whether there was attrition from the study for these participants.
Yang et al. (2020)	Low	Low	Low	Low	Low	Low (n)	"An independent investigator used software to generate a random number table, after which block design randomisation (4)" "the independent investigator placed the written interventions into sealed opaque envelopes according to the random allocation" There was a difference in age that was corrected for in the analysis "participants were aware that different intervention measures would be used in the two groups. ...To ensure blinding, participants were blocked from knowing the training content of results of other participants. Trainers were not allowed to discuss participant grouping" "Randomly assigned participants were included in the final analysis based on the intention-to-treat principle"

[a] Data for this study was a subset of Mudar, et.al. (2017a)

[b] Two publications reporting on different outcomes for the same sample have been combined in line with best practice (Boland et al., 2017)

Acronyms and abbreviations: Y: Yes; PY: Probably yes; N: No; PN: Probably no; NI: No information

Table 3

Assessment of quality summary table: Non-randomised studies (ROBINS-1)

Risk of bias per domain and overall judgement (Risk of Bias in Non-randomised Studies Tool – ROBINS-1)									
Author (yr.)	Confounding	Selection	Classification of intervention	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Overall assessment[a]	Abridged summary
Cipriani et al. (2006)	NI	Low risk	Low risk	Low risk	NI	Moderate risk	Low risk	High risk	No information about potential confounders and no information about baseline characteristics were provided. Control group participants equalled less than 30% of intervention group whilst this was due to the design, this imbalance might have affected the reliability of results. Assessors were blind to group allocation. No potential expectation effects on the part of the experimental group were considered. Overall, insufficient information on which to draw a conclusion.
Djabelkhir-Jemmi et al. (2018)	NI	Low risk	Low risk	Moderate risk	High risk	Low risk	Low risk	High risk	Participants were volunteers so variables like motivation could have introduced bias. No potential confounders were reported or otherwise controlled for. No reported analytic approach to control for attrition.
Manera et al. (2015)	NI	Low risk	Low risk	Moderate risk	Moderate risk	Low risk	Low risk	High risk	"One person dropped out after the first week". The group was not specified. There was already an imbalance in sample size with the AD group being 25% bigger than the MCI group. Proportion of missing data differed slightly between groups and assessors were not blind to participant allocation. There is evidence that reported results correspond to all intended outcomes, analyses and sub-groups.
MatiasGuiu. et al. (2016)	NI	Low risk	Low risk	Low risk	Low risk	Moderate risk	Low risk	High risk	All participants began, and were followed-up, at the same time points. As with other studies there was no reported consideration of confounding factors or procedures to control for them.

Risk of bias per domain and overall judgement (Risk of Bias in Non-randomised Studies Tool – ROBINS-1)

Author (yr.)	Confounding	Selection	Classification of intervention	Deviation from intended intervention (performance)	Missing outcome data	Measurement of the outcome	Reported results	Overall assessment[a]	Abridged summary
Moro et al. (2015)	NI	Low risk	Low risk	Low risk	Moderate risk	Low risk	Low risk	High risk	Participants could choose which group they participated in. Two people (one from each group) were not available for 12-month follow-up for personal reasons. Deemed unlikely to have affected the true outcome. No analytic approaches used to accommodate missing data or correct for bias at the 12 month follow up.
Silivaikul et al. (2019)	NI	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Some concerns	Potential practice effects in using the same tests post training were not controlled for in this or other studies.
Zhang et al. (2019)	NI	Low risk	Low risk	Moderate risk	Serious risk	Low risk	Moderate risk	High risk	"85.19% of participants contributed data for analysis". Reasons for attrition were not given. "We assessed cognition both at the baseline and after training". No explicit information about blinding, or otherwise, of assessors.

[a]Included to facilitate comparisons across studies Acronyms: NI: No information

Table 4

Assessment of quality summary table: Single case design

Paper: Finn & McDonald (2014): A single case study of computerised cognitive training for older persons with mild cognitive impairment

Criteria	Evidence / conclusion
Design	Yes, the design was appropriate for evaluating the intervention
Method details	Yes. Participants' characteristics, selection method, and testing setting specifics were adequately detailed to allow future replication. Published data included appendices that provided details on the training and full information about participant, setting and selection were included
Independent variable	Yes, the independent variable was described in sufficient detail to allow replication and was systematically manipulated by researchers
Dependent variable	Yes. Each dependent variable was quantifiable and measured systematically across time
Internal validity	Some concern. Within multiple-baseline single case study designs there is some consensus that the study should comprise ≥6 phases with ≥5 points (*What works clearinghouse: Standards handbook v.4.1*, 2020) This design had only two phases
External Validity	Yes.
Face Validity	Probably yes. A valid and reliable test of executive function was used but only one measure for each construct under consideration.
Social Validity	Yes. The outcome of interest (executive function) has a clear relevance for health outcomes and the study was arguably more practical and cost effect than a large randomised design.
Sample attrition	Yes. Only one participant left the study
Randomization	NA
Overall assessment of quality[a]	Some concerns

[a]Included to facilitate comparisons across studies
Acronyms: NA: Not applicable

Appendix 1-A

Prisma Checklist

Section/topic	#	Checklist item	Reported on page

TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1-12
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-3 to 1-10
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1-9
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	-
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Appendix 1-C
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	1-10 to 1-11
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1-B
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	1-11 to 1-12 Figure. 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	1-12
Data items	11	List and define all variables for which data were sought (e.g. funding sources) and any assumptions and simplifications	Tables, 1,2,3 & Appendix 1-D to 1-F
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	1-13
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	1-12
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	1-12

Appendix 1-B

Search Syntax

Database	Syntax
PsychInfo, Medline And PubMed	**Population terms**: "Dementia" OR "Cognitive Impairment" OR "Alzheimer's Disease" "Cognitive Dysfunction" AND **Intervention terms**: "Logical Thinking" OR "Metacognition" OR "Decision Making" OR "Problem Based Learning" OR "Problem Solving" OR "Group Problem Solving" OR "Probability Judgment" OR "Judgment" OR "Probability" OR "Uncertainty" OR "Inductive Deductive Reasoning" OR "Reasoning" OR "Inductive Deductive Reasoning" OR "Critical Thinking" OR "Rationality" OR "Digital Technology" OR "Computer Assisted Instruction" OR "Computer Applications" OR "Electronic Learning" OR "Adaptive Learning" OR "Computer Applications" OR "Computer Games" OR "Simulation Games" OR "Neuropsychological Rehabilitation" OR "Cognitive Rehabilitation" OR "Neurorehabilitation" OR "Task Switching" OR "Group Intervention" OR "Intervention" OR "Treatment" OR "Psychoeducation" OR "Client Education" OR "Perceptual Stimulation" OR "Stimulation" OR "Goal Orientation" OR "Cognitive Control" OR "Cognitive Flexibility" OR "Executive Function" OR "Brain Training" OR "Fuzzy Logic" OR "Logic" OR "Thinking" OR "Metacognition" OR "Delay Discounting" OR "Mental Processes" OR "Probability Learning" OR "Overlearning" OR "Discrimination Learning" OR "Cues" OR "Risk-Taking+" OR "Inhibition, Psychological" OR "Impulsive Behavior+" OR "Judgment" OR "Probability" OR "Uncertainty" OR "Technology+" OR "Decision Making, Computer-Assisted+" OR "Simulation Training" OR "Rehabilitation" OR "Internet-Based Intervention" AND **Outcome terms:** "Kohs Block Design Test" OR "Raven Coloured Progressive Matrices" OR "Raven Progressive Matrices" OR "Stanford Binet Intelligence Scale" OR "Wechsler Adult Intelligence Scale" OR "Wechsler Bellevue Intelligence Scale" OR "Executive Functioning Measures" OR "Stroop Color Word Test" OR "Decision Making" "Neuropsychological Tests+" OR "Decision Making" OR "Delay Discounting" OR "Wechsler Scales+" OR "Mental Competency" OR "Mental Status and Dementia Tests+"
Embase OR dementia	**Population terms:** mild cognitive impairment/ OR cognitive defect/ AND **Intervention terms:** decision making/ OR gist/ OR reasoning/ OR investigation/ OR support/ OR group/ OR therapy/ OR intervention/ OR treatment/ OR alleviate/ OR training/ OR multi domain/ OR perception/ OR attention/ OR flexibility/ OR switching/ OR planning/ OR executive function/ OR executive control/ OR logical thinking/ OR judgement/ number/ AND **Decision-making outcome:** decision making/ OR making up mind/ OR flanker /OR stroop/ OR wrat 3/ OR dementia rating scale/ OR clinical dementia rating scale/ OR neuropsychological test/

Web of Science	All free search terms used
Free search terms[a]	**Population terms[b]**: “mild cognitive impairment” OR MCI OR “dementia” OR “alzheimer*” OR “Cognitive impairment” AND **Intervention terms:** “Decision-making” OR “decision making” OR “gist” OR “gist reasoning” OR “reasoning” OR “problem solving” OR “decision support” OR “supported decision making” OR “group intervention” OR “self-monitoring” OR “cognitive stimulation” OR “cognitive rehabilitation” OR “cognitive stimulation” OR “cognitive remediation” OR Neurospsychol* rehabilitation” OR “neuropsychol* intervention” OR “neuropsychol* treatment” OR “pscyhol* intervention” OR “psychol* treatment” OR “response inhibition training” OR “multi-domain cognitive training” OR “multi-domain training” OR “computer-based cognitive” OR “Executive function*” OR “attention” OR “cognitive flexibility” OR “set shifting” OR “task switching” OR“cognitive switching” OR “executive control” OR “planning” OR “ratio processing” OR “number processing” OR “logical thinking” OR “judgement” AND **Outcomes terms:** “decision-making" OR "delay discounting" OR "risk taking" OR "ratio processing" OR "arithmetic" OR "Iowa Gambling Task" OR “IGT” OR "Cambridge Gambling Task" OR CGT OR "Balloon Analogue Risk Task" OR "information sampling task" OR "Bead* Task" OR "Coin Flipping Task" OR "Cups Task" OR "Randomized Lottery Task" OR "Effort-Expenditure for Reward Task" OR "reversal Learning Task" OR "Bandit Task" OR "Game of Dice Task" OR" Probability-Associated Gambling Task" OR "Probability Associated Gambling Task" OR "Foraging Task" OR "flanker" OR "stroop" OR "go/no go" OR "Go/No Go" OR "computerised go/no-go" OR "N back" OR "AX-CPT" OR "reasoning" OR "gist" OR "anchor" OR "framing" OR "capacity" OR "decisional capacity" OR "health decision" or "financial decision" OR "medical decision" OR "medical capacity" OR "financial capacity" OR "Flanker Task" OR "DRS initiation" OR "dementia rating scale initiation" OR "DRS initiation" OR "dementia rating scale perseveration" OR "DRS perseveration" OR "Stroop" OR "stop signal task" OR "Hayling" OR "clock tests" OR "completions and corrections Test" OR "reverse learning task" OR "controlled oral word task" OR "DKEFS sorting test" OR "Brixton" OR "verbal concept attainment test" OR "alternate Uses test" OR "fluency test" OR "Wisconsin Card Sorting" OR "Dimensional Change Card Sorting" OR "Trails B" OR "Cambridge Automated Neuropsychological Test Battery" OR "CANTAB" OR "Intra/extra dimensional set-shifting subtest" OR "IED" OR "BADS rule switch" OR "rule switch" OR "rule-switch" OR "n-back" OR "backwards digit span" OR "self-ordered pointing task" OR "Corsiblock spatial span" OR "Clock" OR "block " OR "BADS key search" OR "key search" OR "zoo map" OR "tower of Hanoi" OR "predicaments task" OR "everyday problem solving inventory" OR "reflective judgement dilemmas" OR "means ends problem solving" OR" everyday problems test" OR "practical problems test" OR "action planning task" OR "WRAT-3" OR "WRAT-3 ARITHMETIC" OR "arithmetic subtest" OR "Columbia card task" OR "Stanford Binet" OR "Figural Analogies" OR "Raven

	Matrices" OR "series completion" OR "odd one out task" OR "digit symbol coding" OR "digit symbol copy" OR "trails A" OR "letter comparison" OR "pattern comparison" OR "substitution test" OR "modality test" OR "TEA phone search" OR "test of everyday intelligence phone search" or "test of everyday intelligence" OR "CLOX 2" OR "DRS construction task" OR "construction task" OR "VOSP" OR "line orientation test"

[a] intervention and outcome terms were selected based on relevant psychological literature, expert consultation and theoretical models including Shiebener and Brand's decision making under risk model (2015a) and the gist reasoning model contained within Fuzzy Trace theory (Reyna & Brainerd, 2011).

[b] Scoping searches indicated that research was often imprecise in the language used to describe the population. Accordingly, words like dementia and impairment were included to try and capture all relevant studies.

Appendix 1-C

Screening Tool Template

Research question:
What neuropsychological interventions are most likely improve or maintain complex decision-making abilities in people with a mild cognitive impairment?

Reviewer name: **Date:**
Author name: **Year of publication:**
Title: **Journal:**

	Include		**Exclude**	
Population	☐	Adults over 18 with mild cognitive impairment (of any type)	☐	People under 18 Adults with additional health problems that could affect cognition including neurological (e.g. stroke dementia or brain injury) or significant psychological difficulties (e.g. a diagnosis of depression). Adults using substances or on medication regimes that could affect cognition (e.g. alcohol or lithium)
Intervention	☐	Neuropsychological interventions that aim to improve or maintain complex decision making skills or the executive functions that are indicated in the literature as most likely to underpin this ability. This should comprise the majority of the intervention or it should be possible to extract this data. This includes CT, CS and CR targeted at reasoning skills, Judgement, cognitive control, inhibition, cognitive flexibility, task monitoring, working memory (if concurrent with another relevant cognitive function, verbal/semantic fluency or ratio processing).	☐	Interventions intended to: compensate for deficits; modify the environment; modify cognitions extensively reviewed elsewhere including memory and working memory; modify cognitions unrelated or distally related to decision making including processing speed; modify personal factors other than cognition including physical health or mood
Outcomes	☐	Any quantifiable measure of decision making or relevant executive function	☐	Any other outcome including other types of cognitive processes like short-term memory or simple attention or where measures of working memory

Screening Tool Template

				are the only measure included
Study design	☐	Any quantitative study that reports data to derive the intervention effects of interest. This is likely to include randomised, non-randomised and cohort studies	☐	Qualitative
Other Features of the study	☐ ☐	Published in English Peer-reviewed	☐ ☐	Published in any language other than English Grey literature including Conference reports and dissertations
Overall decision	☐	Include	☐	Exclude

Notes:

Appendix 1-D

Characteristics of Included Studies

Author (yr.)	Funding source	*N* of participants	Method of diagnosis for MCI	Frequency (session/week) total session, duration and dosage of intervention	Drop-out *N*, (%)	Method and context for intervention experimental condition (EC) and comparator condition (CC)	Outcome of interest
Barban et al. (2016)	European Union.	106	Petersen et al. (2004) criteria.	24 one-hour sessions, twice weekly for three months followed by three months rest (arm A) and reversed for arm B. Software provided by SOCIABLE via a touch-screen computer. 30 mins of CT and 30 mins of episodic reminiscence about their life.	n/r for MCI sub-sample	Groups of up-to three facilitated by a trained therapist. Difficulty could be individually adapted for each task across three levels of difficulty.	EFs including cognitive control and logical reasoning.
Barekatain et al. (2016)	Isfahan University of Medical Sciences.	36	NUCog criteria (Walterfang et al., 2006)	Two hours a week for eight weeks. Practice during the week encouraged.	12 (33) (10 from CR)	Group work in a university clinic facilitated by a trained PhD student. Training comprised attention processing training, goal management work and problem solving activities.	EFs
Boripuntakul et al. (2012)	n/r	10	Petersen et al. (2001) and Grundman et al. (2004) guidelines.	18 sessions over 60 mins, 3 days a week. Over six weeks difficulty progressed each week or once 100% pass rate achieved.		Face-to-face CT with researcher. Pre-set randomised schedule with each person in the EG receiving memory, attention and EF modules.	Short-term effects of cognitive training on cognitive function.
Burgio et al. (2018)	San Camillo Hospital, Venice & Medical University of Innsbruck.	23	Petersen et al. (2004) and Albert et al. (2011) guidelines.	Two interventions of CT: 30 mins on 5 consecutive days for each intervention. "easy" level with optional "difficult" once the easy level was completed.	0 (0)	Task completion was supervised by a psychologist.	Ratio processing and decision-making under risk.
Cipriani et al. (2006)	n/r	13	n/r	Two periods of training comprising 13-45 min. sessions, 4 days a week over 4 weeks with a break of approx. 6 weeks. Difficulty can be tailored but whether this was done is n/r.	0 (0)	Individual computer-based training at an Italian neurorehabilitation day hospital.	Effect of CT on non-verbal intelligence.
Damirchi et al. (2018)	No funding received.	54	Score of 18-23 out of 30 on the MMSE (Folstein et al.,1975).	30 minutes each day rising to 60 minutes for weeks 7 & 8 at a day centre in Iran.	10 (23.76)	Individual computer-based games supervised by a physiotherapist at a day centre.	EFs

Author (yr.)	Funding source	*N* of participants	Method of diagnosis for MCI	Frequency (session/week) total session, duration and dosage of intervention	Drop-out *N*, (%)	Method and context for intervention experimental condition (EC) and comparator condition (CC)	Outcome of interest
Das et al. (2019)	Sammons Enterprises; Barbara Wallace Foundation Trust.	22	Petersen et al. (2001) criteria.	Two one-hour sessions per week over four weeks.	7 (4 from training group only, 3 from training + tDCS).	Small groups of up-to five facilitated by a trained clinician. Encouragement to practice skills as often as possible outside the session.	Gist reasoning: Complex abstraction; innovative thinking; fluency; inhibition and conceptual reasoning.
Djabelkhir et al. (2017)	Foundation des Gueules Cassees and KODRO software.	20	As defined by Petersen et al. (2004).	One session a week lasting 90 minutes for three months (12 sessions total). Difficulty level could be adjusted at the group level. Software by KODRO.	1 (5) (from the CCS group).	Group (up-to 7 people) activity facilitated by a neuropsychologist.	EFs including flexibility, fluency, inhibition and WM.
Djabelkhir-Jemmi et al. (2018)	Foundation des Gueules Cassees and KODRO software.	58	As defined by Petersen (2004) and 1.5 SD below the norm on a test of EF.	24 1.5 hour sessions undertaken twice-weekly for three months. Software by KODRO. Content changed every two weeks and comprised four 15 minute activities.	21 (ten in non-WMH group and 11 in the WMH group)	Undertaken at a hospital. Group activity facilitated by a neuropsychologist. Individual responses to questions on a large screen via individual iPad. Feedback provided after each task.	Mental flexibility, processing speed, working memory, planning, categorization, inhibition and divided attention.
Donneza et al. (2018)	Decathlon sports equipment.	34	Single or multi-domain MCI via Petersen (2004).	Two 1 hour sessions per week over 12 weeks (24hrs total).	6 (17.64) CT:5 - 3 during training and 2 at follow-up C: 1 during training.	Groups of 4-8 people held at memory clinic using "Happyneuron" and Presco" gaming (Yhnell et al., 2018). Exercises projected on a wall and responded to in turn by participants.	EFs (working memory, flexibility, inhibition and reasoning).
Finn et al. (2011)	n/r	25	Single or multi-domain amnestic MCI as per Winblad et al. (2004). and a score of >23 on the MMSE.	4-5 training sessions per week until 30 were completed. Difficulty increased individually after reaching pre-determined performance level. Computerised feedback given. Software by Lumosity Inc.	9 (36). 4 in training gp and 5 in control gp	Completed at home without supervision after the first training session. Weekly prompts and progress monitored remotely online.	EFs (working memory and cognitive control).
Finn et al. (2014)	n/r	2	Single or multi-domain amnestic MCI as per Winblad et al. (2004) and a score of >23 on the MMSE.	Two phases each comprising twenty sessions. Each session lasted 2 hours and contained 3-4 training tasks. Entire data collection over eight weeks. Difficulty of tasks gradually increased once a pre-determined score was achieved. Software by Lumosity Inc.	1 (33.3)	Training delivered at a memory clinic on an individual basis twice a week.	EFs (flexibility, problem solving, reasoning and control).

Author (yr.)	Funding source	*N* of participants	Method of diagnosis for MCI	Frequency (session/week) total session, duration and dosage of intervention	Drop-out *N*, (%)	Method and context for intervention experimental condition (EC) and comparator condition (CC)	Outcome of interest
Gagnon et al. (2012)	n/r	26	MCI with executive deficits (with or without memory impairment). As defined by Petersen (2001) and a score of 1.5 SD below age-matched norms on at least one EF test.	6 one-hour training sessions over two weeks.	4 (15.3)	Trained in sub-groups of two with individual computers and a researcher present.	Attentional control
Li et al. (2019)	Clinical Research Centre, Shanghai University; National Natural Science Foundation.	80	Albert et al. (2011) guidelines.	Three or four sessions of 40 mins each week for six months. Self-adaptive difficulty levels.	97 (60.62): 2 at 6mth follow-up and further 45 at 18mths in training group; 17 at 6mth and further 33 at 18mth in control group.	Alone at home online. Training duration and performance checked by a researcher weekly.	EFs
Manera et al. (2015)	European Commission and Alzheimer's Association.	21	Albert et al.(2011) guidelines.	Five sessions over a four-week period in which new "cooking" scenarios were introduced.	1 (4.7) the group was n/r	Sessions were held at research centre in Nice, France with a trained clinician. Participants encouraged to practice the games as often as possible at home.	EFs (particularly planning).
Matias-Guiu et al. (2016)	n/r	20	As defined by Peterson et al. (2008).	Two sessions of 150 minutes, twice a week for five weeks. Exercises gradually increase in difficulty regardless of previous score. BrainFactory +50 software.	None	Two groups of ten people comprising members of all diagnostic groups. Individual and group tasks were included.	Problem solving, numeracy and spatial thinking.
Moro et al. (2015)	Fondazione Cariverona; Italian ministry of Education and Italian ministry of Health.	30	As defined by Peterson et al. (2008).	Six months of cognitive stimulation. First two months consisted of two one-hour sessions per week. In the final four months one session per week with homework.		Sessions were held at the Centre for Cognitive Disorders in Verona and were facilitated by a trainer. People were encouraged to practice as much as possible at home. A carer attended every session.	EFs including: flexibility; multi-tasking; inhibition; categorical thinking; verbal reasoning based on prior knowledge; planning and problem solving.

Author (yr.)	Funding source	*N* of participants	Method of diagnosis for MCI	Frequency (session/week) total session, duration and dosage of intervention	Drop-out *N*, (%)	Method and context for intervention experimental condition (EC) and comparator condition (CC)	Outcome of interest
Mudar et al. (2017)	Grants from the RGK foundation, Dallas, Texas.	50	As defined by Petersen et al. (2001).	Two one-hour sessions over four weeks. Sessions included training on extracting relevant information from real-world information (e.g. news bulletins), generalising the meaning and generating multiple interpretations.	None	Small groups of up-to five facilitated by a trained clinician. Encouragement to practice skills as often as possible outside the session.	Gist reasoning comprising strategic attention, integrated reasoning and innovative thinking.
Mudar et al. (2019)	Grants from the RGK foundation, Dallas, Texas.	50	As defined by Petersen et al. (2001).	Two one-hour sessions of training over four weeks.	None	Small groups of up-to five facilitated by a trained clinician. Encouragement to practice skills as often as possible outside the session.	Gist reasoning comprising strategic attention, integrated reasoning and innovative thinking.
Nousia et al. (2019)	n/r	46	As defined by Peterson et al. (2013).	15 weeks, two sessions per week. Each session lasting between 30-60 mins. Software provided by RehaCom Cognitive Therapy Software.	0	n/r	Impact of CT on logical reasoning.
Oskoei et al. (2013) & Oskoei et al. (2016)	n/r	40	Score of <25 on the MMSE (Folstein et al., 1975).	12 sessions, twice a week for 2.5 hours. Difficulty progressively increased after pre-defined scores were achieved. Software via NEurocognitive Joyful Attention Training. "Four" tasks each session – details n/r.	10 (25) five from each group. Reasons n/r.	Location of training n/r. Presence of facilitator or monitoring undertaken n/r.	Impact of CT on selective attention and attentional flexibility.
Silivaikul et al. (2019)	Faculty of Associated Medical Science, Chaing Mai University.	24	Score of 11-25 on the MoCA.	Three-hourly sessions per week for six weeks. Activities included games and training drills.	0	Individual and small group work based at the social welfare home.	Impact of cognitive training on EFs.
Unverzagt et.al. (2007)	National Institute on Aging; National Institute of Nursing Research; National Institute of Health.	2802 (main data set) of which, 193 were eligible in this study.	Psychometric algorithm based on RAVL test – 1.5 SD below predicted score.	Ten training sessions of 60-75 minutes over a six week period. Included individual and group exercises and feedback. Difficulty progressively increased after accuracy scores of 75% were achieved. Session 1-5 strategy instruction and 6-10 strategy practice.	n/r	Small groups (max. 5) facilitated by a trainer using a manual. "Make-up" sessions arranged when sessions were missed.	Impact of CT on reasoning ability.

Author (yr.)	Funding source	*N* of participants	Method of diagnosis for MCI	Frequency (session/week) total session, duration and dosage of intervention	Drop-out *N*, (%)	Method and context for intervention experimental condition (EC) and comparator condition (CC)	Outcome of interest
Yang et al. (2020)	Ministry of science and technology, Taiwan.	78	As defined by Peterson et al. (2013).	Three 45-minute sessions three times a week for six weeks. Software from CogniPlus that adapts difficulty to individual ability during training.	7 (4 from experimental) reasons were mainly leaving the home.	A dedicated room at the recruitment centre was provided for each session. Fidelity monitored by the software and researchers who recorded training status of each person.	Effect of multi-domain attention training on cognitive control.
Zhang et al. (2019)	Beijing Municipal Science Commission and China Scholarship Council.	27	As defined by Petersen et al. (2001).	Two hourly-sessions per week for 12 weeks. Five levels of difficulty on each task that would be increased once a pre-defined score had been reached. Software by Beijing Neowave Technology Co.	10. Personal reasons cited.	Completed on individual tablet computers and facilitated by trainers who were not permitted to provide feedback or task support beyond resolving technology issues.	Effect of multi-domain cognitive training on EFs.

[a] In addition: 1.5 SD below the mean on memory tests (single domain amnestic MCI); 1.5 SD below the mean on reasoning or processing tests (multi-domain MCI) or 1.5 SD below the mean on tests of memory and one other domain (Multi-domain amnestic MCI)

[b] In addition, 1.5 SD below the mean score on any composite score of memory, speed of processing or executive function

Acronyms and definitions: MMSE: Mini Mental State Examination; C: Control group; CT: Cognitive training; SD: standard deviation; EF: Executive function; SOPT: Speed of processing training; tDCS: Transcranial Direct Current Stimulation; RAVL: Rey Auditory Verbal Learning test; MoCA: Montreal Cognitive Assessment;

Appendix 1-E

Characteristics of Participants

	MCI Intervention Group				Comparator group				
Author (yr.)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	Exclusion criteria
Barban et al. (2016)	46 (43.39)	25 (54.34)	74.4 (5.7)	9 (4.3)	60 (56.6)	31 (51.66)	72.9 (6)	11 (4.7)	<65 yrs; <5 yrs education;
Barekatain et al. (2016)	17	1 (5.88)	n/r	n/r	19	2 (10.52)	n/r	n/r	<60 yrs; <5 yrs education; psychiatric or neurological disorders, independence in daily living tasks, dementia or medication that could affect cognition
Boripuntakul et al. (2012)	5 (50)	2 (40)	78.4 (5)	12.4 (3)	5 (50)	2 (40%)	77.6 (6.1)	9 (5.2)	<50 yrs; no cerebral infection or disease in last 12 months; no depressive symptoms (as measured by GDS (Debruyne et al., 2009)) and no cognitive-enhancing drugs
Burgio et al. (2018)	12 (arm A) (52.1)	4 (33.3)	76.17 (9.95)[a]	10.92 (3.48)	11 (arm B) (47.8)	6 (54.5%)	77.27 (6.54)	10.18 (4.29)	Neurological, medical or psychiatric co-morbity (measured by HADS (Snaith & Zigmond, 1986)).
Cipriani et al. (2006)	10 (43.4)	n/r	70 (6.0)	n/r	3 (13)	n/r	69 (9.5)	n/r	n/r
Damirchi et al. (2018)	11 (25)	0	67.9 (3.7)	3.5 (1.2)	9 (20.4)	0	69.1 (4.9)	3.2 (1.2)	< 60 or > 85 yrs, ability to read, write, see and hear outside normal range; muscular disorder; depression (as measured by GDS (Debruyne et al., 2009)); history of physical exercise and medication for dementia or depression.
Das et al. (2019)	10 (45.45)	2 (20)	63.3 (7.38)	16.2 (1.75)	12	4 (33.33)	62.58 (8.43)	17.92 (3.94)	<50 yrs and >80 yrs; less than 12 years of education; depressive symptoms; left handed; non-verbal; no reading or writing ability (English); neurological, physical or psychiatric conditions; substance misuse; medical devises in the body; medication.
Djabelkhir et al. (2017)	10 (50)	4 (40)	78.2 (7)	n/r	10 (50)	3 (30)	75.2 (6.4)	n/r	<60 yrs; Neurological or psychological disorders; substance misuse; sensory or motor deficits that could interfere with using the digital technology

	MCI Intervention Group				Comparator group				
Author (yr.)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	Exclusion criteria
Donnezan et al. (2018)	16 (23.1)	n/r	76.3 (1.5)	5.5 (0.36)	14 (20.2)	n/r	79.2 (4)	5.8 (0.4)	<65 yrs, employed, depression (as measured by GDS (Debruyne et al., 2009)) Non-French speaking.
Finn et al. (2011)	12 (48)	n/r	n/r	n/r	13 (52)	n/r	n/r	n/r	Non-amnestic MCI; age <60; psychiatric illness; substance abuse; visual, auditory or motor impairment; recent use of cholinesterase inhibitors.
Finn et al. (2014)	2 (100)	1 (50)	63.5 (n/r)	n/r	NA	NA	NA	NA	Non-amnestic MCI; age <60; psychiatric illness; substance abuse; visual, auditory or motor impairment; recent use of cholinesterase inhibitors.
Gagnon et al. (2012)	12 (46.15)	n/r	68.42 (6.04)	13.08 (5.66)	12 (46.15)	n/r	67 (7.8)	15 (4.63)	Non-French speaking; hospital inpatients; left-handed; hearing or vision impairments; severe psychiatric disorder; substance misuse; dementia and neurological disorders including TBI.
Li et al. (2019)	78[a] (48.75)	45 (57.69)	69.5 (7.3)	13.8 (2.5)	63 (39.37)	21 (33.3)	71.5 (6.8)	13.5 (2.5)	Neurological conditions, mood problems, poor vision and hearing and anyone taking anti-depressive or anti-psychotic medication.
Manera et al. (2015)	9 (42.85)	2 (22.22)	75.8 (9.1)	n/r	12 (57.14)	4 (33.33)	80.3 (6.3)	n/r	Current depression; perceptual impairment; epilepsy.
Matias-Guiu et al. (2016)	6 (30)	3 (50)	72.6 (5.8)	8.3 (1.9)	9 (70)	n/r	74.1 (5.93)	7.3 (5)	age <65; Behavioural disorders or systemic disease that might result in poor compliance; depressive symptoms; poor literacy or mathematical ability.
Moro et al. (2015)	15 (50)	n/r	75.53 (4.98)	9.06 (3.47)	15 (50)	n/r	74.13 (8.45)	10.06 (4.57)	Non-Italian speakers; neurological or physical disease or head injury; history or symptoms of psychosis or depression; substance misuse; dementia.
Mudar et al. (2017)	23 (46)	12 (52.17)	75.65 (8.51)	16.22 (2.26)	27 (54)	11 (40.74)	69.78 (8.01)	17.26 (1.48)	Neurological, physical or psychiatric condition; depressive symptoms; hospital patients; non-English speaking; substance misuse and psychoactive medication.
Mudar et al. (2019)	16 (50)	10 (62.5)	74.5 (8.7)	16.7 (2.1)	16 (50)	8 (50)	70.8 (8.9)	17.5 (1.7)	As above

Author (yr.)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	*N*, %	Male, *N*, %	Age, mean (SD)	Education yrs Mean (SD)	Exclusion criteria
Oskoei et al. (2013) & Oskoei et al. (2016)	20	n/r	n/r	n/r	20	n/r	n/r	n/r	age <55; lower than degree-level education; psychiatric or neurological co-morbities; impaired sensor or motor skills.
Silivaikul et al. (2019)	12 (50)	7 (58.33)	72.75 (5.98)	n/r	12 (50)	6 (50)	72.25 (5.01)	n/r	<60 yrs and >80 yrs; non-Thai speakers or readers; <18 on MMSE for participants with only a primary school education and <23 on MMSE for high school; depressive symptoms; taking anti-depressant medication and no physical impairment that could affect engagement with tasks.
Unverzagt et.al. (2007)	193 (6.88) (reasoning group sub-set not reported)	49 (25.38)	74.5 (6.4)	13.6 (2.6)	705	n/r	n/r	n/r	age <65; Hospital patients; <23 on MMSE as a proxy for dementia; medical condition with high likelihood of functional decline; poor visual acuity; communication difficulties.
Yang et al. (2020)	39 (50)	9 (23.1)	72.2 (8.1)	11.2 (4.9)	39 (50)	7 (17.9)	81.8 (7.1)	9.9 (4.7)	Major mental illnesses; diagnosis or signs of dementia; sensory or communication difficulties, evidence of severe cognitive decline or cognitive attention training in the last year.
Zhang et al. (2019)	17 (62.96)	6 (35.29)	75.2 (3.8)	13.6 (3.3)	NA	NA	NA	NA	age <55; Left handed; <5 yrs of education; Axis one disorders as listed in DSM IV (American Psychological Association, 2010); pharmaceutical regimen including cognitive enhancers or anti-depressant medication; neurological or physical condition including brain injury.

[a] Data provided by author in personal communication

Acronyms and definitions: n/r, not reported; DSM: Diagnostic and Statistical Manual; GDS: Geriatric Depression Scale; HADS: Hospital anxiety and depression scale; MCI: Mild Cognitive Impairment; MMSE: Mini Mental State Examination; TBI: traumatic brain injury

Appendix 1-F

Measures, Analyses and Results

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
Barban et al. (2016)	Whether process-based cognitive training affects EFs compared to a rest period	**VFT** (Novelli et al., 1986); and **TMT B** (Kortte et al., 2002)	**X3**: Before, immediately after and 6-months after training	2 (group) x 2 (time) mixed **ANOVA** Post-hoc *t*-tests for significant interactions	No main or significant interaction effects were found in relation to EF domains
Barekatain et al. (2016)	Whether CT improved EFs (planning, divided and sustained attention, flexibility, inhibition, working memory and fluency)	**TOL** task (Massimo et al., 2011); CTT; **Five-point test of figural fluency**; **Go-No/Go** test and **SFT** (Strauss et al., 2006); **DFT** (Jones-Gotman & Milner, 1977)	**X3**: Before, immediately after and 6-months after training	**Repeated measures ANCOVA**	**TOL:** This was the only task in which the CR group improved significantly against the control group six months after training ($\boldsymbol{p}$ = .02, d = .05). No significant improvements in other tests.
Boripuntakul et al. (2012)	Short-terms effects of cognitive training on executive function.	**DSF** and **DSB** combined score (Ostrosky-Solís & Lozano, 2006) and **TMT B-A**	**X2** : Before and immediately after CT	**Wilcoxon** Signed Ranks test (pre and post outcomes within groups)	**DSF and DSB combined** score pre- and post-training $\boldsymbol{p}$ = <.05 for experimental group $\boldsymbol{p}$ = >.05 for control group **TMT B-A :** $\boldsymbol{p}$ = <.05 for experimental group ; $\boldsymbol{p}$ = >.05 for control group. No other statistics reported or provided.
Burgio et al. (2018)	Whether number processing or EF cognitive training is more effective on both ratio processing and decision-making under risk	**GDT** (Brand et al., 2005); **PAG** (Brand et al., 2006); **Health-related ratio processing task** (Lipkus et al., 2001); **calculation with ratios task** (adopted from a task developed in a previous study (Zamarian et al., 2019). A composite score for ratio processing was achieved by combining the scores from the two ratio tasks.	**X3** :Before first training segment (T0) ; after first training segment (T1) and after second training segment (T2)	**Friedman** test (performance over time) and **Wilcoxon Signed Ranks test** for post-hoc testing within groups **Mann-Whitney U** test	Significant main effect of time for an aspect of the PAG-60 Fixed sum condition) and for ratio-processing. **PAG-60 :** Fixed sum condition in **group A** : $\boldsymbol{\chi}^2$ = 11,261, df = 2, $\boldsymbol{p}$ = <.00 ; T0-T2: Z = -2,943, $\boldsymbol{p}$ = <.00 Fixed sum condition in **group B** : $\boldsymbol{\chi}^2$ = 7,744, df = 2, $\boldsymbol{p}$ = .02 ; T0-T1 Z = -2,191, $\boldsymbol{p}$ = .02 ; T0-T2: Z = -2,090, $\boldsymbol{p}$ = .03[a] **Ratio processing tasks : group A** : $\boldsymbol{\chi}^2$ = 8,167, df = 2, $\boldsymbol{p}$ = .01 ; T0-T1: Z = -2,476, $\boldsymbol{p}$ = .01 ; T0-T2: Z = -2,044, $\boldsymbol{p}$ = .04 ; T0-T2 = n/s **Group B** : $\boldsymbol{\chi}^2$ = 8,909, df = 2, $\boldsymbol{p}$ = ..01 ; T0-T1 = n/s; T1-T2: Z = -1,962, $\boldsymbol{p}$ = .05 ; T0-T2: Z = -2,582, $\boldsymbol{p}$ = .01

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
Cipriani et al. (2006)	Whether CT improves scores on psychometric tests that are proxies for the trained skill/ability. Those of interest for this study were verbal and semantic fluency, divided attention and logical inductive reasoning.	**VFT**; **SFT** (Spinnler & Tognoni, 1987) and **TMT B. Proximal measures** replicating the computerised tasks were also used, of which those labelled working memory, divided attention, verbal comprehension, semantic categorisation and logical reasoning were the most relevant.	**X2** : Before and immediately after CT.	**Wilcoxon** Signed Ranks Test.	Means, SD and ES in MCI group for proximal measures that mirrored computerised tasks: **Working memory** : pre - 1.6 (1.4) / post 3.7 (0.8). p = .04, d = 1.84 ; **Divided attention** : n/s ; **verbal comprehension** : pre – 4 (2.8) / post 5.2 (2.9), p = .02, d = .42 ; **semantic categorisation** : pre – 3.6 (3.1) / post 6.3 (3.4) p = .02, d = .83 ; **logical reasoning** : pre – 1.2 (0.9) / post 2.8 (1.) p = .01, d = 1.29 No significant results for psychometric tests of executive function for either group (statistics not reported).
Damirchi et al. (2018)	Whether "mental training" improves EF conceptualised as WM, planning and problem solving.	Computer versions of **digit-symbol coding** of the WAIS-III and **Stroop color-word** test for reaction time and error number (Tulsky, 2003; Van Der Elst et al., 2006).	**X3**: Before, immediately after and 6-months after training.	One-way **ANOVA** (between group differences) and paired sample t tests (within group changes).	**Post training: Digit-symbol**: $F(3.40) = 4.47$; p =.008, d = 1 ; **Stroop Reaction time**: $F(3.40) = 2.38$; p =.084, d = .73 ; **Stroop Errors**: $F(3.40) = 4.16$; p =.012, d = .96. **Follow-up: Digit-symbol:** $F(3.40) = 1.18$; p =.329, d = .5**;** **Stroop Reaction time**: (EFs): $F(3.40) = 1.24$; p =.30, d = .52; **Stroop Errors** (EFs): $F(3.40) = 8.56$; p =.001, d = 1.38 No significant changes reported in within control group. No statistics reported.
Das et al. (2019)	Whether gist reasoning training improved EF.	**TOSL** (Chapman et al., 2002); **COWAT** (Benton et al., 1994); **Colour-word interference** (Delis et al., 2001); card sort test; **SALT** (Hanten et al., 2007).	**X3** : Before and after intervention and three months follow-up.	**Dependent *t*- tests**	**Experimental group**: Inhibition (colour-word interference): t= -2.04; p =.04; Innovative thinking (TOSL): t= -2.67; p =.01. Comparator group achieved no statistically significant gains. Improvements were not sustained in the experimental group. Other results reported averages across the groups so specific groups scores could not be extracted.
Djabelkhir et al. (2017)	Whether computerised cognitive stimulation (CCS) improved EF compared with an active control group.	**TMT B; VFT; SFT** and **DSB.**	**X2** : before and after training.	**Independent *t*-test or Mann-Whitney** test for between group differences.	No statistically significant differences between groups.

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
Djabelkhir-Jemmi et al. (2018)	Whether CCS results in improved EF and whether scores differ between participants with low or high white matter hyperintensities (WMH)	**TMT B; Digit-symbol** test of the WAIS III; **DSB; VFT; SFT; RCFT** (Hubley, 2010).	**X3** : Before and after intervention and three months follow-up	**ANCOVA**	**Group comparison T0 – T1:** Significant differences for **SFT**: $F(1,44) = 11.09$, $p = .002$, $d = .89$ **T1 – T2:** for **SFT:** $F(1,44) = 17.24$, $p = .00$, $d = 1.11$; **RCFT**: $F(1,44) = 3.97$, $p = .05$, $d = .53$ Other outcomes were non-significant
Donnezan et al. (2018)	Whether CT delivered in a group context improves EFs compared to a passive control group	**MRT** (Stephenson & Halpern, 2013), **Stroop color-word**; **DSB**	**X3 :** Before, immediately after training and six months after training	2 (group) x 2 (time) mixed **ANOVA**	**Interaction effects:** **MRT** ($F(3,65) = 4.46$; p <.0001). Calculated effect size of .96. No other ANOVA statistics reported. **Significant pre-post effects** were found in the CT group, with no significant differences in the control group.
Finn et al. (2011)	Whether cognitive training improves EF	**CANTAB** (Smith et al., 2013) **IED, SWM** (errors and strategy scores) **and RVP tests**	**X2** : before and after training	2 (group) x 2(time) **ANCOVA** with MMSE as a covariate	**Interaction effects** (effects of intervention): **IED**: $F(2,14) = 0.01$, $p = .91$, $d = .04$; **SWM errors**: $F(2,14) = 0.0$, $p = .97$; **SWM strategy**: $F(2,14) = 2.91$, $p = .11$, $d = .71$; **RVP:** $F(2,14) = 11.95$, $p = .00$, $d = 1.44$
Finn et al. (2014)	Whether phased CT beginning with non-memory interventions impacts on the cognitive functioning of adults with MCI.	**TMT B** and **Odd One Out** test (Colman, 2008).	Treatment probes used during training sessions at a ration of 1 :4 with a total of 13 sets of data.	Descriptive statistics and **linear regression** on measures that indicated a trend in scores.	Visual graphs presented for session scores. **Participant 1**: **TMT B**: $R^2 = .27$, $p = .11$; **OOO**: $R^2 = .34$, $p = .03$ **Participant 2**: **TMT B:** $R^2 = .16$, $p = .16$; **OOO**: $R^2 = .14$, $p = .19$
Gagnon et al. (2012)	Whether CT in attentional control will improve sustained attention, divided attention and – more broadly – cognitive switching, problem solving and inhibition in MCI	Version of the dual task used in training sessions modified to manage practice effects (included visual detection and arithmetic tasks); **TEA** (Robertson et al., 1994) - telephone search, telephone search while counting and visual elevator subtests; **TMT B**	**X2** : before and after training	2 (attention) x 2 (time) x 2(group) **mixed ANOVA** (for the dual attention tasks) 2 (time) x 2 (group) - **ANOVA** for TEA and TMT tests	**Bespoke dual attention tasks:** **Visual detection accuracy:** Attention x intervention x group: $F(1,22) = 5.58$, $p = <.05$, $\eta^2 = .20$. Further tests indicate that the experimental group improved in divided attention p = <.01 **Visual detection response time:** Main effect of intervention only: $F(1,22) = 5.12$, $p = <.05$, $d = .56$. **Arithmetic task**: Main effect of intervention (time x group) on accuracy: $F(1,22) = 72.8$, $p = <.00$, $d = 3.63$ and response time: $F(1,22) = 8.18$, $p = <.01$, $d = 1.22$ **TEA** telephone task while counting: main effect of intervention: $p = <.04$ (F = n/r); **TEA elevator**: Main effect of intervention: $F(1,22) = 12.24$, $p = <.01$, $\eta^2 = .37$

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
Li et al. (2019)	Whether computerised CT improves EF compared to a passive control	**ACER** (Fang et al., 2014); **Symbol-digit** test; **SCWT**; **RCFT** and **TMT B**	**X3** : before (T0) and after training (T1) and after 18 months (T3)	Mixed effects regression model with time x group used to calculate the effect of intervention.	**T0 – T1**: significant interaction effects **SCWT** (p = .03, η^2 = .14); **RCFT** (p = .03, η^2 = .37). Other results reported as non-significant. **T1 – T2:** Improvements continued to be observed in the training group for SCWT (p = .01); RCFT (p = .05) and TMT B (p = .02). Differences between groups were not significant.
Manera et al. (2015)	Whether a computerised game simulating everyday tasks would improve EF compared to a group with dementia	Time taken, and errors, across game activities over five weeks were calculated (proximal measures). **Categorised as gnosis (attention) and EF tasks**. EF activities correlated with Stroop task (word/dot and interference dot)	**X2 :** Composite mean scores of all five scenarios at T0 to T1	Descriptive statistics and *t* tests	**MCI group** **Executive function**: Average mean scores of **three minutes 25 seconds** for tests of inhibition in MCI group at T**0 (**d = .96) and **two minutes 13** seconds at T**1, (**d = 1.72) Participants with an MCI diagnosis spent significantly less time completing an activity (p = .01) and showed fewer errors (p = .02) compared to those with Alzheimer's disease.
Matias-Guiu et al. (2016)	Whether a CSS would improve or maintain cognition in MCI compared with healthy controls and a group with probable dementia	**TMT B**	**X2** : before and after training	**Wilcoxon Signed Ranks** Test (pre and post outcomes within groups)	Scores on the **TMT B** improved slightly albeit with greater variance in scores than before training. Improvements did not achieve statistical significance.
Moro et al. (2015)	Whether CS maintains or improves cognitive function in EF	**TOL** task; **Dual Task** (Foley et al., 2011); **TEA**; **TMT** (B-A); **SNA** subtest of WAIS III and **LST** (Komori, 2016).	**X3** : before and after training and after 12 months	**Repeated measures ANOVA** : 3 (time) x 2 (group) Repeated contrasts	**Dual task:** Significant interaction effect: $F(2,27) = 4.59$, p = <.01, d = .81 - *t* tests indicate that the difference arose from a decline in scores for group B as opposed to gains in group A **TEA**: Significant interaction effect: $F(2,27) = 3.94$, p = <.02, d = .75 - Group A improved after training and continued to improve at T3. Group B maintained scores in the waiting period (T1-2) but improved after training (T3). **LST:** Significant interaction effect: $F(2,27) = 3.42$, p = <.04, d = .69. Both groups improved but results were not sustained.

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
					SNA: No significant interaction effects and considerable variation in individual scores. However, Group A improved after training: $t(14) = 2.3$, $p = .03$ and maintained this at T3: $t(13) = 2.52$, $p = .02$. Group B showed no change. **TOL:** Like SNA there are no significant main or interaction effects however there is an indication that Group B improved after training
Mudar et al. (2017)	Whether gist reasoning training improves EF compared to an active control group	**Similarities** sub-test of the WAIS-III; **strategic attention task** (Hanten et al., 2007) and **complex abstraction** task (Anand et al., 2011).	**X2** : before and after training	Interaction contrast of means (pre and post test and group x time effects) transformed to *t* statistics	**Similarities** test: Experimental group achieved an average score of 13.32 before training and 14.27 afterwards (approaching significance - $p = .06$, $d = -.05$ compared to the control group). **Strategic attention**: Experimental group achieved an average score of 2.95 before training and 4.34 afterwards ($p = .01$, $d = .12$ compared to the control group). **Complex abstraction**: Experimental group improved their scores - achieved an average score of 2.96 before training and 3.37 afterwards. No statistical differences compared to the control group ($p = .49$)
Mudar et al. (2019)	Whether gist reasoning training improves EF (inhibition) compared to an active control group	**Go/NoGo** tasks designed for the study that included basic categorisation (of two objects) and superordinate categorisation	**X2** : before and after training	Interaction contrast of means (pre and post test and group x time effects) transformed to *t* statistics	There was a significant main effect of training for response inhibition (No/Go) accuracy in the basic categorisation task: $F(1,30) = 8.04$, p = <.00, $d = 1.03$, with increased accuracy post-training. All other effects were described as non-significant and not reported.
Nousia et al. (2019)	Whether CCT improved logical thinking compared to a passive control group	**Clock drawing** test (Nair et al., 2010); **DSB and SFT** (Tombaugh et al., 1999); **TMT B**	**X2** : before and after training	2 (time) x 2 (group) **ANOVA**	Significant interaction effects for **SFT:** $F(1,44) = 82.13$, $p = <.001$, $d = 2.74$; **CDT**: $F(1,44) = 7.29$, $p = <.01$, $d = .81$; **DSB:** $F(1,44) = 5.26$, $p = <.04$, $d = .69$ (experimental group stable and control group scores worsening); **TMT-B**: $F(1,44) = 9.64$, $p = <.01$, $d = .94$ Other interactions and effects were reported but not significant

Author (yr.)	Outcome(s) of interest	Measures used	Number and timing of outcome measurement	Method of analysis	Outcome results
Oskoei et al. (2013) & Oskoei et al. (2016)	Whether CT improves selective attention and attentional shifting compared to a passive control group	**Stroop color-word** test (time and error measurements) and **WCST** (Borkowska et al., 2009)	**X2** : before and after training	**MANCOVA** (pre-test scores = covariance variables)	**Stroop**: Wilks' Lambda = .75. $F(2,25) = 4.11$, $p = <.05$, $\eta^2 = .24$ **WCST**: Correct responses: Mocheli test = .76, $F(2,25) = 14.07$, $p = <.05$, $\eta^2 = .50$; Number of completed sets: Mocheli test = .87, $F(2,25) = 13.91$, $p = <.05$, $\eta^2 = .49$; perseveration error: Mocheli test = .98, $F(2,25) = 8.98$, $p = <.05$, $\eta^2 = .59$
Silivaikul et al. (2019)	Whether CT improves or maintains EF in a group of disadvantaged older people with MCI in "social welfare" homes	**Block design, clock drawing** and **pictorial A & B** – composite score calculated to provide a proxy for EF	**X2** : before and after training	**Wilcoxon** Signed Ranks Test **and Mann-Whitney** test	After training, the control groups scores had worsened whilst the training group's improved ($p = .03$). The control group declined to significant levels in the six weeks between testing. Full statistics not provided.
Unverzagt et.al. (2007)	Whether CT improves cognitive function and reasoning compared to a passive control group	Composite score of: **Letter Series Task, Letter Sets Task and Word Series Task** (Gonda & Schaie, 1985; Thurstone & Thurstone, 1949)	**X4** : before (T0), after training (T1) after one year (T2) and after two years (T3)	Repeated measures mixed effects model	Reasoning training resulted in significant improvements: $p = <.00$ $d = .57$ (T1) and $p = <.005$, $d = .27$ (T3)
Yang et al. (2020)	Whether multi-domain attention training improves complex attention abilities compared to an active control	**DVT** (Yang et al., 2015); **TMT B**	**X4** : before and after training, at three months and at 6 mths.	Generalised estimating equation modelling	Mean scores improved across most tests in the training group. Differences between groups were non-significant.
Zhang et al. (2019)	Whether multi-domain CT improves EF and language	Picture completion test designed for the study; **SCWT; DSB; SST** (Dick et al., 2002); **SFT**	**X2** : before and after training	Paired *t*-tests	No significant differences in scores before and after training were observed. Some improvements were seen in the picture completion tests but only to the degree that might be anticipated as a result of practice effects.

[a] Full statistics were provided by the author in personal correspondence

Acronyms and definitions: ACER: Addenbrooke's Cognitive Examination Revised; ANOVA: Analysis of variance; aMCI: amnestic mild cognitive impairment; CANTAB: Cambridge Automated Neuropsychological Test Battery; C group: control group; COWAT: Controlled Oral Word Association test; CT: cognitive training; CTT: Colour Trail Test; DFT: Design Fluency Test; DLOTCA: Dynamic Lowenstein Occupational Therapy Cognitive Assessment; DSB: Digit span backwards; ES: DVT: Digit Vigilance Test; Effect size; EXAMINER: Executive abilities: Measures and instruments for neuro-behavioural evaluation and research test*; F*: Fisher ratio; GDT: Game of Dice Task - measures decision making under risk; IED: Intra-/extra- dimensional set-shifting task; LST: Listening span test; MRT: Matrix Reasoning Test; nr: not reported; MCI: Mild Cognitive Impairment; n/s = not significant; OOO: Odd One Out test *; p :* statistical probability value ; PAG: Probability-associated Gambling Task – measures decision making; RCF: Rey Complex Figure task; RVP: Rapid visual processing test; SALT: Selective Auditory Learning Task; SCWT: Stroop Colour-Word Test; SD: standard deviation score; SFT: Semantic Fluency Test; SOPT: Speed of Processing Training; SNA: Symbol-Number Association task; SST: Spatial Span Task; SWM: Spatial working memory test*; t*: t-ratio; TEA: Test of Everyday Attention; TMT B: Trail making test version B; TOL: Tower of London task; TOSL: Test of Strategic Learning; UFOV: Useful Field of View test; VFT: Verbal Fluency; WAIS-III: Wechsler Adult Intelligence Scale-third edition; *W*: Wilcoxon W value; WCST: Wisconsin Card Sorting Test; WM: Working memory; χ^2 : Chi square value ; *Z :* Z score

Appendix 1-G

Five Supplementary Quality Tables for Each Domain of the Revised Cochrane Risk of Bias Tool (ROB 2)

Table 1

ROB-2 Randomisation (selection and performance)

				Bias arising from randomization process	
Author (yr.)	Allocation sequence random?	Allocation concealed?	Did baseline data indicate a problem?	Judgement (Deviation from algorithm? y/n)	Evidence
Barban et al. (2016)	Yes	NI	PN	Some concerns (n)	"Randomisation.... was carried out by centre and sample with a block size of four to prevent imbalance. The allocation procedure was concealed from the raters"
Barekatain et al. (2016)	Yes	NI	PN	Some concerns (n)	"Participants were assigned using block-design randomisation" "participants in each group were unaware of the existence of other groups"
Boripuntakul et al. (2012)	Yes	PY	PN	Low (n)	"Randomisation was performed by opening an opaque sealed envelope" Limited word count does not detail whether the envelope was sequentially numbered or tamper proof but this is reasonably assumed.
Burgio et al. (2018)	PY	NI	PN	Some concerns	"patients were randomly assigned to either training order A or B" No information provided about sequence allocation
Damirchi et al. (2018)	PY	NI	PN	Some concerns (no)	Journal abstract describes participants as “randomised to groups” but no additional information included about how this was achieved.
Das et al. (2019)	Yes	Yes	PN	Low (n)	"A research assistant who was blinded to participant information and cognitive behaviour, randomised the participants into one of two groups...using random function on Microsoft Excel after baseline training". Some differences between groups, including gender balance, but this is to be expected given the small sample size.
Djabelkhir et al. (2017)	Yes	NI	PN	Some concerns (n)	"patients were assigned to...group using a simple computerised randomisation procedure"
Donnezan	Yes	Yes	PY	High (n)	"After being randomly allocated to training groups"...."groups were randomised to the training conditions".

Bias arising from randomization process					
Author (yr.)	Allocation sequence random?	Allocation concealed?	Did baseline data indicate a problem?	Judgement (Deviation from algorithm? y/n)	Evidence
et al. (2018)					The unit of randomization is group. It is unclear how this was achieved but the implication is that it was to create as much similarity between groups as possible given the small sample size. Randomisation, therefore, is limited could have biased results.
Finn et al. (2011)	Yes	Yes	No	Low (n)	"Independent person placed slips of paper with either "treatment" or "waitlist" written on them into opaque envelopes that were sealed". After baseline training participants were asked to select an envelope at random.
Gagnon et al. (2012)	Semi-random design	PN	PN	High (n)	"Randomisation was stratified for education and age in order to equate groups on those dimensions". Semi-random design.
Li et al. (2019)	Yes	NI	PN	Some concerns (n)	"They were randomised to the training or control group"
Mudar. et al. (2017)	Yes	NI	PN	Some concerns (n)	Limited information about the randomization process: "after baseline scores were established they were randomised to two training groups"
Mudar et al. (2019)	Yes	NI	PN	Some concerns (n)	As above [a]
Nousia et al. (2019)	Yes	NI	PN	Some concerns (n)	"patients were randomly divided into two group"
Oskoei et al. (2013) & Oskoei et al. (2016)	Yes	NI	NI	Some concerns (n)	"(Patients)...randomly divided into experimental and control groups". No process information reported.
Unverzagt et.al. (2007)	Yes	Yes	No	Low (n)	Randomisation process detailed in the published article.
Yang et al. (2020)	Yes	Yes	PN	Low (n)	"An independent investigator used software to generate a random number table, after which, block design randomisation was used (4)"

Bias arising from randomization process					
Author (yr.)	Allocation sequence random?	Allocation concealed?	Did baseline data indicate a problem?	Judgement (Deviation from algorithm? y/n)	Evidence
					"the independent investigator placed the written interventions into sealed opaque envelopes according to the random allocation" There was a difference in age that was corrected for in the analysis "participants were aware that different intervention measures would be used in the two groups. ...To ensure blinding, participants were blocked from knowing the training content of results of other participants. Trainers were not allowed to discuss participant grouping"

Acronyms and abbreviations: Y: Yes; PY: Probably yes; N: No; PN: Probably no; NI: No information

Table 2

ROB-2 Deviation from intended intervention

	Bias due to deviation from intended intervention								
Author (yr.)	Participants aware of assigned intervention?	People delivering intervention aware of assigned intervention?	If yes - were there deviations resulting from trial context	If yes, were deviations likely to have affected the outcome?	If yes, were deviations balanced between groups?	Was an appropriate analysis used to estimate effect of ATI?	Impact of failure to analyse participants in the group assigned?	Judgement (Deviation from algorithm? y/n)	Evidence
Barban et al. (2016)	PN	NA	PN	NA	NA	PN	NI	Some concerns (y)	47 people dropped out from the wider sample of 348. It is not clear how many of these had been allocated to the MCI group (106) or the reasons for this and so it is difficult to estimate the effect.
Barekatain et al. (2016)	No	NI	No	NA	NA	Yes	NA	Low (n)	"all analysis was performed using intention to treat method"
Boripuntakul et al. (2012)	Yes	Yes	No	NA	NA	NI	No	Low (y)	All participants were retained. No explicit ITT analysis reported prior to analysing results however this could be due to journal word count. No response from personal correspondence. Small sample as this was a pilot study.
Burgio et al. (2018)	PY	PY	No	NA	NA	NI	No	Low (y)	Authors state that the differences between interventions or expected results were not shared. This factor has therefore been judged as a low concern by the reviewer.
Damirchi et al. (2018)	PY	PY	No	NA	NA	Yes	NA	Low (n)	Unclear if participants knew the differences between groups. However, control group was passive and so it is likely that some participants could have guessed the group to which they were allocated.

Bias due to deviation from intended intervention									
Author (yr.)	Participants aware of assigned intervention?	People delivering intervention aware of assigned intervention?	If yes - were there deviations resulting from trial context	If yes, were deviations likely to have affected the outcome?	If yes, were deviations balanced between groups?	Was an appropriate analysis used to estimate effect of ATI?	Impact of failure to analyse participants in the group assigned?	Judgement (Deviation from algorithm? y/n)	Evidence
Das et al. (2019)	No	PY	No	NA	NA	PN	Yes	High (n)	The gist training group alone received "sham" tDCS to blind participants from their group allocation. No mention of an analysis used. Missing participants are likely to have just been excluded. There was 32% attrition by the third assessment time point with reasons related to time demands.
Djabelkhir et al. (2017)	PN	PY	No	NA	NA	No	PN	High (n)	Whilst there was only one person who dropped out, the sample was small and already under-powered.
Donnezan et al. (2018)	Yes	Yes	Probably yes	NA	NA	No	Yes	High (n)	Analysis excluded participants post-randomisation and a naive "per-protocol" analysis was adopted. 26% attrition in the experimental group with reasons cited including "too time consuming" Accordingly, the ITT analysis and subsequent impact carries the most weight in this domain.
Finn et al. (2011)	PY	PY	No	NA	NA	No	PN	Some concerns (n)	"Non-completers did not differ from those who completed the study in terms of age, sex, education or cognitive scores. The primary reasons for dropout were unrelated medical or personal issues or being commenced on a cholinesterase inhibitor".
Gagnon et al. (2012)	No	Yes	No	NA	NA	No	PN	Some concerns (n)	"This study was a double-blind design: Participants were unaware of the training strategies and pre/post assessments were carried out by different assistants who were

Bias due to deviation from intended intervention									
Author (yr.)	Participants aware of assigned intervention?	People delivering intervention aware of assigned intervention?	If yes - were there deviations resulting from trial context	If yes, were deviations likely to have affected the outcome?	If yes, were deviations balanced between groups?	Was an appropriate analysis used to estimate effect of ATI?	Impact of failure to analyse participants in the group assigned?	Judgement (Deviation from algorithm? y/n)	Evidence
									blinded to assignment intervention and hypotheses" One person dropped out of each group and reasons were only known for one person. The potential impact has been assessed as minimal in the circumstances. Nevertheless, no apparent analytic strategy to deal with changes in assignment to treat resulting from attrition.
Li et al. (2019)	PN	PY	No	NA	NA	No	PY	High	"...to minimise Hawthorne effect both groups were told that the study purpose was observation, follow-up and early diagnosis" Per-protocol analysis used.
Mudar et al. (2017)	NI	PY	No	NA	NA	NI	PN	Some concerns (n)	
Mudar et al. (2019)	NI	PY	No	NA	NA	NI	PN	Some concerns (n)	
Nousia et al. (2019)	PY	PY	No	NA	NA	NI	PN	Some concerns (n)	No one left the study and no deviations in treatment allocation. Authors state that the presence of the Hawthorne effects cannot be ruled out.
Oskoei et al. (2013) & Oskoei et al., (2016)	NI	NI	PN	NA	NA	PN	PY	High (n)	Small sample and no discussion as to the reasons for attrition or how this was managed in the analysis.
Unverzagt et.al. (2007)	PY	PY	No	NA	NA	NI	NI	High (n)	The parent study from which the data was extracted reported an appropriate analytic

Bias due to deviation from intended intervention									
Author (yr.)	Participants aware of assigned intervention?	People delivering intervention aware of assigned intervention?	If yes - were there deviations resulting from trial context	If yes, were deviations likely to have affected the outcome?	If yes, were deviations balanced between groups?	Was an appropriate analysis used to estimate effect of ATI?	Impact of failure to analyse participants in the group assigned?	Judgement (Deviation from algorithm? y/n)	Evidence
									technique to calculate the effect of assignment to intervention. Authors, however, do not report whether there was attrition from the study for these participants.
Yang et al. (2020)	PN	PY	No	NA	NA	Yes	NA	Low (n)	"participants were aware that different intervention measures would be used in the two groups. ...To ensure blinding, participants were blocked from knowing the training content of results of other participants. Trainers were not allowed to discuss participant grouping" "Randomly assigned participants were included in the final analysis based on the intention-to-treat principle"

Acronyms and abbreviations: Y: Yes; PY: Probably yes; N: No; PN: Probably no; NI: No information; ATI: Assignment to intervention; ITT: Intention to treat analysis

Table 3

ROB-2 Missing Outcome Data

	Bias due to missing outcome data					
Author (yr.)	Data available for all or nearly all participants?	If no, were result not biased by missing data?	If no, could missingness depend on true value?	If yes, is it likely that missingness depended on true value?	Judgement (Deviation from algorithm? y/n)	Evidence
Barban et al. (2016)	No	No	NA	NA	High (n)	No information as to whether people who dropped out of the study belonged to the MCI group and reasons were not provided so difficult to estimate bias in this area.
Barekatain et al. (2016)	No	PN	PY	PY	High (n)	Intention to treat analysis used but the reasons for attrition were not reported. Small sample of which 58% dropped out of the treatment group.
Boripuntakul et al. (2012)	Yes	NA	NA	NA	Low (n)	Data for all participants randomised was included.
Burgio et al. (2018)	Yes	NA	NA	NA	Low (n)	Data for all participants randomised was included.
Damirchi et al. (2018)	No	PN	PY	PY	High (n)	High degree of attrition. No record of the reasons and no reported analysis of how missing data would be, or was, treated. Assumption made that the data was excluded and a per-protocol approach taken.
Das et al. (2019)	No	No	Yes	Yes	High (n)	
Djabelkhir et al. (2017)	Yes	NA	NA	NA	Low (n)	
Donnezan et al. (2018)	No	No	Yes	Yes	High (n)	Randomised participants who failed to complete the intervention (3) were not included in the analysis. This amounted to 11% of participants. At six-month follow-up 26% (5) people originally randomised were not included in the analysis. No analysis or procedure reported to correct for bias.

	Bias due to missing outcome data					
Author (yr.)	Data available for all or nearly all participants?	If no, were result not biased by missing data?	If no, could missingness depend on true value?	If yes, is it likely that missingness depended on true value?	Judgement (Deviation from algorithm? y/n)	Evidence
						Reasons for attrition included "too difficult" or "too time consuming", which suggests an impact on the true outcome value. Predicted direction of bias is away from the null.
Finn et al. (2011)	No	PN	PY	PY	High (n)	
Gagnon et al. (2012)	PY	NA	NA	NA	Low (n)	
Li et al. (2019)	No	No	PY	PY	High (n)	Considerable attrition that was mainly observed in the control group "the main reason was that the contacted physicians for medication"
Mudar et al. (2017)	Yes	NA	NA	NA	Low (n)	
Mudar et al. (2019)	Yes	NA	NA	NA	Low (n)	
Nousia et al. (2019)	Yes	NA	NA	NA	Low (n)	
Oskoei et al. (2013) & Oskoei et al. (2016)	No	No	PY	PY	High (n)	25% attrition in an already small sample. No reasons reported that could indicate minimal impact on results.
Unverzagt et.al. (2007)	NI	No	NI	NI	High (n)	
Yang et al. (2020)	No	Yes	NA	NA	Low (n)	6 of the 7 people who dropped out left the study because they left the home. One person was admitted to hospital

Acronyms and abbreviations: Y: Yes; PY: Probably yes; N: No; PN: Probably no; NI: No information

Table 4

ROB-2 Measurement of the outcome

	Bias due measurement of the outcome						
Author (yr.)	Was the method of measurement inappropriate?	Could measurement of have differed between groups?	Were outcome assessors aware of the intervention received?	If yes, could awareness have influenced the outcome?	If yes, is it likely that awareness influenced the outcome?	Judgement (Deviation from algorithm? y/n)	Evidence
Barban et al. (2016)	PN	No	No	NA	NA	Low (n)	Valid and reliable measures used for the functions training however only two measures used for a range of complex EFs.
Barekatain et al. (2016)	No	No	No	NA	NA	Low (n)	Multiple valid and reliable tests of EF used that were relevant to the trained domains of attention, problem solving and working towards goals.
Boripuntakul et al. (2012)	PY	PN	NA	NA	NA	High (n)	Trail making test B-A as a sole measure of EF. Using just one measure is probably sub-optimal and there is evidence that B-A may only measure speed across age ranges (Salthouse, 2011). The DSB test was used as a measure of attention however this test might be more accurately conceptualized as a test of WM.
Burgio et al. (2018)	No	PN	No	NA	NA	Low (n)	
Damirchi et al. (2018)	PY	PN	NA	NA	NA	High (n)	
Das et al. (2019)	PN	No	NI	NI	NI	High (n)	Narrow number of tests to measure complex cognitions however they appear valid and reliable for EFs.
Djabelkhir et al. (2017)	PN	PN	No	NA	NA	No	Five valid and reliable measures used to measure EF.
Donnezan et al. (2018)	No	No	Yes[a]	Probably yes	Probably no	Some concerns (n)	Reliable and widely used psychometric tests used.

	Bias due measurement of the outcome						
Author (yr.)	Was the method of measurement inappropriate?	Could measurement of have differed between groups?	Were outcome assessors aware of the intervention received?	If yes, could awareness have influenced the outcome?	If yes, is it likely that awareness influenced the outcome?	Judgement (Deviation from algorithm? y/n)	Evidence
Finn et al. (2011)	PN	PN	No	NA	NA	Low (n)	Measures correlated to task scores and have valid and reliable properties. However, only one test was used for each function which could limit the ecological validity of results.
Gagnon et al. (2012)	PN	No	No	NA	NA	Low (n)	Use of proximal measurement of a similar design to the training task and multiple distal measures related to broader function.
Li et al. (2019)	PN	No	No	NA	NA	Low (n)	
Mudar et al. (2017)	PN	PN	Yes	PN	NI	Low (n)	Three different EF measures to capture the concept.
Mudar et al. (2019)	PN	PN	Yes	PN	NI	Low (n)	
Nousia et al. (2019)	PN	PN	No	NA	NA	Low (n)	Multiple measures used to assess complex processes that have good validity and reliability for the specific cognition or skill.
Oskoei et al. (2013) & Oskoei et al. (2016)	PN	PN	NI	NI	NI	High (n)	Only one measure used to test EF
Unverzagt et.al. (2007)	PY	PN	NA	NA	NA	Low (n)	
Yang et al. (2020)	No	No	No	NA	NA	Low (n)	

Table 5

ROB-2 Selection of reported results

	Bias due to selection of reported results				
Author (yr.)	Data outlined according to a pre-specified plan before unblinded outcome data was available?	Is the data likely to have been selected from multiple eligible measurements in the domain?	Is the data likely to have been selected from multiple eligible analyses?	Judgement (Deviation from algorithm? y/n)	Evidence
Barban et al. (2016)	Yes	No	No	Low (n)	It would have been useful to have all the results including the non-significant outcomes
Barekatain et al. (2016)	PY	No	No	Low (n)	
Boripuntakul et al. (2012)	Yes	No	No	Low (n)	A quality note here is that no other statistics beyond *p* value were reported.
Burgio et al. (2018)	Probably yes	No	No	Low (n)	
Damirchi et al. (2018)	PY	No	No	Low (n)	
Das et al. (2019)	Yes	No	No	Low (n)	
Djabelkhir et al. (2017)	Yes	No	No	Low (n)	
Donnezan et al. (2018)	Yes	No	No	Low (n)	Clear rationale for planned tests based on hypothesised results. Detailed tables of results or explicit reporting on non-significant findings.
Finn et al. (2011)	Yes	No	No	Low (n)	

Bias due to selection of reported results					
Author (yr.)	Data outlined according to a pre-specified plan before unblinded outcome data was available?	Is the data likely to have been selected from multiple eligible measurements in the domain?	Is the data likely to have been selected from multiple eligible analyses?	Judgement (Deviation from algorithm? y/n)	Evidence
Gagnon et al. (2012)	Yes	No	No	Low (n)	Importantly for clinical contexts, effect sizes were also reported.
Li et al. (2019)	PY	No	No	Low (n)	
Mudar et al. (2017)	Yes	No	No	Low (n)	
Mudar et al. (2019)	Yes	No	No	Low (n)	
Nousia et al. (2019)	Yes	No	No	Low (n)	All statistics were reported fully regardless of whether statistical significance was achieved.
Oskoei et al. (2013) & Oskoei et al. (2016)	PY	PN	PN	Low (n)	
Unverzagt et.al. (2007)	Yes	PN	PN	Low (n)	
Yang et al. (2020)	PY	No	No	Low (n)	

Acronyms and abbreviations: Y: Yes; PY: Probably yes; N: No; PN: Probably no; NI: No information

Appendix 1-H

Seven supplementary quality tables for each domain of the Risk of Bias in Non-randomised Studies Tool (ROBINS-1)

Table 1

ROBINS-1 Confounding

				Bias due to confounding						
				Baseline confounding			Baseline and time-varying confounding			
Author (yr.)	Potential confounding of the outcome?	If yes, analysis based on splitting follow-up according to intervention?	If yes, were changes to intervention likely related to prognostic factors?	Appropriate analysis to control for confounding domains?	If yes, were confounders measured validly by study variables?	Were post-intervention variables controlled for?	Appropriate analysis for time-varying and domain confounders?	If yes, were confounders measured validly by study variables?	Judgement of bias (based on guidance)	Description
Cipriani et al. (2006)	Yes	No	NA	NI	NA	No	NI	NA	NI	No information about whether pre-intervention prognostic variables were measured or controlled for.
Djabelkhir-Jemmi et al. (2018)	Yes	No	NA	No	NA	No	NA	NA	Serious risk	Participants were volunteers so factors such as motivation could result in bias. This was not considered or controlled for.
Manera et.al. (2015)	Yes	No	NA	No	NA	No	NA	NA	Serious risk	Age, gender and education were measured but no description of potential confounding. Allocation to groups resulted in no significant differences. However, bias arising from motivation or expectation could still be a concern.
Matias-Guiu et al. (2016)	Yes	No	NA	PN	NA	No	NA	NA	Serious risk	

				Bias due to confounding						
				Baseline confounding			Baseline and time-varying confounding			
Author (yr.)	Potential confounding of the outcome?	If yes, analysis based on splitting follow-up according to intervention?	If yes, were changes to intervention likely related to prognostic factors?	Appropriate analysis to control for confounding domains?	If yes, were confounders measured validly by study variables?	Were post-intervention variables controlled for?	Appropriate analysis for time-varying and domain confounders?	If yes, were confounders measured validly by study variables?	Judgement of bias (based on guidance)	Description
Moro et.al. (2015)	Yes	No	NA	No	NA	No	NA	NA	Serious risk	Participants could choose which group they participated in depending on their preference
Silivaikul et al. (2019)	Yes	No	NA	No	NA	No	NA	NA	Serious risk	Potential practice effects in using the same tests post training were not controlled for in this or other studies
Zhang et.al. (2019)	Yes	No	NA	No	NA	No	NA	NA	Serious risk	

Acronyms and abbreviations: NI: no information; NA: not applicable

Table 2

ROBINS-1 Selection

	Bias in selection of participants						
Author (yr.)	Selection based on characteristics observed after start of intervention?	If yes, were variables influencing selection likely associated with intervention?	If yes, were variables influencing selection likely influenced by outcomes?	Do start of intervention and follow-up coincide for most participants	Were adjustment techniques used that are likely to correct for selection bias?	Judgement	Description
Cipriani et al. (2006)	No	NA	NA	Yes	NI	Low risk	Design and reported results do not indicate that participant characteristics observed after the start of the intervention affected selection into a group. All participants began, and were followed-up, at the same time points. These factors were true for all studies.
Djabelkhir-Jemmi et al. (2018)	No	NA	NA	Yes	No	Low risk	
Manera et.al. (2015)	No	NA	NA	Yes	No	Low risk	
Matias-Guiu et al. (2016)	No	NA	NA	Yes	No	Low risk	
Moro et.al. (2014)	No	NA	NA	Yes	No	Low risk	
Silivaikul et al. (2019)	No	NA	NA	Yes	No	Low risk	
Zhang et.al. (2019)	No	NA	NA	Yes	No	Low risk	

Acronyms and abbreviations: NI: no information; NA: not applicable

Table 3

ROBINS-1 Classification of interventions

Author (yr.)	Intervention groups clearly defined?	Information used to define groups recorded at the start of the intervention?	Could classification of intervention status been influenced by knowledge or risk of the outcome?	Judgement
Cipriani et al. (2006)	Yes	Yes	No	Low risk
Djabelkhir-Jemmi et al. (2018)	Yes	Yes	No	Low risk
Manera et.al. (2015)	Yes	Yes	No	Low risk
Matias-Guiu et al. (2016)	Yes	Yes	No	Low risk
Moro et.al. (2015)	Yes	Yes	No	Low risk
Silivaikul et al. (2019)	Yes	Yes	No	Low risk
Zhang et.al. (2019)	Yes	Yes	No	Low risk

Acronyms and abbreviations: NI: no information; NA: not applicable

Table 4

ROBINS-1 Deviation from intended intervention

	Bias due to deviation from intended intervention			
Author (yr.)	Deviations from intended intervention beyond usual practice?	If yes, deviations between groups unbalanced AND likely affected the outcome?	Judgement	Description
Cipriani et al. (2006)	No	NA	Low risk	No attrition or movement between groups during the experimental period
Djabelkhir-Jemmi et al. (2018)	Yes	Yes	Moderate	
Manera et.al. (2015)	Yes	Yes	Moderate	"One person dropped out after the first week". The group was not specified. There was an imbalance in sample size with the AD group being 25% bigger than the MCI group
Matias-Guiu et al. (2016)	No	NA	Low risk	
Moro et.al. (2014)	Yes	No	Low risk	Two people (one from each group) were not available for 12 month follow-up for unclear reasons. Judged unlikely to have affected the true outcome
Silivaikul et al. (2019)	No	NA	Low risk	
Zhang et.al. (2019)	Yes	Yes	Moderate risk	

Acronyms and abbreviations: NI: no information; NA: not applicable

Table 5

ROBINS-1 Missing outcome data

	Bias due to missing outcome data						
Author (yr.)	Data available for all or nearly all participants?	Were participants excluded due to missing data on intervention status?	Were participants excluded due to missing data on other variables	Are proportion of participants / reasons for missing data similar across interventions?	Is there evidence results were robust to the presence of missing data?	Judgement	Description
Cipriani et al. (2006)	No	NI	No	NI	NI	NI	Data was missing for baseline characteristics that might act as confounders or have affected intervention status (e.g. whether they were included). Control group participants equaled less than 30% of intervention group albeit this was due to design and not missingness. Overall, insufficient information on which to draw a conclusion
Djabelkhir-Jemmi et al. (2018)	No	No	Yes	NI	No	Serious risk	
Manera et.al. (2015)	Yes	No	Yes	NA	No	Moderate risk	Proportion of missing data differ slightly.
Matias-Guiu et al. (2016)	Yes	No	No	NA	NA	Low risk	
Moro et.al. (2015)	Yes	No	Yes	Yes	No	Moderate risk	No analytic strategy to address missing data or correct for bias at the 12 month follow up
Silivaikul et al. (2019)	Yes	No	No	NA	NA	Low risk	
Zhang et.al. (2019)	No	No	NI	NI	No	Serious risk	85.19% of participants contributed data for analysis. Reasons for attrition were not given.

Acronyms and abbreviations: NI: no information; NA: not applicable

Table 6

ROBINS-1 Measurement of the outcome

	Bias due to measurement of the outcome					
Author (yr.)	Could outcome measures have been influenced by knowledge of intervention received?	Were outcome assessors aware of the intervention received?	Were outcome measures comparable across groups?	Were any systematic errors in measurement related to intervention?	Judgement	Description
Cipriani et al. (2006)	NI	No	Yes	No	Moderate risk	Assessors were blind to group allocation
Djabelkhir-Jemmi et al. (2018)	No	No	Yes	No	Low risk	
Manera et.al. (2015)	No	Yes	Yes	No	Moderate risk	Measures were comparable across groups. However, assessors were not blind to participant allocation
Matias-Guiu et al. (2016)	No	NI	Yes	No	Moderate risk	
Moro et.al. (2015)	No	Yes	Yes	No	Moderate risk	Measures were comparable across groups. However, assessors were not blind to participant allocation
Silivaikul et al. (2019)	No	No	Yes	No	Low risk	
Zhang et.al. (2019)	No	NI	Yes	No	Moderate risk	"We assessed cognition both at the baseline and after training". No explicit information about blinding, or otherwise, of assessors.

Table 7

ROBINS-1 Selection of reported results

	Bias due to selection of reported results				
Author (yr.)	Is the reported effect estimate likely to have been selected from multiple eligible measurements in the domain?	Is the reported effect estimate likely to have been selected from multiple eligible analyses?	Is the reported effect estimate likely to have been selected from different subgroups?	Judgement	Description
Cipriani et al. (2006)	No	No	No	Low	There is evidence that reported results correspond to all intended outcomes, analyses and sub-groups
Djabelkhir-Jemmi et al. (2018)	No	No	No	low	
Manera et.al. (2015)	No	No	No	Low	There is evidence that reported results correspond to all intended outcomes and analyses
Matias-Guiu et al. (2016)	No	No	No	Low	
Moro et.al. (2015)	No	No	No	Low	
Silivaikul et al. (2019)	No	No	No	Low	
Zhang et.al. (2019)	No	No	No	Low	

Acronyms and abbreviations: NI: no information

Appendix 1-I

Neuropsychology Review Instructions for Authors

Instructions for Authors

Types of papers

Review, Editorial, Commentary

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Manuscript Standards

Manuscript Submission

Manuscripts submitted to Neuropsychology Review should conform to the style of the American Psychological Association Publication Manual (6th edition: 2010). Neuropsychology Review is an EQUATOR adopter. The EQUATOR network represents a collaboration of researchers and journal editors who aspire to improve accuracy and transparency in research by promoting better reporting standards. Because Neuropsychology Review publishes review articles, the EQUATOR elements most relevant are the PRISMA guidelines for preparation and reporting of systematic reviews and meta-analyses (http://www.equator-network.org/reporting-guidelines/prisma/).

While narrative reviews will still be considered for publication when appropriate, Neuropsychology Review encourages publication of systematic reviews of treatment, intervention and diagnostic validity studies as well as systematic reviews of research relating to scientific questions in all aspects of clinical neuropsychology and behavioral neuroscience. Systematic reviews are enhanced by inclusion of a carefully conducted meta-analysis whenever appropriate. Authors of systematic reviews and meta-analyses submitted to Neuropsychology Review should prepare their manuscripts according to the PRISMA guidelines and include a PRISMA checklist (http://prisma-statement.org /PRISMA Statement/Checklist.aspx) with manuscript submission. When completing the checklist, authors should consider whether their manuscript requires editing to address all of the reporting requirements.

Neuropsychology Review discourages use of numerical rating scales that assign a single number to rank the quality of studies included in the review. Instead authors should separately rate or classify individual study quality and risk of bias using established criteria such as those included in the critical appraisal checklists (e.g., randomized controlled trials or diagnostic validity studies (http://www.cebm.net/critical-appraisal/)). For treatment and intervention studies key risk-of-bias criteria include, but may not be limited to, adequacy of randomization, pre-treatment equality of groups, blinding of patients, therapist or person undertaking outcome evaluation, adequacy of follow-up and objectivity in outcome measurement. For diagnostic validity studies, risk-of-bias criteria include representativeness of sampling, full information on the test-to-be-evaluated (the index test) and diagnostic group status (the reference standard) and independent, blinded acquisition of reference and index test information. Other risk of bias criteria may be important in some contexts

including commercial or other conflict of interest.

Prior to undertaking their systematic review, authors are encouraged to read the PRISMA Explanation and Elaboration paper (http://www.ncbi.nlm.nih.gov/pubmed/19621070). For authors not familiar with preparation of systematic reviews or the PRISMA guidelines, there are extensive information resources available on the PRISMA website (http://www.prisma-statement.org/).

Authors are encouraged to register their systematic review protocol early in the review process (e.g., PROSPERO), and use the PRISMA extension specifically written for reporting a systematic review protocol (i.e., , PRISMA-P (http://www.equator-network.org/reporting-guidelines/prisma-protocols/).

Authors of narrative reviews that are not based on systematic literature searching should justify in their cover letter and in the body of their manuscript why a systematic review was not feasible or appropriate. Likewise, authors of systematic reviews without meta-analysis should explain in their cover letter and in the body of their manuscript why meta-analysis was not considered appropriate (e.g., reviewed studies were not of sufficient quality).

Authors should avoid use of non-standard abbreviations.

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Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Title page

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Funding (information that explains whether and by whom the research was supported)

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Code availability (software application or custom code)

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

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Please see the relevant sections in the submission guidelines for further information as well as various examples of wording. Please revise/customize the sample statements according to your own needs.

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Text

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

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References

Citation

Cite references in the text by name and year in parentheses. Some examples:

- Negotiation research spans many disciplines (Thompson 1990).
- This result was later contradicted by Becker and Seligman (1996).
- This effect has been widely studied (Abbott 1991; Barakat et al. 1995; Kelso and Smith 1998; Medvec et al. 1999).

Ideally, the names of six authors should be given before et al. (assuming there are six or more), but names will not be deleted if more than six have been provided.

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

Reference list entries should be alphabetized by the last names of the first author of each work.

Journal names and book titles should be *italicized*.

- Journal article Harris, M., Karper, E., Stacks, G., Hoffman, D., DeNiro, R., Cruz, P., et al. (2001). Writing labs and the Hollywood connection. *Journal of Film Writing, 44*(3), 213–245.
- Article by DOI Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. *Journal of Molecular Medicine*, https://doi.org/10.1007/s001090000086
- Book Calfee, R. C., & Valencia, R. R. (1991). *APA guide to preparing manuscripts for journal publication.* Washington, DC: American Psychological Association.
- Book chapter O'Neil, J. M., & Egan, J. (1992). Men's and women's gender role journeys: Metaphor for healing, transition, and transformation. In B. R. Wainrib (Ed.), *Gender issues across the life cycle* (pp. 107–123). New York: Springer.
- Online document Abou-Allaban, Y., Dell, M. L., Greenberg, W., Lomax, J., Peteet, J., Torres, M., & Cowell, V. (2006). Religious/spiritual commitments and psychiatric practice. Resource document. American Psychiatric Association. http://www.psych.org/edu/other_res/lib_archives/archives /200604.pdf. Accessed 25 June 2007.

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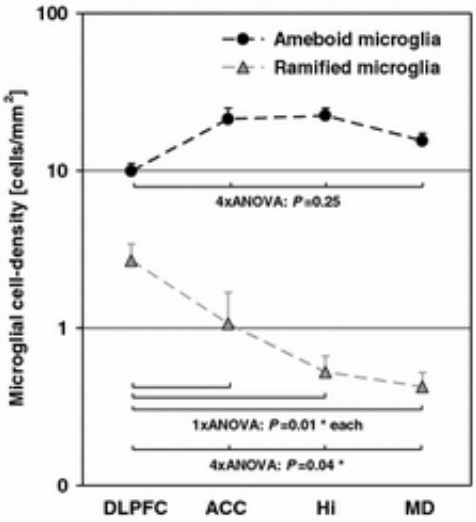

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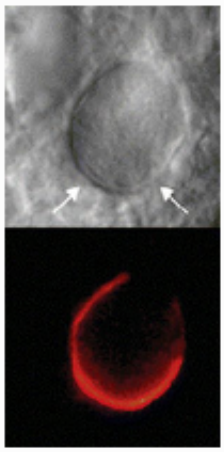

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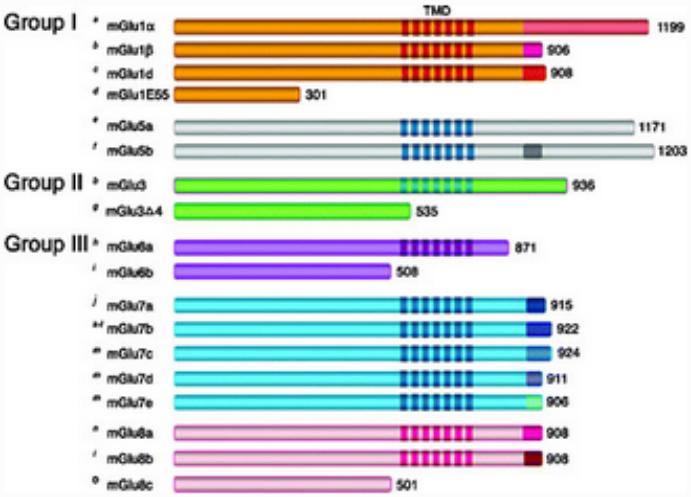

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Chapter 2

Section Two: Empirical Paper

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study

Word count: 7998

Emma Fowler

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

All correspondence should be addressed to:
Emma Fowler, Doctorate in Clinical Psychology, Division of Health Research, Faculty of Health and Medicine, D Floor, Health Innovation One, Sir John Fisher Drive, Lancaster University, LA1 4AT.
Email: e.l.fowler@lancaster.ac.uk
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[3] Please note this manuscript was prepared in line with author guidelines for *The International Journal of Law and Psychiatry (See Appendix 2-).* Where these guidelines have not been followed, most notably the word count, Lancaster University thesis guidelines have.

Abstract

The aim of this study was to explore the feasibility of using a capacity assessment tool designed to support remote assessment work during the COVID-19 health crisis. A qualitative design was employed that used thematic analysis to explore focus group and individual interview data. Eight Best Interests Assessors were recruited who had experience in undertaking capacity assessments in the context of the Deprivation of Liberty Safeguards (DoLS). Two focus groups were held comprising three participants each. In addition two individual interviews were conducted. Data analysis resulted in four themes: (1) Structure is Crucial for remote DoLS assessments , (2) Facilitating Effective relationships; (3) Being Person-Centred and (4) Bridging the Gap Between Training and Practice. Some sub-themes were also identified. All participants judged that it was feasible for the tool to be used in practice. The structure, sequence of questions and examples provided in the document received particular praise. Further, participants reported that the tool could be useful for social workers, care staff, doctors and allied health professionals across a range of settings. Amendments to the tool were put forward that could provide additional clarity about the assessment process and improve the experience of clients. Recommendations for future research are discussed.

Keywords: Decision-making, crisis, feasibility, mental capacity, cognition, deprivation of liberty, remote assessment.

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study

In western philosophy, decision-making has been intimately linked with ideas of personhood and autonomy (Gemes & May, 2009; Sensen, 2013; Strawson, 2009). There is compelling evidence that being able to make choices about our lives contributes to a perceived sense of control (Deci & Ryan, 2000). From a political and legal perspective, the right to liberty and privacy are considered a fundamental human right and are enshrined in treatises and legislation (Council of Europe, 1950; Human Rights Act, 1998). The rights of others to make decisions on our behalf is therefore governed by legal principles and processes and often rests on the question of whether someone has become unable to make decision for themselves (Mental Capacity Act: Code of Practice, 2005).

In England and Wales an inability to make a decision, otherwise referred to in the Mental Capacity Act (MCA) as a lack of capacity, rests on two criteria; the person must have a mental impairment, such as dementia or depression, and there must be a belief that the person is functionally unable to make a decision at a the time it needs to be made (Mental Capacity Act: Code of Practice, 2005).

Difficulties in Undertaking Capacity Assessments in Practice

Since the introduction of the Mental Capacity Act (MCA) in 2005, national and local training has been developed to support professionals to assess a person's capacity (Currie, 2015; Mental Capacity Act (MCA) Directory, 2015; Ruck Keene et al., 2016). Recent scrutiny, however, has established that capacity assessments are often insufficiently thorough and fail to comply with statutory requirements (Emmett, Poole, Bond, & Hughes, 2013; Hinsliff-Smith et al., 2017; House of Lords Select Committee on the Mental Capacity Act 2005, 2014). Practitioners report a lack of confidence in applying MCA training to every-day practice, which could account for ongoing concerns over quality (Emmett et al., 2013; Murrell & McCalla, 2016; Willner, Bridle, Dymond, & Lewis, 2011; Willner, Jenkins, Rees,

Griffiths, & John, 2011). Moreover, funding cuts over the last decade has reduced the feasibility of face-to-face training to address gaps in competency (Cummins, 2018).

The Unique Nature of Capacity Assessments Relating to Deprivation of Liberty

Some clients experience significant restrictions on their liberty as part of their care arrangements (Deprivation of Liberty Safeguards: Code of Practice, 2008). Such circumstances require independent assessment (including a capacity assessment) typically undertaken by Deprivation of Liberty Safeguards (DoLS) assessors (Deprivation of Liberty Safeguards: Code of Practice, 2008). An amendment to the Mental Capacity Act 2005 has been passed into law that will replace the DoLS with a new framework called the Liberty Protection Safeguards (LPS) (Mental Capacity (Amendment) Act, 2019). The LPS will come into force in 2022, introducing a new process of assessment (Department of Health and Social Care, 2020a). DoLS assessors will continue in their current role, however, until this time.

DoLS assessors are amongst the best equipped to undertake capacity assessments as they receive in-depth training and complete complex assessments on a regular basis (Work, 2009). However, even amongst this professional group, Jones et al (2019) found that insufficient documentation was described as something that DoLS assessors noticed in each other's assessments.

Undertaking remote assessments in the Context of COVID-19

Against this backdrop of miriad challenges, the United Kingdom (UK) government implemented public health measures in March 2020 to manage the rate of infections resulting from the COVID-19 virus, which included a requirement for DoLS assessors to work remotely (Cabinet Office, 2020; Department of Health and Social Care, 2020b; Mithran, 2020).

The use of remote assessments in health and social care is increasing (American Psychological Association, 2010; Maheu et.al., 2012). Undertaking remote assessments could provide a range of benefits including increased access to services, cost savings and, in the current pandemic context, reduced risk of infection transmission (Luxton et. al., 2014). However, there are many factors that can influence the quality and reliability of remote assessments (Luxton et. al., 2014). These factors include: The assessment environment, which encompasses consideration of adequate space, sufficient privacy and comfort for clients and technological difficulties arising from the use of telephones or web-based conferencing, such as disrupted internet connections or poor audio quality (Jones et. al., 2001; Kramer et. al., 2013; Luxton et. al., 2011; Luxton et. al., 2012).

Another consideration is the extent to which remote assessments are considered acceptable to both clients and professionals as this has been shown to affect the validity and reliability of assessments (Elhai et. al., 2012; Rogers, 2001). However, acceptability is difficult to predict and can depend on a range of factors that include culture, confidence, motivation and clinical difficulties (Luxton et. al., 2012; Modai et. al., 2006). For example, older or more disadvantaged, populations might have less experience with technology or access to it (Rohland, et. al., 2000). Moreover, for clients with a cognitive impairment, it might be necessary to have someone physically present to support them in using technology or in engaging with a professional who is not present (Grady & Melcer, 2005; Grayson & Monk, 2003).

A crisis can be defined as a negative event that commands attention (Sweeny, 2008). Sayegh et al (2004) argue that both rational and intuitive processes are required for optimal decision-making in crises. They suggest that professional experience triggers explicit and tacit knowledge, which combines with personal efficacy to drive decision-making in crises. However, they posit that tacit knowledge can become progressively less helpful the more a

crisis situation differs from practice-as-usual (Rhonda & Timothy, 1996; Sayegh et al., 2004). Concordant with appraisal theory, authors suggest that experience, knowledge, self-efficacy and levels of emotional arousal combine to determine whether a crisis is perceived as a threat or as an opportunity (Scherer, Schorr, & Johnstone, 2001).

A new tool to support remote capacity assessments

A capacity tool in the form of a semi-structured interview has been developed to support professionals undertaking capacity assessments in the context of the DoLS (Mackenzie, Lincoln & Newby, 2008). The tool was developed from post-doctoral research work undertaken in a stroke population. The author, Dr Janice Mackenzie, has revised the tool over several iterations in line with informal feedback from experienced professionals working across health and care services (personal communication with Dr Mackenzie, May 2019). The tool is underpinned both by legal requirements and neuropsychological theory. The tool was adapted in response to the COVID-19 outbreak in April 2020 by Dr Mackenzie to support remote assessments.

DoLS assessors are required to record assessments on prescribed organisational or legal documentation. Accordingly, whilst the tool includes both aspects of the two-stage legal test of capacity, it is anticipated that its primary value will be as a supplement to current practice. The tool aims to address challenges in practice by: increasing awareness of potentially salient assessment information; providing a supportive structure that scaffolds practice and improving accuracy through questions and prompts intended to elicit detailed information about the clients difficulties and strengths. The tool has the potential to support practice in an evolving and challenging context. However, it has yet to be formally studied and the feasibility of undertaking research on the tool has yet to be established.

The aim of the research, therefore, is to establish the feasibility of disseminating the tool amongst DOLS assessors and of undertaking a full research trial.

The research will answer the following question: *Is a tool designed to support remote capacity assessments with people with a psychological or cognitive impairment around their admission to hospital or a care home experienced as practical, acceptable and useful by decision-makers?*

To answer this question, the study will specifically explore the following areas of feasibility: Whether participants judged that the tool was suitable and appropriate in the context of remote working; an examination of how the tool was used to support remote assessments; consideration of the settings and contexts that the tool could be implemented remotely in and limited efficacy testing, specifically whether the tool has the potential to enhance the quality of professional judgements when working remotely.

Method

Design

This qualitative feasibility study involved DoLS assessors trialling a remote capacity assessment tool for six weeks during May and June 2020. At the end of the trial period participants attended an online focus group or individual interview to answer questions about their experiences of using the tool to support remote assessments. If it had not been possible to use the tool with multiple clients, participants were still encouraged to participate. The study used a thematic analysis approach and employed focus group and individual methodology. Reporting of the study conforms to the Consolidating Standards of Reporting Trials (CONSORT) guidelines for feasibility studies (see Appendix 2-A) (Eldridge et al., 2016).

Information was required to establish whether it would be beneficial to undertake further research on the tool. As such, a feasibility design was selected (Bowen et al., 2009). Whilst qualitative approaches to feasibility studies are an emerging field, they can facilitate a more refined understanding of how and why an intervention worked in real-world contexts

than quantitative methods (O'Cathain et al., 2015; Wells, Williams, Treweek, Coyle, & Taylor, 2012).

Thematic analysis has been described as appropriate for applied health research and has proven utility in this field (Braun & Clarke, 2006; Dowling, Hodge, & Withers, 2018; Fugard & Potts, 2015; Radosteva, 2018). Understanding perceptions of an intervention within a specific context is central to this study. As such, the analysis was informed by a critical realist epistemology (Price & Martin, 2018). Critical realism is concerned with understanding how knowledge is shaped by, and positioned within, context and culture (Gorski, 2013). Critical realism assumes that objective phenomena exist, which can be partially understood through empirical enquiry (Alderson, 2016). Further, it assumes that unseen and indirect contextual forces have a reciprocal influence on people (agents) as individuals and in relation to each other albeit such forces may only be visible in their effects (Bhaskar, 2016). This epistemological framework provides concepts, therefore, that could elucidate how policies arising from the current health crisis are impacting professionals and how the capacity tool might enable them to influence their context (Alderson, 2016).

Ethics

Ethical approval was sought and obtained from Lancaster University's Research Ethics Committee (REC) and from the Health Research Authority (HRA) (see Appendix 4-L and 4-P). Following a decision to amend the study title and design, making it relevant to practice during the COVID-19 outbreak, changes were heard as part of a scheduled National Health Service (NHS) REC ethics board meeting and processed in line with procedures specific to COVID-related studies (NHS Health Research Authority, 2020). The NHS REC approval letter is contained in Appendix 4-O.

Participants

Purposive sampling was employed to obtain a sample of experienced Deprivation of Liberty Safeguards (DoLS) assessors in the Northwest of England who could speak to the feasibility of using the capacity tool within remote assessments (Palinkas et al., 2015). DoLS assessors comprise Mental Health Assessors (MHAs), who have a psychiatry background, and Best Interests Assessors (BIAs), who have a background in clinical psychology, social work, occupational therapy or mental health nursing. Independent assessors and those employed directly by a statutory service were eligible to participate. As a result of service pressures arising from the COVID-19 health crisis, it was not possible to recruit DoLS assessors employed by NHS Trusts. Everyone who expressed an interest in taking part in the study was recruited.

Eight participants were recruited to the study (seven identifying as female and one male participant). Participants were all DoLS BIAs and had between five and 15-years-experience in undertaking capacity assessments. Two participants were employed as BIAs within a Local Authority and the remainder worked as independent professionals.

Recruitment

Emails promoting the study were sent to Local Authority DoLS managers. Four participants were recruited through these networks. Four participants were recruited after they responded to a research advert posted on Twitter (see Appendix 4-A). Once consent forms had been returned, participants were sent a copy of the capacity tool, associated guidance and a combined client/frontline worker consent form (see Appendix 4-C, 4-G, 4-I and 4-D respectively). Participants were also sent a consent procedure flowchart (see Appendix 4-E). Participants completed a demographic information sheet, indicating whether they had appropriate equipment for online interviews and their availability for data collection

(see Appendix 4-D). Arrangements were made to conduct the focus groups or interviews at a time convenient to participants.

Data collection

Focus groups and individual interviews were used to collect the majority of participant data. To improve the trustworthiness of findings proper consideration was given to the rationale for this approach given the potentially divergent epistemological assumptions of these two approaches to data collection (Barbour, 1998; Lambert & Loiselle, 2008; Morse, 2003). From a practical and ethical perspective, using groups and interviews was useful in obtaining information efficiently and in offering participants choices in how the contributed to the study (Rees et. al., 2003; Taylor, 2005). Moreover, this approach was selected to generate rich feasibility data by combining information about the range of differences and similarities of perspectives that can be a unique feature of focus groups with in-depth perspectives that can be explored in interviews (Lambert & Loiselle, 2008; Macdonald, 2006).

Within critical realism, experiences are understood as arising from interdependent planars of dialogue (Bhaskar, 2016). An epistemological assumption is that perspectives are shaped and strengthened through intra- and interpersonal dialogue (Bhaskar, 2016). Seen through this epistemological lens, critical realism can provide a frame within which the question of feasibility can be explored both through both individual reflections shared with an interviewer and interpersonal dialogues within groups (Alderson, 2016; Morgan, 2012; Price & Martin, 2018).

A question route resembling a structured interview was preferred over a topic guide to increase the likelihood of obtaining comparable data across groups (Krueger, 2009) (see Appendix 4-I). The question route was adapted into an individual interview schedule for two participants who were unable to attend a group. In line with good practice recommendations,

questions were uni-dimensional, and did not contain synonyms (Freeman, 2006; Krueger, 1998b).

Experts-by-experience were consulted on the type of questions included in the focus group question routes and individual interviews by the student researcher. This group comprised four people with an acquired brain injury who had experience of having their capacity assessed. During this process there was no indication that these adults lacked the capacity to provide consultation. Following conversations with this group an additional question was included: "If we asked a client or front line worker how they experienced the tool what might they say?"

Two online focus groups comprising three participants each and two individual interviews were undertaken. Confidentiality arrangements and the participants' rights to withdraw from the study were reiterated at the beginning of each group or interview. People were offered the opportunity to ask questions and a debrief sheet was provided via email after each discussion. Participants were invited to select their own pseudonym for the report Consistent with focus group best practice, the full data corpus included transcripts of discussions, notes taken by an assistant psychologist during the group interviews, notes from debrief sessions held between the student researcher and assistant psychologist and the researcher's reflective journal.

Procedure

Participants had six weeks to trial the tool with clients. This timeframe was set following a scoping exercise with four potential participants who confirmed that at least three assessments could feasibly be undertaken over this period. When the tool was emailed to participants it was explained that it was designed to be used flexibly. Ideas for how the tool might be used were also outlined. For example, it was suggested that participants could ask care staff to complete the tool with clients on their behalf and use the information gathered to

inform their decision. Participants were also directed to the guidance document that accompanied the tool for additional information about using it (see Appendix 4-H). During the trial period two contacts were made with each participant to offer them an opportunity to ask questions about using the tool or to clarify any aspects of the study.

The question route to be used in the focus groups was trialled in an online pilot focus group conducted on Microsoft Teams (Krueger, 1998b). The pilot group comprised two academic supervisors and two friends of the researcher who were informed about the research topic. The assistant psychologist was unavailable during this period so a researcher supervisor acted in the role of notetaker; sharing learning with the assistant psychologist prior to the real groups. The pilot tested the accessibility of questions, explored the ease with which participants could use software and identified unique challenges arising from online discussions. Relevant adaptations were then made to improve the process, such as suggesting to participants that they raise their hand to indicate that they would like to talk. Convergent with the literature, the pilot indicated that groups should comprise no more than three participants for optimal participation (Finch & Lewis, 2003; Tuttas, 2015). Further, the pilot suggested that short test sessions to practice using the software with participants would be useful.

Focus groups and interviews ranged in duration from 52 to 68 minutes. Discussions were recorded with the consent of participants and transcribed verbatim. At the end of each group the assistant psychologist supporting the research, shared the main ideas that they had noticed arising from the discussion with the group. Participants were asked to comment on whether these ideas were an accurate reflection of their views and any additions or comments were noted. The researcher and assistant psychologist met for approximately fifteen minutes after each group to compare their interpretations of what had been shared.

Analysis

Focus groups are not associated with a particular analytic framework but some principles of focus group analysis were used to produce richer data and to scaffold the analysis (Krueger, 1998a). Freeman (2006), suggests that analysis begins with thoughtful question sequencing to allow people to gather their thoughts and feel comfortable in sharing their views within a group context. As such, the first question related to participant recollection of the tool and general opinions about it (Freeman, 2006) (see Appendix 4-I). Braun and Clarke's (2006) stages of thematic analysis were followed to provide a clear structure and rigour in the analysis.

The full data corpus was read over more than three times to establish familiarisation with the data. Notes were taken of potential themes, which were periodically referred back to throughout the analysis. A top-down analytic approach was employed, with data reviewed for units of meaning that may be pertinent to the research question (Braun & Clarke, 2014). An example of a coded extract of data is contained in Table 3. Codes were reviewed, revised or merged where appropriate and an initial thematic map containing twelve themes was created (Braun & Clarke, 2006; Kitzinger & Barbour, 1999) (See Figure 1). Themes were refined during supervision discussions and following participant feedback. Whilst candidate themes corresponded closely with aspects of the research questions this was not felt, on reflection, to be the best representation of the data (Braun & Clarke, 2006). These themes were refined into four final themes that were checked for internal coherence and overall fit with the data (see Figure. 2). A final coding frame is contained in Table 5.

Reflexivity and quality of analysis

The researcher reflected on their assumptions, expectations and responses to the data throughout data collection and analysis using supervisions and a reflective journal (King, 2010). This was done to promote greater transparency and created space for alternative accounts of the data in supervision (Power & Williams, 2001). The research team included

two academic supervisors who were experienced in qualitative analysis. They reviewed the analysis at each stage to ensure that thematic development was valid and true to the data (Yardley, 2000, 2017). At the end of each focus group and individual interview either the researcher or assistant psychologist summarised some of the main ideas discussed. Participants were invited to comment on the accuracy of summaries. Three participants gave immediate feedback to clarify their ideas and perspective. Provisional themes were emailed to each participant for review and comment. All participants responded to the email to say that they were satisfied that the themes accurately depicted their thoughts and experiences. Quotes were used extensively to support interpretations.

Results

Four themes were identified from the analysis. These were: (1) Structure is Crucial for remote DoLS assessments, (2) Facilitating Effective Relationships; (3) Being Person-Centred and (4) Bridging the Gap Between Training and Practice. The first theme comprised two sub-themes: Reducing Complexity and Obtaining Rich and Relevant Data. Theme three included the sub-themes: Getting the Balance Right and Language is Important. Theme four incorporated the subthemes: Building Resilience within and Across Services and Implementation May Require Support (see Table 2). Supporting quotes for each theme can be reviewed in Appendix 2-B. Table 1 details how many times each participant used the tool and whether they participated in a group or an interview.

Theme 1: Structure is Crucial for Remote DoLS Assessments

This theme relates to how staff felt that the tool provided a structure to follow in relation to assessing capacity and how vital this was in a time when they were doing remote assessments in a pressurised context. Remote assessments were characterised as sub-optimal and more time consuming, in part because of limited resources within hospitals and care homes. Several participants outlined how they often had to get information quickly, "*you*

only really have one shot at it on the phone so you need to, sort of, cover as much as you possibly can" (Ruth). Most participants voiced concerns about the difficulty clients faced in engaging with communication technology, which slowed their assessments down. Against this, clients' abilities to concentrate in an interaction were sometimes limited; "*I've got about 3 minutes left here to get the questions that I need*" (Eve).

Reducing the Complexity of Remote DoLS Assessments

This sub-theme encapsulates how all participants evaluated the tool as a useful structure for remote assessments, which helped to reduce their complexity. Every participant felt that remote assessments compared poorly to face-to-face interactions for their client group. However, the tool helped to increase the perceived acceptability of assessments and the benefits offered by the tool in preparing for an assessment were particularly emphasised. Space to record care restrictions encouraged a focus on salient information:

> *"I think one of the lessons is that it's necessary to do quite a lot of preparation before doing a remote assessment and quite often, erm, you know… it's easy to miss that out if you're trying to do a lot of these* assessments but clearly having a grasp of that information before you start is very important." (Grayson)

Moreover, a prompt in the document to list client problems was recognised as something new and useful (see Appendix 2-C for an annotated version of the tool that reflects findings), "*It's helpful at the start when it asks you to be clear about the main problems that people involved in the person's life think could put them at risk*." (Grayson). During assessments, four participants said that the sequence, and types, of questions and prompts helped them to stay on track during the assessment; In turn, they described how this facilitated a more efficient use of time:

> *"I think the way that it is sequenced is really good 'cause once you get past the first... 11 questions you've generally by then got a pretty good idea…of whether the person's got capacity at that point."* (Elizabeth)

Rich and Relevant Data

The majority of participants listed questions or prompts that they had found novel, useful or illuminating. Two participants said that asking about physical health difficulties was helpful in establishing the person's understanding of their care needs, "*Asking about physical problems was helpful as it's easy to focus on memory*" (Grayson). Examples were depicted as a useful scaffold that could be offered to clients:

> "*You've got prompts within it…like…"Are they in a care home", … "Do they think they're in a hotel?" So I think those… they get you thinking on the right track*." (Zoe, *"uhm, yes"*). (Elizabeth)

Four participants highlighted the value of questions that related to more complex thinking skills like problem-solving and insight that promoted a more nuanced understanding of decision-making abilities:

> *"I quite like the question, "have they found difficulties solving problem or paying attention". So actually more than just saying do you have problems remembering things …actually giving somebody…you know…opportunity to talk about problem-solving and concentration, I think that's useful."* (Grayson).

Some aspects of the tool were described as less helpful in obtaining relevant information. Two participants recounted being confused about the section that explores options available to the client. A suggestion was made that this could be improved by leaving options blank or being clear that the number of options was not prescribed. More broadly, some participants expressed confusion about how the tool was intended to be used in practice and said it could be improved by highlighting that it is not, "*a list you have to go through and*

complete" (Grayson). One participant suggested the tool could be enhanced by including a question that prompts the client to summarise their understanding of the assessment conversation.

Theme 2: Facilitating Effective Relationships

This theme reflects the complexity of working through others to undertake remote assessments. It depicts the various ways in which the tool achieved good evidence through effective joint-working and the evolving nature of these processes as participants reflexively evaluated practice.

All participants outlined how remote assessments created more reliance on client support systems at a time when services were experiencing unprecedented demands. Participants described a range of emotions in response to this, including empathy for clients and staff alongside frustration and, at times, a sense of powerlessness, "*Remote assessments make you "beholden to a member of staff.*" (Eve)

Most participants highlighted dilemmas about how to get the best information without over-burdening professionals on the frontline. There was some debate about how to use the tool in this context, albeit most participants felt that sharing the tool for information was, or would, be useful, "*It's a good thing to share with.. I think it should be shared. I mean… it has had a very good response*" (Grayson). One participant said that the tool would be a good guide for conversations with frontline workers about client circumstances, "*It's a priority to speak to a carer who knows the person*." (Elizabeth). Some participants identified that it was useful for care staff to go through the questions verbally with clients before an assessment. Moreover, one participant had shared the tool with an interpreter before an assessment, which was depicted as being well received by the interpreter and facilitating a more effective conversation with the client:

"Yeah she (interpreter) said it was very helpful. It helped her to understand, you know the purpose of the assessment because she'd come from interpreting other things, not in a social care setting with somebody who may lack capacity." (Zoe)

Another participant suggested that remotely observing staff asking the client questions from the tool would be useful, *"…often they (frontline staff) are better placed, no… generally very much better placed to communicate with the person than you are appearing on a phone or a screen."* (Grayson).

Most participants expressed the view that it felt unacceptable to ask frontline staff to complete the tool on their behalf, *"I would say no, because it's a time issue"* (Helen). Within one focus group, however, this point was debated and participants' perspectives evolved through dialogue with each other:

"I think that (asking frontline staff to complete the tool) would be useful. (Jill)
At the moment I would be a bit concerned that it would be another task on the pile as they are in the thick of it trying to manage COVID." (Elizabeth)
"I know what you mean about adding an extra task in…I suppose though if I was really struggling to be able to see the person, or … I assessed someone where it was just gonna be way too distressing for them to see this complete stranger on a screen… specific questions from the tools that really do link to them being able to assess their functional capacity. I think might be useful." (Z & E, *"yeah", "yes"*) (Jill).

Overall, participants' processes for working with direct staff were portrayed as evolving. Principles that guided these processes were those of respect for the work being done by colleagues and the importance of working together.

Theme 3: Being Person-centred

This theme depicts participants' exploration of how to remain client-oriented during remote working and how this influenced their use of the capacity tool. Participants had

reflected on assumptions and received wisdom to help adapt practice over time. Sending the tool to frontline staff before assessments, as described in Facilitating Effective Relationships was an example of this, as was their use of communication, *"…now I'm not… I consider it's not suitable to do a Skype call or a Zoom call with the person for all variety of reasons."* (Jill)

Getting the Balance Right

Most participants construed the tool as a good balance between prescription and flexibility, *"The tool avoids being patronising whilst not assuming everyone has the same knowledge."* (Grayson). Some participants reported having incorporated questions from the tool into their crib sheet, half had drawn on language or examples in the tool and four had used the tool in full, *"I did exactly what Jill did, which was…changed it slightly according to who I was speaking to (Zoe nods) and what was wrong with them as well."* (Elizabeth). How it was used varied depending on the clients' needs and context. Tacit knowledge from experience in the role was something participants described as drawing on to adapt the tool as needed.

Most participants reported that the section of the tool exploring clients' options was too prescriptive. Participants felt this had practical relevance as it limited the scope to record alternative choices that might be available. Further, one participant described how this section illustrated an unhelpful use of power; *"Who gets to write the menu of choices?"* (Grayson). Ideas put forward to amend this section by two participants included keeping a table to record choices but leaving blank space for the professional and client to personalise the options, *"The tool could be enhanced by making space to record where the person wants to go and what they want to do. Whether that can happen is a separate question."* (Grayson).

Three participants spoke of the complexity of balancing clients' physical health with their right to liberty during the health crisis, recounting feelings of ambivalence about the work:

> *"…especially at this time when everyone is so busy trying to keep everyone safe…erm…that you do feel…I don't know…not a nuisance because we have to do it but you sort of think, they're trying to save lives here and we just want to ask a few questions."* (Eve)

Using the tool flexibly in practice was interpreted as going someway to resolving these dilemmas.

Language is Important

Participants described some words used in the tool, like "problem", "mood" and "personality" as too medicalised and oppressive, *"I think probably some of the wording I would I change because I…tend not to use particular phrases with people, so I wouldn't necessarily use words like "personality""* (Jill). Moreover, all participants talked about the challenges of protecting clients' wellbeing during a process that is, by its nature, somewhat concerned with deficits. These ideas were illustrated through constructive criticism of language used in the tool:

> *"…you've got "Have you noticed any changes to your mood or relationships?" (Elizabeth nods), I would tend to... I might want to ask, "Is there anything that makes you cross here".* (Jill)

> *"I would agree with that 'cause, with some people, particularly that don't have insight, you can scupper your whole assessment if you say the wrong thing or if you're too formal."* (Elizabeth)

Perspectives varied about the general tone of the assessment, *"The language was soft and chatty"* (Eve); *"the tool read as a bit cold-blooded."* (Ruth). Following a review of the

transcripts, language used in prompts and examples was generally evaluated more favourably than the questions that preceded them. Only one participant discussed the guidance that accompanied the capacity tool. The document was described as important but criticised as using too much legal language, *"…it could adapted to more user-friendly language and be incorporated into the interview."* (Grayson).

Theme 4: Bridging the Gap Between Training and Practice

On a micro level, this theme reflects how participants believed that DoLS assessors would benefit from the tool, regardless of experience, as there is no formal training on undertaking remote assessments to date. More broadly, participants reported that the tool could support anyone undertaking capacity assessments to translate legal principles into practice, whether in the context of remote or face-to-face assessments.

Building Resilience Within and Across Services

This sub-theme captures ideas of how the tool could build resilience in systems through increased efficiency, consistency and professional self-efficacy. In addition to providing structure, participants outlined how the tool could create greater consistency between DoLS assessors, *"You know, a section 12 doctor (MHA) might say if this person hasn't got capacity or has got capacity and you think it's the other way around."* (Ruth)

Some participants described how the tool could be used by frontline care home or hospital staff prior to DoLS applications to the benefit of local authorities and clients:

> *"I actually think it would be useful for Managing Authorities (care homes and hospitals) to use it. We would have better informed applications and some applications may actually turn out not to be necessary at all."* (Jill, "*yeah"*; Elizabeth, *"yes"*). (Zoe)

Moreover, most participants described how the tool could support frontline staff in making the transition to the Liberty Protection Safeguards (LPS) that will replace the DoLS in 2022:

> *"I think, you know, given that LPS will be coming in…it's the sort of tool that could be very helpful, because they will be either doing it, or maybe commissioning other people…but, yeah, I could see this really having a lot of use going forward* (Elizabeth; *"yeah"*) *in the new era, yeah."* (Zoe)
>
> *"I mean, I would absolutely second that Zoe in terms of helping skill-up Managing Authorities."* (Jill)

More generally, the tool was cited by every participant as being something that could improve the confidence of social workers, doctors and allied health professionals that are involved in care or treatment decisions:

> *"Because initially you know you have the training and it says "can the person understand the information" and you, sort of like, when you actually get out there in the person's house with, you know, the dogs running around and everything else that's going on I think at the beginning you are thinking "what information…actually, what information do they need to understand?"* (Jill, *"yeah"*). (Elizabeth)

The perception of most participants was that capacity assessments are experienced as mystical and frightening by less experienced colleagues and that the tool could help overcome this by translating abstract ideas into a practical guide, *"If they aren't a BIA doing it all the time… they might appreciate that structure and find it less daunting."* (Alisha).

Implementation May Require Support

Five participants voiced concerns that the training for colleagues, particularly in care homes, was typically infrequent and inadequate. As such, a thoughtful approach to the dissemination of the tool, tailored to the needs of professional groups, was communicated. Ideas for how this could be achieved included the use of more experienced colleagues as mentors or using online software applications to record and demonstrate how the tool could be used in practice.

Discussion

The aim of this study was to establish the feasibility of using a capacity assessment tool for remote DoLS assessments in the context of a health pandemic. To establish feasibility, the research was interested in the extent to which the tool was perceived by participants as: Acceptable and practical; having utility and being implementable in practice. Four overarching themes were developed during the analysis that provided the best fit with the data and the most utility in addressing the research question.

The tool was well received and there was a consensus view that the tool was useful for all clients. Positioning this finding in context is important (Bhaskar, 2016). In line with the extant literature, there was a bias in favour of face-to-face assessments in a context where there was a perception of limited resources to support cognitively impaired clients to access and engage with technology (Loh et. al., 2004). Brooks et. al. (2013) state that remote assessments should be tailored to the needs of the population. Whilst some authors have judged that remote interactions might not be appropriate for every client there is some evidence that well-structured and tailored assessments can be acceptable to cognitively impaired clients and their families (Loh et. al., 2004; Luxton et. al., 2014; Morgan et. al., 2009). The findings of this study lends some support for this position as participants found that the tool provided a flexible structure for remote assessments that improved the quality of the data obtained.

Beyond remote working, all participants felt that that the tool would be acceptable to DoLS Mental Health Assessors as well as inexperienced professionals across services, regardless of context. Taken together, participants' perspectives about why the tool was acceptable in practice converge with decades of evidence that perceived control over our work and organisational support can ameliorate the impact of demanding workloads (Karasek, 1979; Landsbergis, 1988; Wilberforce et al., 2014).

Aspects of the tool that were experienced as less acceptable related to some of the language used. For examples, words like problem and personality were frequently judged to be too medicalised or potentially provocative or demeaning of clients. Further a section within the tool that explores clients' options, perceived by most participants to be too prescriptive. Capacity work has been described as embedded in relationships of power (Series, 2015) (p.81). Participants' criticisms can be interpreted as, in part, a judgement that power had been used unhelpfully by leaving too little room for client perspectives (Banner, 2012). Nevertheless, judgements in case law have cautioned against too loose a framework for assessments that might result in clients being insufficiently informed of their options (Keene et al., 2019).

The majority of participants felt the tool could be enhanced by explicitly acknowledging the interpersonal competencies required for assessments. This is consistent with the findings of Rogers and Bright (2019) where participants emphasised the importance of positive relationships with clients. This perspective also echoes ideas emerging from theories of relational autonomy. (Committee on the rights of persons with disabilities, 2014; Series, 2015). This paradigm challenges the medical and legal concepts of capacity as an objective phenomenon (Banner, 2012). Instead, capacity is reconceptualised as something that is shaped by relational dynamics and subjective professional judgements (Banner, 2012; Series, 2015). Nevertheless, balancing relationships and client wellbeing with a requirement to achieve best evidence can be complex. Moreover, legal commentators and some recent studies indicate that alternative perspectives can be over-emphasised and that a properly implemented legal definition provides scope to uphold client rights (Clerk, Schaub, Hancock, & Martin, 2018; Ruck Keene, 2017).

Participants were able to draw on a rich landscape of experience and tacit knowledge to "weave" the tool into their practice (Sayegh et al., 2004). Practical applications of the tool

described by participants often involved other practitioners. Sharing the tool before assessments, for instance, was experienced as instrumental in gathering information and in building relationships. This finding is encouraging as interprofessional collaboration in pressurised contexts has been shown to facilitate improved clinical judgement and better client outcomes (Piquette, Reeves, & Leblanc, 2009; Reeves, Pelone, Harrison, Goldman, & Zwarenstein, 2017; Wheelan, Burchill, & Tilin, 2003).

Counter to expectation, most participants felt it was too much to ask staff to complete the tool on their behalf. In reaching this decision, principles of respect for colleagues' circumstances were foregrounded. This conclusion was also informed by perspectives on the skills of frontline staff who were perceived by several participants as having stronger verbal skills that written abilities. Moreover, experiences of professional dissonance appeared relevant to this finding as participants endeavoured to balance patient health, colleagues' stress and obligations to promote clients' right to liberty (Donnelly, 2009).

Participants described several ways in which the tool enhanced the quality of their assessments. The tool was praised for encouraging preparation, which reflects recommendations in national guidance (National Institute for Health and Care Excellence, 2018). There were, however, several descriptions of how this can be inherently challenging for independent professionals in the current climate; reflecting findings in the literature (Jayes et al., 2019). Furthermore, some questions were depicted as addressing areas of cognition and function that were not typically explored. This included client insight into difficulties. This is significant as guidance suggests this should be considered but, to date, there has been limited practical guidance of how to achieve this (British Psychological Society, 2018b; George & Gilbert, 2018; National Institute for Health and Care Excellence, 2018).

Moreover, participants felt that the tool could "set standards" and create greater consistency between DoLS assessors. Consistency was depicted as an inevitable result of greater clarity about relevant evidence, thereby reducing the scope for professional bias to influence judgements (Banner, 2012; Clerk et al., 2018). Nevertheless, procedural guides are likely to be insufficient without other processes, like effective supervision, that can encourage professionals to reflect on personal values and assumptions that they might bring to bear on assessments (Rogers & Bright, 2019; Alex Ruck Keene, 2017). Participants described how, with relevant revisions, the tool could improve the confidence of professionals by helping them to translate the legal framework into practice. There is compelling evidence to suggest this is needed in practice, with findings indicating that traditional training can improve knowledge but not necessarily application (Hinsliff-Smith et al., 2017; Jenkins, Webster, Smythe, & Cowdell, 2020; Samsi, Manthorpe, Nagendran, & Heath, 2012).

The new Liberty Protection Safeguards will require frontline services, in many instances, to assess clients' capacity to consent to restrictive care regimes as part of an internal process (Mental Capacity (Amendment) Act, 2019). Participants highlighted how future research should examine the value of the capacity tool for frontline staff preparing for the LPS.

Implications for Clinical Psychology

As scientist-practitioners, clinical psychologists are uniquely placed to support complex capacity assessing both in terms of applied research and clinical support (British Psychological Society, 2018a, 2018b). Within the profession there are practitioners who are knowledgeable about complex presentations and how difficulties, such as reduced insight, can complicate decision-making. This was an aspect of the tool that was valued, and, in line with guidance in the MCA Code of Practice, as a profession we should examine how we can

make this knowledge more available to colleagues through consultation, training or informal multi-disciplinary support. Alongside this, Clinical Psychologists are trained to a high level in psychological formulation and therapeutic techniques. There would be utility in considering how these skills might help colleagues explore the various factors that might influence client decision-making (Brown & Marchant, 2013; Case, 2016).

Offering clinical supervision to colleagues could provide an important space to reflect on how best to support client wellbeing during remote assessments (Craigie, Freyenhagen, & O'Shea, 2013). For example, this study highlighted the importance of adhering to ethical principles such as confidentiality in circumstances where privacy can be difficult to ensure (Luxton et. al., 2010; Luxton et. al., 2012). Moreover, protecting client wellbeing during remote assessments might require detailed consideration of risk and the recruitment, for example, of local collaborators who can assist with onsite support (American Telemedicine Association, 2009; Gros et. al., 2011).

Whilst services continue to grapple with the impact of the COVID-19 outbreak clinical psychologists could also offer valuable psychological support to staff undertaking assessments in the face of innumerable challenges.

Strengths and Limitations of the Study

This study was timely, it took account of the opinions of stakeholders in the design and offered flexibility to participants in how data was collected. The development of participants' opinions during the focus groups is considered a strength of the research. Collecting data through focus groups and interviews highlighted how the process of forming views and deciding future actions was dynamic and evolving. Exchanging views and ideas during data collection facilitated a richer understanding of how the tool could be used in context for both the participants and the researcher (Frey & Fontana, 1993; Morgan & Bottorff, 2010).

It was not possible to recruit DoLS Mental Health Assessors in the timeframe available and the majority of the Best Interests Assessors who did participate were independent professionals. Moreover, the sample represented the minimum necessary for the research. Furthermore, whilst experts-by-experience were consulted on the questions put to participants in the groups and interviews they were not included in decisions about methodology or analysis and were not included as participants. Nevertheless, the researcher is appreciative of the thoughtful and considered views expressed by participants and the analysis yielded useful and important findings for practice.

Recommendations and Future Research

Revisions to the tool put forward in this study should be given due consideration before additional research is undertaken (see Appendix 2-C). Findings indicate it is feasible to undertake additional research on the tool and a pilot design would be considered appropriate. Additional supplementary guidance around undertaking assessments remotely might also be useful for future research. This could include considerations around privacy, confidentiality and ensuring client wellbeing. Additional research could be undertaken with frontline staff in care homes and hospitals. For instance, these findings indicate that frontline workers and clients may benefit from a similarly structured capacity tool that is relevant to decisions in their settings regardless of whether they are being undertaken face-to-face or remotely. Further, results in this study suggest that professional training for health professionals and social workers may not adequately equip them to undertake capacity assessments in real-world settings. The development and implementation of relevant structured capacity tools for these professional groups would, therefore, also have potential value.

Conclusion

The tool was used and valued by most participants and they all judged that it had potential utility for DoLS assessors and colleagues in other settings. The structure, sequence, questions, examples and prompts were praised, which indicated that all participants found it feasible in practice. Suggestions of possible amendments and ideas for future research were provided that are reflected in the recommendations section. Ultimately, this feasibility study showed that with some amendments the tool will be useful for assessing capacity in remote contexts for DoLS assessors. The qualitative design generated a richer understanding of the evolving nature of remote capacity assessment work and the contribution brought by a new resource than might otherwise have been possible using quantitative methods.

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Figure 1

Candidate thematic map

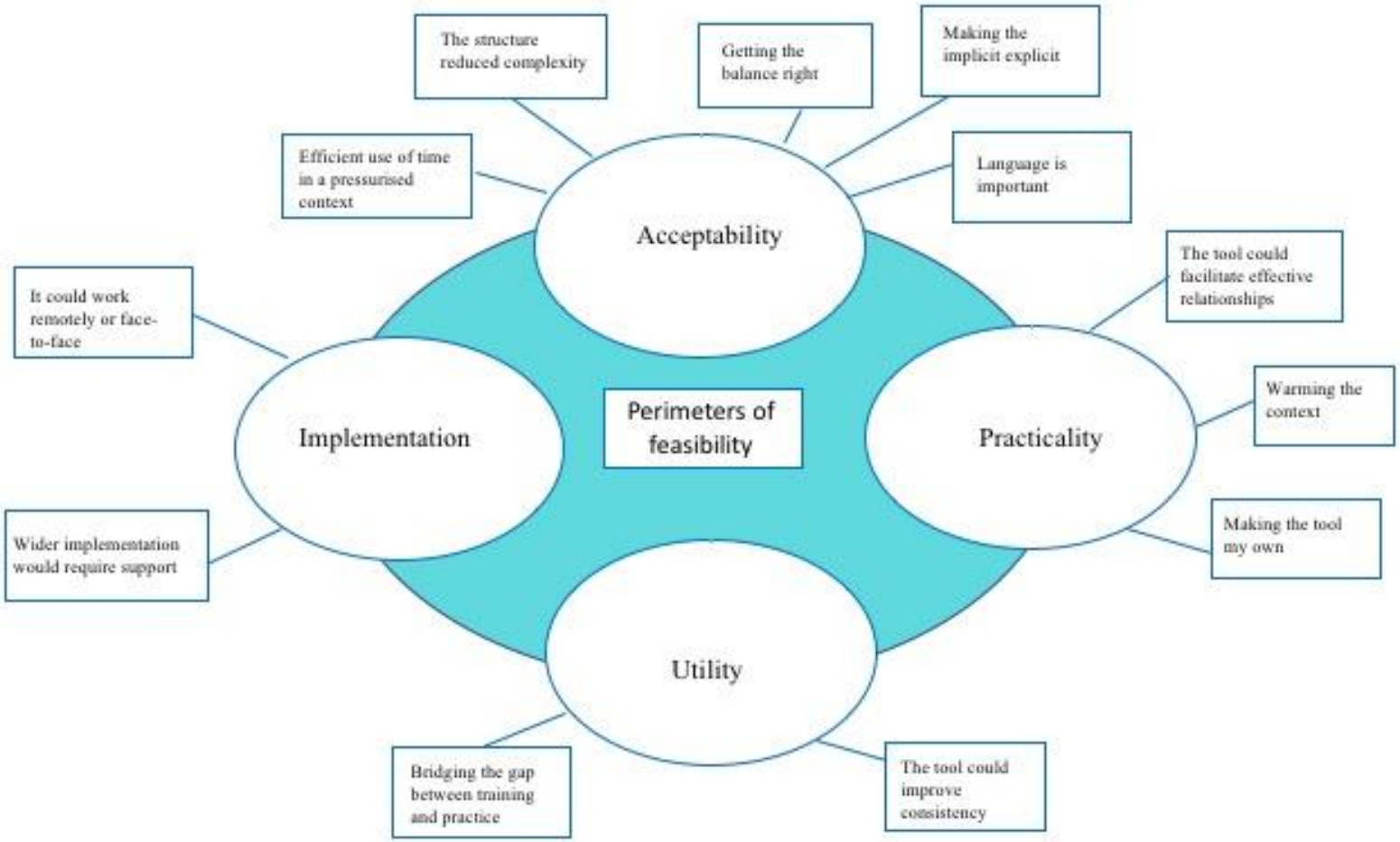


Figure 2

Final thematic map

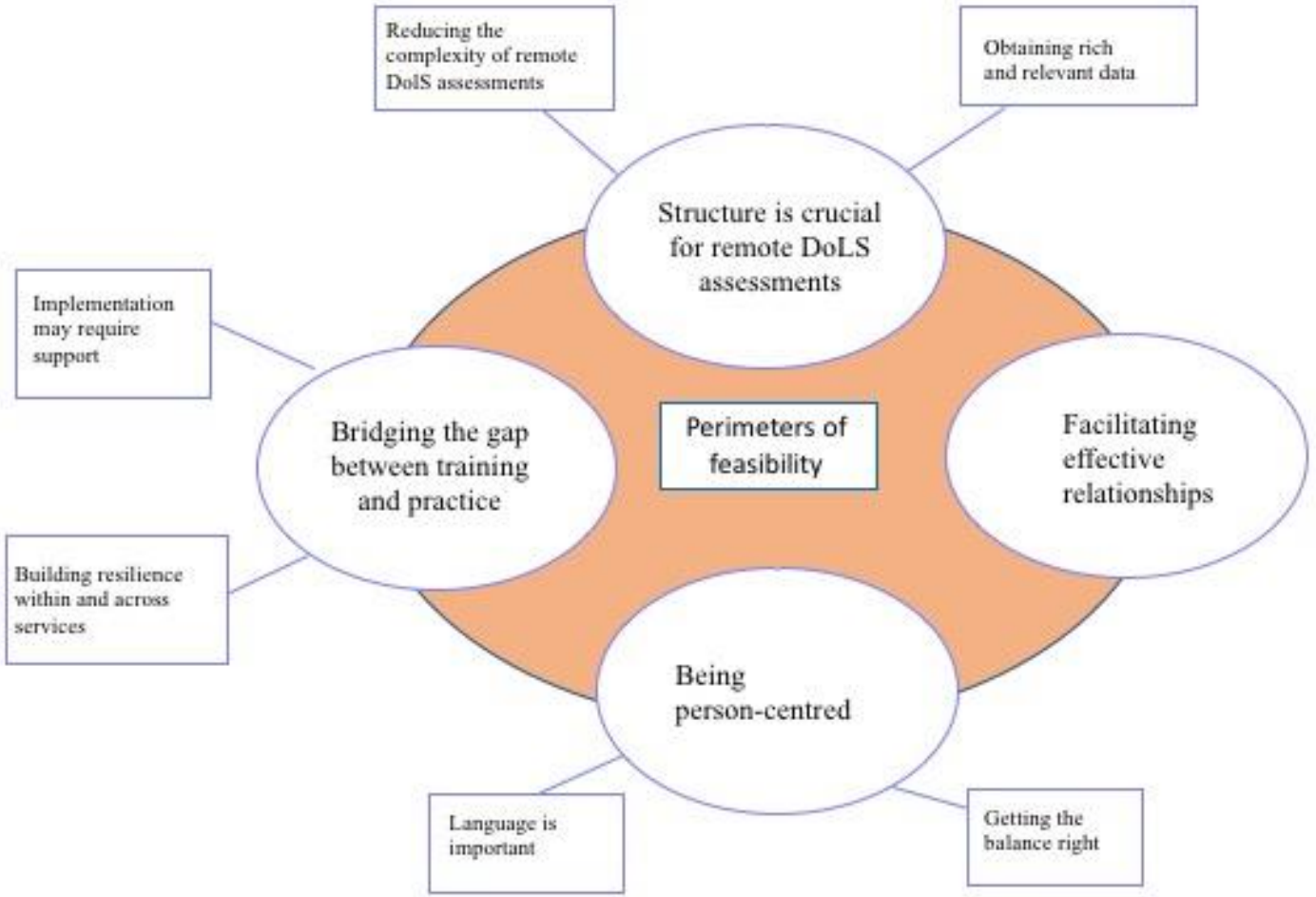


Table 1

Participant Demographic Information

Participant	No. of times the person used the tool with their assessment [a]	Data collection method
Jill	2	Focus Group
Elizabeth	3	Focus Group
Zoe	3	Focus Group
Ruth	1	Focus Group
Alisha	4	Focus Group
Eve	3	Focus Group
Grayson	2	Individual interview
Helen	3	Individual interview

[a] Use of the tool was counted when the person either used the tool in full or in part, for example by including some questions from the tool in the assessment

Table 2

Themes and Sub-themes

	Themes and sub-themes
1	**Structure is crucial for Remote DoLS assessments** 1.1 Reducing the complexity of remote DOLS assessments 1.2 Obtaining rich and relevant data
2	**Facilitating effective relationships**
3	**Being person-centred** 3.1 Getting the balance right 3.2 Language is important
4	**Bridging the gap between training and practice** 4.1 Building resilience within and across services 4.2 Implementation may require support

Table 3

Data Extract and Corresponding Initial Codes

Data extract	Early descriptive codes
Yeah, I found it quite helpful actually, erm… to have that sort of structure even though, you know, we may have lots of experience, I think doing it remotely is another situation altogether…erm…and … *I found it a very useful…tool and check you know for myself but also in terms of talking with staff who know the person…erm…* *to gauge their sort of, you know, uh, get a better picture of the situation. So yeah, it offered me some structure in a bit of a weird time I think.*	Tool as a helpful structure "in a bit of a weird time" Remote assessments require a different approach Tool as a way to scrutinise personal practice Tool as a guide for conversations with direct care staff Tool as a way to understand client context during contact restrictions
Yeah, I would agree with that. It did, it offered some structure. I have my own sort of crib sheets at…and it was very.. it was…but mine are generally just single words. So while you're there (face-to-face) it's easier to expand on those…on the word that just reminds us. But when you're on the phone it's…it's…I think it's more difficult to focus.	Tools as a helpful structure Practice as usual Remote assessments make it more difficult to focus

Table 4

Development of a candidate theme from descriptive codes

Descriptive codes	Emerging themes
Tool as a helpful structure “in a bit of a weird time” The tool provided a focused guide Remote assessments need more structure Tool “helps to keep you on track” during remote assessments It has got a real value in getting people to think about the areas that they need to consider Prompts elicited useful information Tool provided useful pointers Remote assessments can be chaotic, which makes it's hard to focus	The structure reduced some of the complexity of undertaking remote assessments

Table 5

Development of Final Themes

Codes	Sub-theme	Final theme
Remote assessments can be chaotic, which makes it hard to focus Grappling with technology to do an assessment is hard Remote assessments during the pandemic are pressurised Getting what information you can within a window of client tolerance Some clients have limited concentration You often only get "one shot" Remote assessments need more structure Preparation is particularly important when you're under pressure The questions in the tool are a useful reminder of what's needed It has got a real value in getting people to think about the areas that they need to consider Examples in the tool remind you of what to ask about The tool breaks a complex process down and makes clear what evidence is needed The tool provided a focused guide Tool "helps to keep you on track" during remote assessments Tool provided useful pointers Using the tool provided a reference point Incorporating the tool into practice elicited the most useful information in the shortest amount of time Tool as a helpful structure "in a bit of a weird time" It's useful to summarise care /treatment plans in such a way the person can understand them Being clear about problems is helpful as often professional mindset is configured towards needs Being clear about problems is a key thing for clients to understand	1.1 Reducing the complexity of remote DOLS assessments	Theme 1: Structure is crucial for Remote DoLS assessments

Codes	Sub-theme	Final theme
It was helpful to write the risks down Writing down the risks gets you to focus Writing down restrictions reminds you to talk to the client about them		
Asking if the client believes the concerns of others is important as it can be key to whether the person understands the decision Do they think they need this help is a good question Asking about physical problems was helpful as it's easy to focus on memory Asking about executive functions is helpful Prompts elicited useful information Add a question asking the client to summarise the discussion Options were confusing Unclear if the whole tool has to be completed Using the tool interpreted as using it formally Be more explicit that this is not "a list you have to go through and complete"	1.2. Obtaining rich and relevant data	
Remote assessments take longer because you are reliant on others Nurses' ability to help is limited during pandemic restrictions Managing Authorities have inadequate resources to facilitate remote assessments Managing Authorities have insufficient resources to fill in more paperwork Asking Managing Authorities to complete the tool is "a bit much" Asking Managing Authorities to complete parts the tool could be useful in some circumstances In an ideal world the client and care professional would be familiar with the tool before the assessment		Theme 2: Facilitating effective relationships

Codes	Sub-theme	Final theme
Carers going through questions with the client before assessment Warming the context Care homes were receptive to seeing questions beforehand Tool as a guide for conversations with direct care staff Tool perceived as useful by a professional involved in the assessment Co-production as best practice Observing the care worker asking the questions can be better for the client “It’s about sharing the power” Remote assessments make you “beholden to a member of staff” Joint working is better for the client The tool could help dispel myths about decision-makers being “do-gooders just letting the person put themselves in harm’s way”"		
Able to draw on background knowledge to adapt questions, examples and options Tool provides questions that can be woven into an assessment Weaving questions into existing practice “I have used it as my own crib sheet” “It’s a good document to dip in and out of” Using some of the wording from questions The tool avoids being patronising whilst not assuming everyone has the same knowledge Useful to use the whole tool where necessary It's challenging to balance client's right to life with their right to liberty in this context DOLS deprioritised by hospital staff during the pandemic The options section reads like a closed list that someone else has imposed	3.1: Getting the balance right	Theme 3: Being person-centred

Codes	Sub-theme	Final theme
It's important to use power appropriately Who gets to write the menu of choices?		
The language is a “bit cold-blooded” Saying the wrong thing can scupper an assessment Adapt the guidance using more user-friendly language and incorporate it into the tool The language was soft and chatty Appropriateness of language in the tool “personality” Theoretical orientation of some language not acceptable The word problems needs to be softened Using language unacceptable to clients is oppressive Needs more everyday language Adapt the guidance to more user-friendly language and incorporate into the interview Using the wording from questions	3.2: Language is important	

Codes	Sub-theme	Final theme
The tool can be implemented with experienced DOLS assessors in the context of remote working Tool would be useful for DOLS Mental Health Assessors The tool could work remotely or face-to-face Using it face to face might be better for less experienced decision-makers Tool can improve understanding of what's needed Tool as a way to scrutinise personal practice Managing Authorities would provide DOLS assessors with better informed applications if they used the tool The tool could improve the quality of assessments undertaken by general social workers The tool would help identify people who have capacity and avoid putting them through an unnecessary assessment Training doesn't always prepare you for the reality of doing assessments "The tool could set standards" The tool could provide utility over time as remote assessments are likely to be required in the future Tool as filling a gap between training and practice Care homes often interpret restrictions as being about physical restraint Information about capacity on DOLS applications can be minimal Managing Authorities would be more likely to make accurate capacity judgements if they used the tool The tool could create consistency through shared meaning Inconsistent approaches to assessments affects professional relationships The tool could provide a scaffold for care providers when LPS is introduced	4.1: Building resilience within and across services	Theme 4: Bridging the gap between training and practice

Codes	Sub-theme	Final theme
The tool could guide Managing Authorities Helpful for students or new BIAs The tool would be useful for inexperienced assessors Tool would be useful for newly qualified staff or people “who have been out of the job for a while” The tool could help equip care homes to undertake complex assessments under LPS Tool as useful for allied health professionals		
Managing Authorities have had insufficient capacity training Managing Authorities will need support doing assessments Use technology to demonstrate the tool Managing Authorities need more knowledge about DOLS Capacity assessments are perceived as mysterious Capacity assessments can be frightening when you’re not used to doing them	4.2: Implementation may require support	

Appendix 2-A

CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2-1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2-3 – 2-7
	2b	Specific objectives or research questions	2-8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	NA
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	2-10
	4b	Settings and locations where the data were collected	2-10 – 2-11
	4c	How participants were identified and consented	2-11 – 2-12
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2-12 – 2-13
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	NA
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA

	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	2-8
Sample size	7a	Rationale for numbers in the pilot/feasibility study	2-10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2-11
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	NA
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	NA
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	2-14 – 2-23

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	2-27
Generalisability	21	Generalisability of pilot trial methods and findings to future definitive trial and other studies	NA
Interpretation	22	Interpretation consistent with trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	2-28
	22a	Implications for progression to future definitive trial, including any proposed amendments	2-28
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the trial protocol can be accessed, if available	4-38
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4-2
	26	Ethical approval or approval by research review committee, confirmed with reference number	4-106

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 2-B

Additional Supporting Quotes

Theme 1: Structure is crucial for remote DoLS assessments

"you spend your first 10 minutes saying…you know…"can you hear me? can you hear me?"... can you see me, hello?" (general laughter and nods) and in the end…by the time they say yes, you've forgot what you, what you're doing, why you're there…so I think from that from that point of view it's been…it keeps you on track (Zoe *"yeah"*)" (Elizabeth)

"I think doing it remotely is another situation" (Zoe).

"When you're on the phone, it's…I think it's more difficult to focus" (Elizabeth)

"I found once I switch to remote assessments I needed to have a list of actual questions …it was my way of explaining why this is going to take longer than just two minutes erm..and also to explain why I didn't want them to just sort of plonk a screen in front of somebody" (Jill)

"This whole remote way of working and technology has been a bit of an eye opener for me…erm… and I think when you're under so much pressure to do DOLS assessments anyway like they always want them yesterday, then to have to grapple with technology and how best to try to talk to the person..erm…has been really hard so for me" (Eve).

"I don't know why I feel there is a difference because there shouldn't be because an Assessment is an assessment. I suppose…old people that you…they're not used to things like video calls so they're seeing you on a screen, which they wouldn't normally do…seeing you and seeing themselves" (Alisha).

"…because I have started to ask that more now and I don't know if I did before …erm… because if they believe you and if they can take that on board …then you may be actually closer to having capacity…it's often about insight, isn't it" (Helen)

"I found it quite helpful actually, to have that sort of structure in a bit of a weird time." (Zoe)

"I think those of us who have been assessing capacity for donkeys years have, sort of our own ways of doing it, but…like we were saying, doing things ..doing it over the phone, it's been really helpful for that." (Elizabeth)

"It did give me a lot of pointers in…erm…when we're doing remote assessments, Pointers for, sort of, questions to ask that you probably take a bit more for granted When you're sat with someone in conversation" (Eve)

"It comes back to that word structural framework really" (Zoe)

"So yeah, it just offered me some structure I think. Even though, you know, we may have lots of experience, I think doing it remotely is another situation altogether" (Elizabeth)

"It's a fine line between getting what you need and not during remote assessments" (Elizabeth)

"…what I would do to sort of just… for me to test out their understanding and their retention as we're going through I would be saying, "oh, just so that just so I know that you've understood what we've been talking about. Could you maybe just put some of that into your own words?" So for instance, I did one the other day and then I asked them at the end "what have we been talking about?" and she said, "old jobs and my housework"…So that was her perception of the conversation" (Helen)

"Stopping when needed – absolutely because otherwise it actually starts to feel a bit

oppressive, because sometimes you can get what you need very, very quickly" (Helen)

"You'll be asking, you know, "Well who lives at home?"…"well…mum and dad live at home"..so you're picking all that up, which gives you a really clear indication that there's no point then in going on to talk in-depth about .."if you were to go home with a care package" (Elizabeth)

"The other problem is the shortage of iPads and laptops…so because…you know they're using them a lot to try to keep families in touch with people so social workers and doctors have to fit in the time slot when the equipment is actually available." (Grayson).

Theme 2: Facilitating effective relationships

"I was sending questions to the care home first anyway…it was my way of...sort of explaining why this is going to take longer than just two minutes...also to explain why I didn't want them to just sort of plonk a screen in front of somebody…so they knew we were going to go through a list of things" (Jill)

"In many situations it is much more appropriate that the person alongside the client is the one who asked the questions 'cos very often people with dementia, erm…can't make any sense of phones and iPads and faces appearing on screens" (Grayson)

"I was sending questions to the care home first anyway… it was my way of explaining why this is going to take longer than just two minutes...also to explain why I didn't want them to just sort of plonk a screen in front of somebody…so they knew we were going to go through a list of things" (Jill)

"The reality of it tends to be that I will ask my questions, the person won't respond, then the carer who's heard my question will repeat it or rephrase it for the person then the person will respond to the person who is actually in the room." (Eve).

"The social worker or the doctor asks the questions because they're the ones with the Power and expertise and carers have traditionally been very low status, despite the fact they're doing very difficult jobs, which is why this whole thing with COVID has been so good, because it has actually made people realise how skillful hands on carers actually are. So I think it would be a sign of respect to send a copy of this to the person who's gonna be with the person so they know what's going on." (Grayson)

Theme 3: Being person-centred

"I think probably some of the wording I would change because I…tend not to use particular phrases with people, so I wouldn't necessarily use words like "personality"" (Jill)

"*You could rephrase problems as, "do you need help with anything" or, "do you have any issues?""* (Helen)

"I did borrow some of your lovely wording Emma, from the questions" (Jill)

Theme 4: Bridging the gap between training and practice

"Without structure, information recorded can be irrelevant. Some stuff like, "they didn't know who the Prime Minister was" well…that's irrelevant isn't it…it's too generalised, it's not specific enough…you have to make it more specific and I think people don't normally do that so I would be happy to say to my managers, "I'm happy to go through this with staff as a good guide for your assessments...so I'm going to rob it for them!" (Alisha)

"I actually think it would be useful for Managing Authorities to use it…we would have better informed applications but some applications may actually turn out not tobe necessary at all (J *"yeah"* – E nods)." (Zoe)

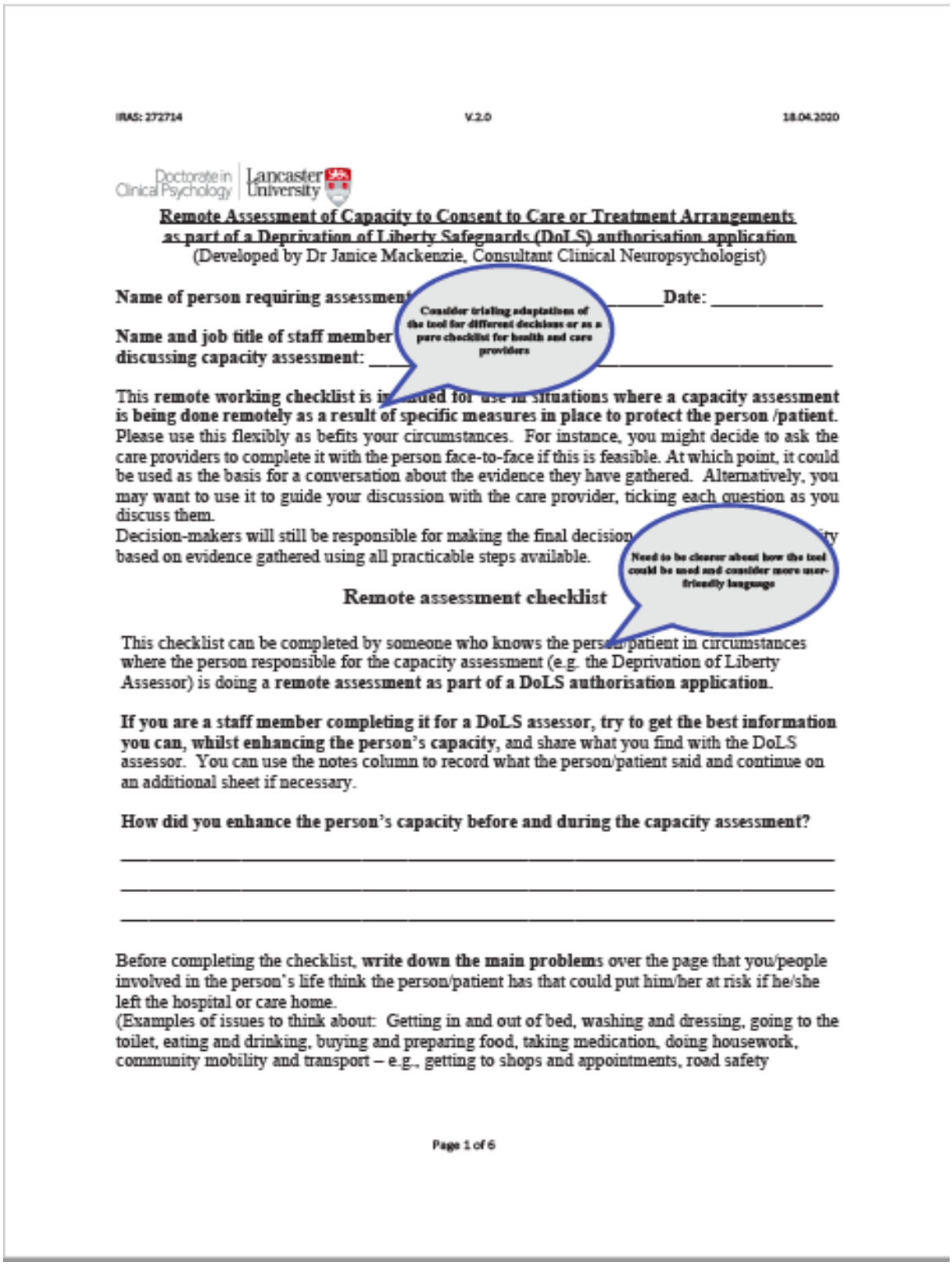
"So, but it would be good for them (Managing Authorities) to maybe get a checklist based on this tool. That wouldn't be the assessment…It would be a checklist which would then inform their assessment. So…"for your assessment…have you considered these areas" so very similar to what you've done really." (Helen)

"People are fearful of capacity assessments when you're not used to doing them (Ruth & Eve "yeah"; "um")...So I really think this would be beneficial to have this as a good guide." (Alisha)

"I think general social workers might do better assessments because they will be definitely covering the things that need to be asked. Sometimes we have to look at previous assessments, say if they have been placed in a care home, I'll read the capacity assessment and it's all about… well… the person didn't know how old they were or…well that can be relevant at times but some stuff like "they didn't know who the Prime Minister was" well…that's irrelevant isn't it…it's too generalised" (Alisha)

Appendix 2-C

Capacity Tool Annotated in line with Findings



IRAS: 272714 V.2.0 18.04.2020

Doctorate in Clinical Psychology | Lancaster University

Remote Assessment of Capacity to Consent to Care or Treatment Arrangements as part of a Deprivation of Liberty Safeguards (DoLS) authorisation application
(Developed by Dr Janice Mackenzie, Consultant Clinical Neuropsychologist)

Name of person requiring assessment _____ **Date:** _____

Name and job title of staff member discussing capacity assessment: _____

Consider trialing adaptations of the tool for different decisions or as a pure checklist for health and care providers

This **remote working checklist is i[illegible]ued for use in situations where a capacity assessment is being done remotely as a result of specific measures in place to protect the person /patient.** Please use this flexibly as befits your circumstances. For instance, you might decide to ask the care providers to complete it with the person face-to-face if this is feasible. At which point, it could be used as the basis for a conversation about the evidence they have gathered. Alternatively, you may want to use it to guide your discussion with the care provider, ticking each question as you discuss them.
Decision-makers will still be responsible for making the final decision [illegible]ty based on evidence gathered using all practicable steps available.

Need to be clearer about how the tool could be used and consider more user-friendly language

Remote assessment checklist

This checklist can be completed by someone who knows the person/patient in circumstances where the person responsible for the capacity assessment (e.g. the Deprivation of Liberty Assessor) is doing a **remote assessment as part of a DoLS authorisation application.**

If you are a staff member completing it for a DoLS assessor, try to get the best information you can, whilst enhancing the person's capacity, and share what you find with the DoLS assessor. You can use the notes column to record what the person/patient said and continue on an additional sheet if necessary.

How did you enhance the person's capacity before and during the capacity assessment?

_____

_____

_____

Before completing the checklist, **write down the main problems** over the page that you/people involved in the person's life think the person/patient has that could put him/her at risk if he/she left the hospital or care home.
(Examples of issues to think about: Getting in and out of bed, washing and dressing, going to the toilet, eating and drinking, buying and preparing food, taking medication, doing housework, community mobility and transport – e.g., getting to shops and appointments, road safety

Page 1 of 6

awareness, vulnerability, risk to self and others – e.g., anger management problems or challenging behaviour)

Main problems

1.....

2.....

3.....

4.....

Any others?.....

Useful to complete as this is not always considered and it vital for the person to understand

Structure was useful in a "weird time"

Sequence was useful, time efficient and minimised the impact on clients

	Questions to explore with the person / patient	Yes	No	Not sure	Notes (e.g. what the person said or observations of behaviour) – continue on another page if required
1	Does the person know where they are and what type of place they are in? *(Give options if necessary, e.g., is it a care home, a hospital, or a hotel? Provide the answer if the person is incorrect)*				
2	Does the person know why they are there? (Note response) *(If necessary, provide the answer for them.)*				
3	Has the person noticed any physical problems they might be having? (Note responses) *(Prompt as needed: e.g. any problems with legs/walking, arms, vision, washing and dressing, going to the toilet, eating and drinking?)*				

Prompts and examples are really helpful

Words like problem, personality and mood don't fit with everyone

Asking about issues other than memory is useful and doesn't always happen

	Questions to explore with the person / patient	**Yes**			**Notes**
4	Have they noticed any changes to their memory, their attention or their problem-solving skills? (Note responses)				
5	Have they noticed any changes to their mood, personality or their relationships with other people? (Note responses)				
6	Go through the problems you've listed at the top of this checklist with the person, explaining that these are things the staff / their family have noticed. Does the person think they are having problems with these things? (Note responses)				
7	If the person agrees that they are having some problems: Does the person think these problems would affect them if they left hospital or the care home now? How?				
8	Describe the treatment and care plan to the person. *(e.g. help with washing and dressing / going to the toilet, physiotherapy to help them walk, OT to help them relearn kitchen tasks etc)*				

Person might have been told they have a problem but might not have noticed it

Asking questions that explore insight is important as it can be key to the person understanding information

Outline the plan and risks in a way the person can understand is important

	Do they think they need this help?				
	Questions to explore with the person / patient				**Notes**
9	Describe to the person the restrictions you will use to provide treatment and/or care or to keep them safe. *(e.g. locked door, supervision from staff, being escorted when leaving the ward/home, no access to their medication)* Do they think they need these restrictions? If not, why not?				
10	Does the person think that they would need help/care/support if they left the care home/hospital now? (What would they need help with, how often, for how long and who would provide this help?)				
11	Does the person think that there would be any problems if they were to leave and live without support at this moment?				

Some language in the tool can read as a bit "cold blooded"

Share the options below with the person. If there are more than three you can add them to the bottom of the table. Ask them about the reasons to say yes / good things about each option and the reasons to say no / problems / risks of each option.

	Questions to explore with the person / patient	Yes	No	Not sure	Notes (e.g. what the person said or observations of behaviour) – continue on another page if required
12	Which of the options discussed with the person would be their choice? Why?	-	-	-	
13	Does the person think that their choice would affect anyone else? If so, whom? How would it affect them? *(e.g. those expected to provide the care)*				
14	When you tell the person that you think they would be at risk leaving hospital/ the care home now due to (the problems you listed), do they believe you? If not, why not?				

This is useful but issues like this need to be explored with sensitivity and tact - should be made clear

Additional notes.....

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.....

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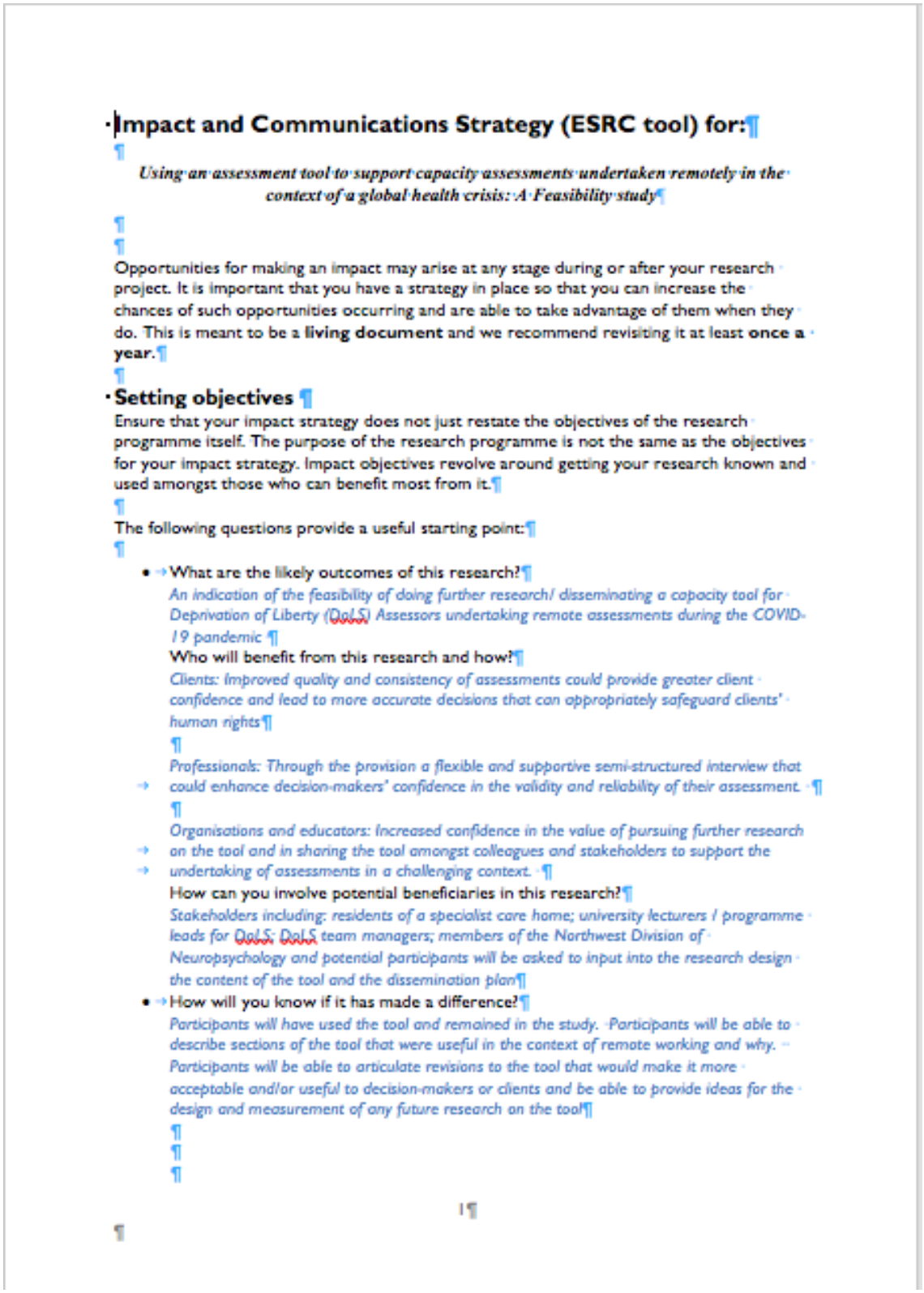
Thank you for your help if you have completed this on behalf of the DoLS assessor

Appendix 2-D

Research Dissemination Strategy



Impact and Communications Strategy (ESRC tool) for:

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A Feasibility study

Opportunities for making an impact may arise at any stage during or after your research project. It is important that you have a strategy in place so that you can increase the chances of such opportunities occurring and are able to take advantage of them when they do. This is meant to be a **living document** and we recommend revisiting it at least **once a year**.

Setting objectives

Ensure that your impact strategy does not just restate the objectives of the research programme itself. The purpose of the research programme is not the same as the objectives for your impact strategy. Impact objectives revolve around getting your research known and used amongst those who can benefit most from it.

The following questions provide a useful starting point:

- What are the likely outcomes of this research?

  An indication of the feasibility of doing further research/ disseminating a capacity tool for Deprivation of Liberty (DoLS) Assessors undertaking remote assessments during the COVID-19 pandemic

  Who will benefit from this research and how?

  Clients: Improved quality and consistency of assessments could provide greater client confidence and lead to more accurate decisions that can appropriately safeguard clients' human rights

  Professionals: Through the provision a flexible and supportive semi-structured interview that could enhance decision-makers' confidence in the validity and reliability of their assessment.

  Organisations and educators: Increased confidence in the value of pursuing further research on the tool and in sharing the tool amongst colleagues and stakeholders to support the undertaking of assessments in a challenging context.

  How can you involve potential beneficiaries in this research?

  Stakeholders including: residents of a specialist care home; university lecturers / programme leads for DoLS; DoLS team managers; members of the Northwest Division of Neuropsychology and potential participants will be asked to input into the research design the content of the tool and the dissemination plan
- How will you know if it has made a difference?

  Participants will have used the tool and remained in the study. Participants will be able to describe sections of the tool that were useful in the context of remote working and why. Participants will be able to articulate revisions to the tool that would make it more acceptable and/or useful to decision-makers or clients and be able to provide ideas for the design and measurement of any future research on the tool

1

The key impact and communications objectives are:

- Build awareness of the research amongst a target audience
- Secure the commitment of target stakeholder and potential participants to the project aims
- Encourage stakeholder input into the research design or dissemination plan
- Maintain ongoing dialogue about dissemination plans and refine accordingly
- Create a dissemination plan that is dynamic and responsive – sharing findings in ways that best meets the stated needs of participants and stakeholders
- Create a dissemination plan informed by relevant theory and literature
- Influence policy makers and senior decision-makers to support the tool. This will include longer-term buy in to the potential integration of the tool within curricula and practice. This would influential brokers such as the NW DoN, DoLS peer support neworks or student educators

Developing messages

An effective strategy needs to have clear, succinct messages that summarise your research and the purpose of your research programme.

If your research project is long and complex, it may be difficult to set out these key messages at the beginning. But it is useful to consider whether there are any overarching messages about your research programme that can be used while it is underway, or any specific messages that relate to particular parts of the project. For projects running over many years these messages may change over time – we recommend reviewing them yearly.

The key messages to communicate are:

- This tool is intended to provide a supportive structure when undertaking remote capacity assessments
- We want to know what aspects of a remote capacity tool are acceptable, practical and useful to decision-makers
- We want to know how our tool could be improved
- We want to know if it is possible and appropriate to undertake more research into the tool

Audiences

Who are the audiences you wish to communicate to? What do you know about them; how influential are they; how do you want them to respond?

People who might use the tool – DoLS Best Interests Assessors and DoLS Mental Health Assessors

People who might support decision-makers to use the tool – frontline health and care providers¶

¶

People who could be recipients of the tool – clients with impairments arising from poor mental health or cognitive difficulties staying in care homes or hospitals. ¶

¶

People who could encourage the use of the tool – DoLS managers; university leads for DoLS/ social work; The British Association of Social Workers (BASW); the British Medical Association (BMA); the British Psychological Society; Royal College of Occupation Therapists; Royal College of Nursing¶

¶

With a view to the tool being shared, endorsed and supported¶

¶

¶

- **Prioritising your audiences** ¶

It is vital to know who your key audiences are. You should already have an idea of this, but it is worth taking time to ensure that you have considered all those who may have an interest in your research.¶

¶

As there can be many audiences or stakeholders, it is helpful to differentiate audiences in your strategy. This will help you to target your resources - particularly in the early stages.¶

¶

- **How will you reach your audience?**¶

It is important to consider the most appropriate channels to reach your target – for example through press articles, workshops, regular user groups, or conferences. This will help you to frame the main activities of your impact strategy, for example:¶

¶

- Why a regular newsletter rather than a more occasional briefing?¶
- Why a large national conference rather than a series of smaller regional seminars?¶
- Why an email bulletin rather than face-to-face contact?¶
- Why invite them to come to you when you can go to them?¶

¶

¶

Prioritised audiences¶ (most research investments will need to target government/parliamentarians; business/private sector; civil society; media/public)¤	**Details** ¶ (which government departments, which sectors specifically?)¤	**Overview of engagement activities and communication channels**¤
Author of the tool¤	Dr Janice MacKenzie¤	Sharing of themes arising from the research data and recommendations for any revisions of the tool as soon as possible following the analysis. Support to undertake joint dissemination where appropriate including talks or articles¤

3¶

¶

Research stakeholders, particularly participants		
DoLS peer support groups that include employed and independent DoLS Assessors	Local to the region in which the research was undertaken and where the research lives	Attendance at a peer support group to share findings and, if appropriate, arrange to share revised versions of the tool following the research
DoLS team managers	Initially those local and known to the researcher and to other services following communication on social media	Share outcomes of the research. Sound out the possibility of their team/organisation supporting future research / if appropriate and with agreement arrange to share revised versions of the tool for use in their service
Senior staff in local care homes and hospitals that currently apply for DoLS applications in the researchers region	Local care homes and hospital – specifically to leads identified by academic supervisors or who are known to the researcher	Share outcomes of the research and plans for any future research or dissemination that could affect their service for information and to seek ideas for research design and support for recruitment
University Leads (DoLS)	Specific to the City closest to the research who provide training in DoLS assessment and assessor qualification	Share outcomes of the research and request opportunity to share outcomes of the research at future training events for DoLS assessors. Explore whether / how they might support dissemination or future research
University Leads / govt officers involved in commissioning, developing and delivering student training in social work; medicine and allied health professions	In the region local to the research and author initially	Researcher and author to connect with commissioners and educators to explore the possibility of sharing the tool as part of student training once appropriate revisions have been made
Societies for: clinical psychology; occupation health; medicine and nursing who regulate professionals eligible to be DoLS assessors	Press / marketing departments and leads for special interests groups	Attend special interests groups to share the research; write a summary of the research that could be included in society communications e.g. social media messaging or

		newsletters; seek support of special interests groups for any future training or dissemination of the tool
Social Care Institute for Excellence (SCIE)	SCIE's National Mental Capacity Forum	Submit the tool and research findings to be included in their databases of initiatives to improve MCA implementation across England and Wales
Relevant professional journal	International journal of law and psychiatry	Submit a report of the research for publication
Relevant magazines: Community Care	Existing contact who has published the study authors research on previous occasions	Write an article summarising the research findings and future plans to be published in the online magazine
Relevant social media: Twitter		
NHS REC that approved the research		As required, submit a summary of the research to the REC including next steps and details of the journal that will be approached to publish the research

Achieving your impact and communications objectives

Detail of activities

List the details of all the relevant engagement activities; include deadlines and responsibilities. Remember to add key milestones and review dates, and think carefully about the resources required and costs including staff and consultants you will need to carry out your proposed engagement activities.

Below are some suggested groupings; the table is led by activity but you may prefer to have one for each year of activity.

Consider how you will evaluate your activities and their successes

Were your activities and communications channels successful? The only way to find out is to build in evaluation from the beginning. Evaluation offers an opportunity to demonstrate how well an activity worked – whether it is a one-off or on-going - and also to identify areas that could be developed or enhanced. It should take place through the entire programme – from the early planning stages through to final delivery.

There are a variety of ways to evaluate: quantitative metrics like press monitoring or the number of website hits, and qualitative measures such as event feedback and quotes from people. Your evaluation metrics will be specific to your programme and the communications channels you use.

Evaluating success¶

¶

How will you know if you have met your impact and communications objectives? It will be important to review your activities regularly and see if they are achieving these. We recommend reviewing this strategy at least once a year – so set a target date.¶

¶

The research author hopes to maintain ongoing relationships with key stakeholders, including potential service-user groups. The aim of which will be to monitor the use of the tool following dissemination, receive informal feedback and consult on future revisions or research plans.¶

I will know if the impact strategy has been successful if:¶

- Research findings are accepted as valid and reliable by participants and the author of the tool and revisions made to the document in line after consideration of comments and ideas¶
- Timely dissemination of a revised tool to people continuing to undertake remote capacity assessments in 2020¶
- Future research is developed in line with principles of co-production where service-user groups and decision-makers from relevant professional groups are involved in the design, delivery and dissemination of results¶
- Support and endorsement of the research and the tool is obtained from relevant professional bodies¶
- Open channels of communication are established with student educators, commissioner and regulators with a view to including a version of the assessment tool in training¶
- The tool is expanded to include different decision areas and adapted to be used by a range of professionals¶

¶

¶

Date to review strategy:¶

¶

December 2020¶

¶

Appendix 2-E

International Journal of Law and Psychiatry Instructions for authors

INTERNATIONAL JOURNAL OF LAW AND PSYCHIATRY

AUTHOR INFORMATION PACK

TABLE OF CONTENTS

ISSN: 0160-2527

DESCRIPTION

The *International Journal of Law and Psychiatry* is intended to provide a multi-disciplinary forum for the exchange of ideas and information among professionals concerned with the interface of **law** and **psychiatry**. There is a growing awareness of the need for exploring the fundamental goals of both the **legal** and **psychiatric systems** and the social implications of their interaction. The journal seeks to enhance understanding and cooperation in the field through the varied approaches represented, not only by law and psychiatry, but also by the social sciences and related disciplines. The Editors and Publisher wish to encourage a dialogue among the experts from different countries whose diverse legal cultures afford interesting and challenging alternatives to existing theories and practices. Priority will therefore be given to articles which are oriented to a comparative or international perspective. The journal will publish significant conceptual contributions on contemporary issues as well as serve in the rapid dissemination of important and relevant research findings.

The views expressed in this journal do not necessarily reflect those of the editors.

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EDITORIAL BOARD

GUIDE FOR AUTHORS

INTRODUCTION

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

All papers in IJLP must be written for an international audience, whether you are a native English speaker or not, please ensure you use clear English language when writing your article.

BEFORE YOU BEGIN

Ethics in publishing

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Chapter 3

Section Three: Critical Appraisal

Word count: 2890

Emma Fowler

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

All correspondence should be addressed to:
Emma Fowler, Doctorate in Clinical Psychology, Division of Health Research, Faculty of Health and Medicine, D Floor, Health Innovation One, Sir John Fisher Drive, Lancaster University, LA1 4AT.
Email: e.l.fowler@lancaster.ac.uk

Critical Appraisal

This thesis comprises two pieces of original research, a systematic literature review and an empirical study. The review examined the efficacy of cognitive interventions designed to improve decision-making skills in people with Mild Cognitive Impairment (MCI). A narrative synthesis approach identified that interventions can be effective and that further research should be undertaken. Of the 26 papers identified, interventions targeting logical reasoning and cognitive control demonstrated notably strong results. However, most studies were judged to be at high risk of bias overall, with limited rigour in the randomisation process of particular concern. This limited the extent to which conclusions could be drawn about effective interventions at this time.

The research paper explored the feasibility of using a tool intended to support capacity assessments undertaken remotely during a health crisis in the spring of 2020. Findings indicated that the capacity tool was valued by experienced professionals. Four themes were identified: (1) Structure is Crucial in a Pressurised Context; (2) Facilitating Effective Relationships; (3) Being Person-Centred and (4) Bridging the Gap Between Training and Practice. Six subthemes were also identified. Results provided strong evidence for the feasibility of the tool in practice.

The extent to which these topics can be explored is limited by the thesis format and reporting limitations set by relevant journals. As such, this critical appraisal aims to elucidate my reflections on the research process, the topics selected and implications for clinical practice. I will explore my own motivations for undertaking each piece of research and my reflections on how they complement each other. I will examine some of the strengths and limitations of the thesis as a whole and outline my hopes for future work.

Background

My interest in decision-making and capacity assessment in health and care settings started before clinical training. I began my professional life working with homeless people in city-centre hostel settings. Alongside the understandable distress experienced by clients as a result of their circumstances, I was struck by the number of homeless people who were struggling with the effects of cognitive difficulties. These difficulties included traumatic brain injury (TBI) and alcohol-related dementia. I now understand that cognitive difficulties in this population are common and that issues such as TBI may affect around half of all homeless people (Oddy et al., 2012). I was keen to understand whether, and how, cognitive difficulties might affect the choices and decisions clients made and what provisions were available to support and protect them. This interest informed a professional move to work in a social care adult safeguarding team, which included training delivery on the Mental Capacity Act 2005. In my personal life, I was also supporting my grandmother who was experiencing her own difficulties with decision-making as a result of dementia. The cumulation of these experiences heightened my awareness of how challenging it can be to navigate the world when you have a cognitive impairment. Moreover, I developed an understanding of the complexities faced by professionals and families supporting people in these contexts.

In my clinical training, I have sought placements in later-life settings that have provided me with opportunities to undertake both therapeutic and mental capacity-related work with people experiencing cognitive impairments. Moreover, I have followed some of the innovative work being done by clinical psychologists in the Northwest over recent years to support professionals and clients working in these fields. Consequently, it felt like a natural progression to develop these interests through my own research.

The Systematic Literature Review

I support the perspective amongst some health and legal commentators that there is often insufficient focus on supported decision-making in practice (George & Gilbert, 2018; House of Lords Select Committee on the Mental Capacity Act 2005, 2014). Accordingly, I wanted my thesis to echo the process that should apply in practice; namely consideration of support that could be provided before a formal assessment (Mental Capacity Act: Code of Practice, 2005). Supported decision-making can be defined as any process in which someone is provided with as much help as they need to either make a decision for themselves or to express their preferences (Mental welfare commission for Scotland, 2016). The right to support to make a decision is one of the five core principles of the Mental Capacity Act 2005 (Mental Capacity Act: Code of Practice, 2005). Despite this, services have been described as being somewhat hesitant in promoting supported-decision making (Zingler, 2019). Moreover, professionals have expressed concerns about how best to provide support in the context of perceived resource constraints (Zingler, 2019). Pathare and Shields (2012) suggest that a paucity of evidence for effective decision-making interventions may partly account for this problem.

My inspiration for the literature review topic began after reading a review by Verdejo-Garcia et al. (2019) on decision-making interventions for people with addiction. After some initial scoping, it was clear that there were few reviews addressing this topic. Consequently, I decided to explore the topic of effective interventions in decision-making with a different population, namely people with mild cognitive impairment (MCI) (Petersen, 2011). I was aware of the evidence indicating that people with MCI are able to strengthen, and develop, neural networks relating to function (Miotto et al., 2018). Furthermore, at the time of choosing a topic, I was working with clients experiencing MCI on placement and I wanted to research something that might inform my own clinical practice.

The Empirical Research: Reflections on the Process

Reflexivity is defined as explicit self-awareness (Finlay, 2016a). To support the process of critical self-reflection, I recorded my assumptions, decisions, feelings and behaviour throughout the process in a reflective journal (Finlay, 2016b; Morrow, 2005). This helped me to identify how these factors might have influenced the research process and maintained my confidence in the integrity and trustworthiness of the research (Finlay & Gough, 2003).

My original research proposal was to trial a capacity tool designed to support senior ward staff in hospital settings to undertake face-to-face assessments with patients subject to restrictive care regimes. When designing the research, I reflected that I was a healthy adult who had never experienced being at the receiving end of a capacity assessment. Moreover, I had always worked in situations where there were clear power differentials with clients. As such, I had hoped to be able to undertake co-productive research and I recorded feelings of disappointment that the timeframe for completing the thesis was unlikely to allow scope to fully include service-users in the study (National Institute for Health Research INVOLVE, 2018). Recognising my position on client involvement helped to inform later research choices. For example, I prioritised the inclusion of experts-by-experience as consultants on the project and allocated as much time as was mutually possible to hear their perspectives.

At the late stages of the research approval process, the impact of the COVID-19 virus was beginning to be felt in the UK. Consequently, to protect public health, restrictions on research in health and care settings were implemented (www.hra.nhs.uk/covid-19-research/). With the support of my supervisors, which included the author of the tool Dr Janice Mackenzie, the research was adapted to make it relevant to professionals undertaking remote assessments under the Deprivation of Liberty Safeguards (DoLS) (Deprivation of Liberty Safeguards: Code of Practice, 2008). Whilst this was a challenging and busy time, we

reflected that the research could offer real and timely value to professionals responding to a rapidly changing context (Department of Health and Social Care, 2020; HM Government, 2020). Following the completion of the research, the findings indicated that our hopes were well founded as feedback on the capacity tool was positive and encouraging.

Strategy.

Everyone who expressed an interest in the study, and who was eligible to participate, were recruited to the study. This was largely a pragmatic decision following significant delays in approval and recruitment, which generated some urgency in the process. This was a limitation of the research as it resulted in a somewhat homogenous sample of DoLS Best Interests Assessors made up of mainly female participants. Moreover, the participant sample may also have been more likely to comprise people who perceive new ways of working in a crisis as an opportunity to try new things, as opposed to a potential threat to professional identity or wellbeing (Scherer et al., 2001). To increase the heterogeneity of future research samples, consideration could be given to a quota sampling approach (Robinson, 2013). This strategy would involve professional settings and/or groups being identified in advance and a minimum number of participants set for each group (Robinson, 2013).

Data Collection

My journal reflects feelings of apprehension about the use of online focus groups. To date there is limited best practice guidance on conducting focus groups online (Cyr, 2015). By naming my apprehension that online groups, a necessity in the research context, would be less useful than face-to-face, I was able to have a constructive conversation with my supervisors about how best to prepare. This led to the implementation of a pilot focus group. It also resulted in individual software testing sessions with participants. The extensive preparation employed, helped me feel more equipped to facilitate the groups and participants reported that testing software enabled them to feel more relaxed in discussions. The pilot

group challenged some of my expectations of what strategies might support the process. For instance, we identified that more formal measures, like raising a hand before speaking, could be useful. Whilst somewhat counter-intuitive, imposing more explicit structure than might be warranted in face-to-face groups was reported as reducing awkwardness and uncertainty by participants.

Whilst I had some experience of collecting data using focus groups from a previous assignment, I was still reasonably new to the process. Reflective practice, including debrief conversations with the assistant psychologist supporting the groups, helped me to refine my skills and to improve my confidence during data collection. For example, through discussions with the assistant psychologist I became aware that I had sometimes deviated from the question route in the first group by asking compound, instead of uni-dimensional, questions (Krueger, 1998). I was able to correct this in the following group by adhering more closely to the questions listed and mindfully allowing silence to enable participants to consider their answers. I aimed to make groups and interviews conversational in tone to create a good rapport and establish a discussion space where people felt safe to share their views (Pezalla et al., 2012). Accordingly, my initial question enquired about participants' general thoughts on the tool (see Appendix 4-I).

In the journal, I noted that I had experienced some unease that participants seemed to have spent a substantial amount of time, approximately 10 – 15 minutes, discussing this question in the first group. Moreover, the discussion included a lot of exploration of their experience of working during the health crisis and I was concerned that this was not central to the research question. In conversation with a research supervisor I reflected that, rather than being unhelpful, some time discussing the context could be useful in helping participants to make sense of their experience and provide important context for interpreting the data (Wolgemuth et al., 2015).

Analysis

During the analysis, I reflected that some of my assumptions about how the tool might be used and experienced by participants had perhaps been somewhat naïve to the reality of the context. I had assumed, for instance, that it might be straightforward to enlist the support of frontline workers in completing the tool on the participants' behalf. Hearing about the challenges of working in a dynamic and pressurised context, I was able to notice such assumptions, which enabled me to attend more fully to the realities of participants' experiences. Participants reflected on how the capacity tool, in its current or adapted formats, could benefit any health or care professional. This resonates with research undertaken with clinical psychologists that has emphasised the need for guidance that application of legal principles in practice (Walji et al., 2014).

Reflections on the process

Throughout the thesis process, I noticed how much of the literature reflects a biological, individualist and deficit-based epistemological framework. This represents a dominant paradigm that operates across research and practice (Series, 2015). As a researcher aligned to critical realist (CR) principles, I recognised that I am comfortable acknowledging that, for me, cognitive difficulties are a real phenomenon that have real functional affects (Alderson, 2016). Working within this dominant paradigm, my aim was to support professionals who were also working within the constraints of medical/legal frameworks in the service of client autonomy and wellbeing. Nevertheless, I recorded some feelings of ambivalence about my research foci as I take the position that cognitive aspects of decision-making only partially reflect the reality of decision-making and I was concerned that this might be insufficiently acknowledged in this thesis (Banner, 2012; Grigorovich et al, 2018).

I was aware throughout the research of the ongoing theoretical and epistemological debate about the nature of autonomy (Series, 2015). Gambrill (2012) argues that the

individualist account of decision-making, which privileges ideas of cognitive strengths and deficits, encourages the stigmatisation of clients. This is echoed in the human rights fora where disability is predominantly conceptualised as a social construct and where there is increasing focus on the influence of effective relationships and environmental support on decision-making (Flynn, 2019; United Nations, 2006). Nevertheless, there is limited acknowledgment of alternative accounts of capacity in the literature. For instance, I noticed how, whilst reviews depict the importance of the participant-facilitator relationship in determining the efficacy of interventions, this was not considered in the analysis of any papers included in the systematic review (Basak et al., 2020; Chandler et al., 2016; Sherman et al., 2017). In this context, the absence of potential relational influences in analyses, and lack of acknowledgement of this, could imply the deprioritisation or discounting of such factors (Carey et al., 2009).

I take the position that safeguarding people in our communities who may be at risk of abuse or harm should be core to the work of health and care, including clinical psychology. The process of undertaking this research has also reinforced my view that clear legal and policy frameworks are an essential part of effective safeguarding work (Mantell, 2010; Ruck Keene, 2017). I reflected that this work should include supporting people who are experiencing difficulties in decision-making, assessing their capacity to make a decision where necessary and making a decision on their behalf where appropriate and lawful. Equally, my clinical training, and particularly my experiences in undertaking family therapy, have heightened my understanding of the influence of context, relationships and language on our experiences. My clinical training and research experience has also helped me to, partially, reconcile differing decision-making paradigms with the effect that I value an holistic and relational perspective on a client's strengths and difficulties.

Another theme that emerged from my reflections on the extant literature was the absence of clients' voices and perspectives. Moreover, there was little account taken of the power differentials inherent within research designs (Carey et al, 2009). This is perhaps to be expected given that much of the literature is quantitative and, therefore, traditionally less concerned with such questions (Ross, 2017). Nevertheless, I reflected that aspects of the research design and reporting could be interpreted as unhelpful and disempowering by participants in my own culture. One example was the use of language in publications with many studies using descriptive words like "geriatric", "elderly" and "subjects" (reflective journal entry, March 2020). This reflection reinforced my decision to use inclusive and empowering language wherever possible in the thesis that aligned with my personal ethics and cultural context. Moreover, in my journal I reflected on how my knowledge of ethical practice, and ability to embody this, evolved through the research process. Participants in the empirical study, for instance, shared their experiences of trying to maintain empowering relationships with clients whilst working in very challenging circumstances. These stories provided new ideas for my own practice and increased my commitment to multi-disciplinary working in practice.

Conclusions

The process of completing the thesis has been challenging but rewarding. A core theme of the work has been the nature of decision-making and the many factors that can influence it. Practising reflexivity whilst undertaking the research, has helped me to remain aware of my own perspective, assumptions and biases. In turn, this has enabled me to remain curious and open to the ideas and perspectives of supervisors, stakeholders and participants and seek support when needed. I have taken from this work the sense that decision-making is shaped, for all of us, by relationships, contexts and physiology and that each facet is deserving of acknowledgement and attention in research. Indeed, research designs that,

themselves, acknowledge the value of context and relationships (whether through co-production with stakeholders or data collection methods like focus groups) can provide fresh perspectives and enriched findings.

Academic pressures, deadlines and an uncertain context meant that the practical demands of completing the thesis were often substantial and complex. Nevertheless, choosing topics that resonated for me both professionally and personally helped to sustain my motivation and determination to complete the work to the best of my ability. I hope that I am able to pursue research in the future that expands on the findings of this thesis and more actively includes experts-by-experience. I also hope to incorporate new learning acquired, both from research findings and reflections, into my clinical work when I begin in my first post as a clinical psychologist.

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Section Four: Ethics Section

Emma Fowler

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

All correspondence should be addressed to:
Emma Fowler, Doctorate in Clinical Psychology, Division of Health Research, Faculty of Health and Medicine, D Floor, Health Innovation One, Sir John Fisher Drive, Lancaster University, LA1 4AT.
Email: e.l.fowler@lancaster.ac.uk

IRAS Application

IRAS Form | Reference: 20/NW/0103 | IRAS Version 5.15

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Using a tool that prompts exploration of decision making abilities

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(●) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[✓] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or MedTech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

6b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and Inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

8. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The research is being undertaken as part of a Doctorate in Clinical Psychology at Lancaster University. Accordingly, the student will undertake the majority of the work in relation to recruitment, data collection, analysis and writing of the final report with the support and input of the research and field supervisors. The student is eligible to undertake this role as they are training at doctoral level and undertaking research whilst employed by an NHS Trust.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

IRAS Form | Reference: 20/NW/0103 | IRAS Version 5.15

Integrated Research Application System
Application Form for Research Involving qualitative methods only

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Using a tool that prompts exploration of decision making abilities

Please complete these details after you have booked the REC application for review.

REC Name:
[redacted]

REC Reference Number:
[redacted]

Submission date:
06/02/2020

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Using an assessment tool to support capacity assessments with people with an acquired brain injury in the context of admission to hospital or a care home: A feasibility study

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Mrs	Emma	Fowler

Address [redacted]
Post Code
E-mail
Telephone
Fax

Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/ degree:

Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

Title	Forename/Initials	Surname
Dr	Guillermo	Perez Algorta

Address [redacted]

Post Code
E-mail
Telephone
Fax

Academic supervisor 2

Title	Forename/Initials	Surname
Dr	Anna	Duxbury

Address [redacted]

Post Code
E-mail
Telephone
Fax

Academic supervisor 3

Title	Forename/Initials	Surname
Dr	Suzanne	Hodge

Address [redacted]

Post Code
E-mail
Telephone
Fax

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mrs Emma Fowler	☑ Dr Guillermo Perez Algorta ☑ Dr Anna Duxbury

[redacted]

☑ Dr Suzanne Hodge

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Guillermo	Perez Algorta
Post	Lecturer		
Qualifications			
ORCID ID			
Employer			
Work Address	[redacted]		
Post Code			
Work E-mail			
* Personal E-mail			
Work Telephone			
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
Address	[redacted]		
Post Code			
E-mail			
Telephone			
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	n/a
Sponsor's/protocol number:	n/a
Protocol Version:	0.1
Protocol Date:	13/12/2019
Funder's reference number (enter the reference number or state not applicable):	n/a
Project website:	n/a

Additional reference number(s):

Ref.Number Description	Reference Number
n/a	n/a

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Almost one million people are living with the effects of a brain injury in the UK. Sometimes people who have experienced a brain injuries have restrictions placed on them when they go into hospital, or in a care home, to keep them safe or to make sure they get support. These restrictions can include someone sitting with them for long periods of time, medication that has sedating effects or locked doors within the building that the person can't open on their own. Sometimes the amount of restriction used amounts to a deprivation of the person's liberty.

This is a feasibility study that will trial a tool designed to support decision-making. The tool is intended to be used by professionals whose role is to decide if someone with a brain injury can consent to their care arrangements. The tool is designed to prompt consideration of psychological factors that could be relevant to clients in order to enhance the accuracy and thoroughness of professional decisions. The tool is not intended to replace existing practice or procedures and will not determine client treatment or care.

A group of fifteen decision makers will try out the tool for two months. They will be recruited from rehabilitation units and through relevant professional forums and social media. Focus groups will then be held to explore how participants used the tool, whether it was easy to use and if it was useful. We will run at least two focus groups with between two and six people in a group. Groups will last for approximately 90 minutes. If anyone can not attend a group we will interview them individually about their experiences for approximately 60 minutes. Findings will be shared formally and informally to help influence and shape practice.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study*

and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Recruitment
NHS-employed participants will be recruited from NHS Trusts [redacted] Independent professionals will be recruited from adverts posted on relevant social media sites including professional online forums. Where online forums and social media is used, the student will create an account specifically for the research and not use their personal account. Participants expressing an interest in the study will be sent an information sheet and consent form by email from the researchers work email address. Potential participants will be able to email or phone (via a university-allocated mobile phone) the researcher to ask any questions about the research. Consent forms can be returned by email or by post to the researcher's university address. Fifteen participants will be recruited and a minimum of two focus groups will be conducted. The literature indicates that this should result in optimal data saturation whilst allowing for some attrition during the research. Everything will be done to recruit this number of participants however, if it is not possible, guidance and literature indicates that a minimum of eight people is required to obtain useful data for research of this design. Specifically, this research will uses a question route containing scripted questions, is interested in participant's experiences, will recruit participants with some homogeneity in terms of professional context and will not undertake very fine grained analysis. A minimum of eight should therefore obtain sufficient data to successfully in answer the research question (Guest, Namey & McKenna, 2017). Where possible groups will be made up of four or five participants to balance the need to obtain both rich and interactive data. Where this is not feasible groups of between two and six will be held as this represents the minimum recommended number to achieve useful interactive data (Morgan, 2013).

Participants may need to allocate some additional time to using the tool and incorporating it in their practice. However, professionals who decide to participate will self-determine how and when they utilise the tool. It is anticipated that it will be used to support decisions in complex situations and that it will facilitate effect and efficient decision-making by providing clear guidance about what to consider, informed by legislation and psychological theory. It will not change or determine client care or treatment albeit that it is intended to enhance the quality of decisions that professionals are already required to make within their role.

Participants will also be asked to allocate time to attending a 90 minute focus group. Practical difficulties that could arise in allocating the time to using the tool or in attending a group will be overcome by providing thorough details on the project and the rationale for using the tool with clients. Moreover, consideration will be given to running more than two focus groups (with a minimum of two participants) if this is more convenient to participants. It will be the choice of the professional whether they participate and, if responding to an advert, it will be the professional that initiates contact with the student researcher. This will minimise the likelihood of them feeling pressurised or coerced into giving their time, either by the researcher or their employing organisation. Participants will be given regular opportunities to contact the researcher or field supervisor to ask questions before agreeing to participate and whilst trialing the tool. Further, focus groups or interviews will be scheduled at a time that is as convenient to the participants as possible. To encourage recruitment, potential participants will be [redacted]

Confidentiality
Quotes from participants will be used in academic submissions and any subsequent publications. Participants will be made aware of this and informed that that every effort will be made to ensure that information in the report can not identify participants or their clients. For instance, potential quotes will be scrutinised to ensure that they don't reference names, locations, organisations or details about client circumstances. Further, participants will have the opportunity to review quotes before they are included in the final report.
To minimise the likelihood of any identifying participant or client information being shared in discussions or interviews, a detailed summary of confidentiality will be given verbally and in written form before focus groups and interviews. If confidentiality needs to be breached because the student researcher or the assistant psychologist supporting the focus groups believes that they, or another person, is at risk of harm, participants will be made aware of this. They will also be made aware if any member of the research team feels it is appropriate to share information about poor practice disclosed during discussions that could compromise client care.

Any reference to names, organisations, or any client information, will be carefully removed from anonymised transcripts. To elucidate data and provide context, reference to the professional role or assessment setting might be made in the analysis and discussion. However, this will not be done where there is only one person recruited from a particular profession or setting. Transcripts will use participant assignment identification (ID) numbers instead of

names. These numbers will be stored separate to audio files. Regular meetings will also be held between the student researcher, chief investigator and academic supervisors to discuss any practical or ethical concerns.

Data confidentiality will be maintained by using secure methods of transfer including encrypted equipment. Participant assignment ID numbers, audio files, transcripts, consent forms and any other document related to the project will be password protected and stored on Lancaster University's encrypted network. Data will be backed up using the University's virtual private network (VPN). audio files will be transcribed and analysed on the researcher's personal laptop using the University's VPN. All paper documents including consent forms and notes made by the focus group moderation team (made up of the student researcher and an assistant psychologist) will be typed up, or scanned, by the researcher on the University's network within one week and disposed of using the University's confidential waste services. On completion of the project all anonymised research data will be stored on the University's encrypted network for ten years. The Doctorate in Clinical Psychology programme will be responsible for storing and deleting the data once the researcher has submitted the thesis and completed the course. Accordingly, there are no anticipated issues with processing identifiable data.

Informed consent

Participants will be given time to consider if they want to participate. This will be at least two weeks or until recruitment is complete. Participants will be informed verbally and in the information sheet that they have a right to withdraw their participation up until the focus group. Participants will also be informed that they can withdraw their data from the final report up-to two weeks after the focus groups. Anyone taking part in individual interviews will have up-to two weeks after the interview to withdraw their participation. Participants will be using the assessment tool with some of their clients. Clients have the right to refuse to participate in a capacity assessment and participants will be encouraged to use their professional judgement in instances where the use of the tool may be unhelpful or contribute to any client distress. Moreover, participants will be asked to seek a client's verbal consent to include the tool as part of their professional guidance / support documentation. Clients will be offered the option of looking through the tool as part of this process or the opportunity to ask that a nominated person, for example, a family member look over it for, or with, them. Consent will be recorded in clinical notes to protect their confidentiality and ensure that their details are not shared with members of the research team. If they refuse consent the tool will not be used as part of their assessment. Professionals will also be discouraged from sharing any client details during data collection. All of which is in line with how they would be expected to act as part of their practice as usual.

Risks and burdens

It is not anticipated that participants will experience discomfort or harm as a result of taking part in this study. Inconvenience will be minimised by arranging focus groups at a time and venue that suits them and the researcher or supervisor will be available to answer questions at any point during the study. It is anticipated that groups will take place at the end of existing meetings organised by local health networks or special interest groups. These meetings usually take place within health premises (offices or hospitals). Questions asked will not be intentionally sensitive or distressing. However, the process of sharing experiences might elicit discomfort if using the tool was experienced as challenging or as highlighting areas of practice where improvements could be made. If participants experience any distress during a discussion or interview they will be made aware that they can stop or pause the interview or discussion at any time. The researcher will also stay mindful of any distress that might be elicited and decide whether to stop a discussion or interview. The researcher, where appropriate, will draw on clinical skills to support participants and provide a containing space for them to share their views. Participants will be provided with a debrief sheet after discussions that will include information about sources of support where needed. Supervision will be used where necessary to identify additional sources of support for participants where required. The focus group moderation team (the researcher and an assistant psychologist) will debrief from discussions at the end of focus groups and supervision will be used for this purpose where needed.

Lone working

It is not expected that there will be any risks to the researcher or the focus group note taker who will make up the focus group moderation team. Data collection will take place at health premises and the Lancaster University Lone Working Policy will be adhered to throughout this project. This includes the use of Skyguard lone worker protection technology. A university email and mobile phone will be used when communicating with participants. If any information is shared that could cause distress to the participant or researcher, academic supervision will be used to discuss this. The person supporting the focus group, which includes taking some basic notes, will be an assistant psychologist who has expressed an interest in supporting the research. They will have the opportunity to talk to the researcher about any issues raised by the project who will seek advice from their supervisors where required.

Service related issues

Trialling the tool may require the decision maker to spend more time on an assessment than they might otherwise do. However, the tool is intended to be used flexibly to enhance practice and to fit with client and organisational circumstances. Further, participants are only being asked to try the tool with approximately three people in a short window of time and participants can seek support with using the tool from the researcher at any time. Accordingly, it should not be experienced as burdensome, deprive other clients of time or resources or create resource difficulties for

organisations. The best use of practitioner time and resources will be made by arranging focus groups or interviews at a time that best suits their needs and requirements.

Conflict of interest
The field supervisor may know, or have a professional relationship with, one or more participants as they will be recruited from the same NHS Trust or local area. As such, the field supervisor will not have access to any participant data and will not know who has been recruited to the study. Participants will also be informed of this. The field supervisor will only have access to data once it has been analysed. At which point, themes arising from the data will be made available to them. It is not expected that academic supervisors will know or be aware of study participants. Should this occur however, care will be taken to ensure that transcripts or audio recordings that they review do not include these participants. This is only likely to apply to Dr Duxbury who is supporting data analysis.

B. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Is a tool designed to support capacity assessments with people with an acquired brain injury around their admission to hospital or a care home experienced as practical, acceptable and useful by decision makers?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

The research is interested in:
Acceptability of the tool:
1) How do assessors of mental capacity (decision makers) respond to using the tool with people who have an acquired brain injury in a hospital or care home setting? For example, was the tool used? If so, how often was it used and in what circumstances?
2) Were some sections of the tool perceived as useful or not useful by decision makers?

Practicality
3) Could it be used by decision makers within services?

Implementation:
4) Are there groups of decision makers that might benefit the most from the tool? For example, decision makers with limited experience in undertaking capacity assessments or with limited knowledge of neuropsychological functioning?

Clinical utility / limited efficacy testing:
5) How effective might the tool be in improving practice based on decision makers' experience of using it? (including whether the tool can provide a supportive structure, raise awareness of information or knowledge gaps or increase the accuracy of professional judgements)

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

From a legal perspective the Mental Capacity Act 2005 (MCA) states that a person lacks capacity to make a specific decision if they have a mental impairment and are unable to make the decision at the time it needs to be made (Mental Capacity Act: Code of Practice, 2005). Recent scrutiny of formal capacity assessments has highlighted that they are often of poor quality and frequently do not comply with statutory requirements (National Institute for Health and Care Excellence, 2014).

Challenges in the assessment of capacity in practice are exemplified when assessing the capacity of people with a brain injury, particularly in instances where the person has reduced insight and difficulties with executive function (British Psychological Society, 2018a). Executive functions (EF) are higher-order thinking skills like planning, organising, self awareness, sequencing actions, monitoring behaviour and inhibition. In a health context, difficulties with insight, particularly insight into EF deficits, following brain injury can translate as clients denying the presence of any difficulties (anosognosia). Alternatively, the person may be able to describe their impairment and the advice they have been given about coping with changes in function but have difficulty drawing on this knowledge in real life situations (intellectual insight without emergent or anticipatory skills). This latter scenario has been described as a thinking/doing dissociation or the "frontal lobe paradox" (Walsh, 1985). The prevelance of this phenomenon is unclear as no formal data collection has been undertaken to date. However, some authors have speculated that as much as 97% of people with a brain injury experience issues with insight or self-awareness (Oden, Bergloff, Levin, & High, 1998).

Using interviews as the sole method of capacity assessment in circumstances where the person has insight difficulties is problematic (George & Gilbert, 2018). For example, where verbal fluency and social communication skills have been retained after injury, this paradoxical presentation can be overlooked as the person can appear unaffected by their impairment in conversation (British Psychological Society, 2018a; George & Gilbert, 2018). However, functional difficulties might still be present and therefore failing to enquire into issues like functional skills with the person's family, friends or professionals can prevent disrepancies between what a client can do, against what they report, coming to light. Consequently, decision makers can be left with a skewed perspective on the question of whether the person can understand, use and weigh information relvant to the decision (Holloway, 2014; Holloway & Fyson, 2015). It therefore becomes more likely that the person is misclassifed as having capacity about important decisions in their life, like receiving medical treatment or choosing where to live; sometimes with dire results for them and their family (British Psychological Society, 2018b; Somerset Safeguarding Adults Board, 2016).

A semi-structured capacity tool has been developed to support non-specialist decision makers in undertaking capacity assessments with people who have complex cognitive difficulties in relation to hospital or care home stays (Mackenzie et al., 2008). The tool has been developed from post-doctoral research work undertaken in stroke populations and has been revised in line with feedback from experienced professionals working across health and care services over the last decade [redacted] The tool is underpinned both by legal requirements and neuropsychological theory. For instance, the tool assumes that some difficulties in decision making ability in complex presentations can be explained by the "frontal lobe paradox" and therefore includes questions designed to gather evidence to establish the presence of any thinking/doing dissociation. It is accompanied by written guidance that outlines threshold levels of understanding required to make a capacity decision about hospital or care home stays.

Whilst the tool includes all aspects of the two-stage legal test of capacity and can therefore be used as a template to record formal assessments, it is anticipated that its primary value will be as a supplement to current practice. For example as an aide memoire.
The tool aims to address challenges in practice by providing: Awareness of salient information for this client group in relation to restrictive care in hospital or a care home; Improved accuracy of professional judgments through questions and prompts intended to obtain information about cognitive abilities and functional skills and a supportive structure that scaffolds practice with the aim of increasing professional competence and self-efficacy in this area of work over time. The tool has the potential to improve client outcomes and increase cost effectiveness in statutory services. However, it has yet to be formally studied.

This study aims therefore to gather exploratory, qualitative information using a semi-structured question schedule in focus groups and / or interviews as part of a feasibility study. Given limited evidence of what works well for decision makers having flexible, open discussions with participants should allow for a more detailed understanding of what might work best both in terms of future research design and support for practice.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Design

The study will use a qualitative approach. Participants will try out a capacity tool as part of their usual practice and focus groups will be held to explore their experiences of using it. Two groups of six participants will be undertaken. More than two groups will be held with fewer participants if required. Literature suggests that useful interactive data can be achieved with two or three people (Morgan 1998). Individual interviews will be undertaken where it is not possible for a participant to attend a group. Data will be analysed using theoretical thematic analysis within a critical realist (CR) epistemological framework.

Procedure

NHS-employed participants will be recruited from [redacted] Independent professionals will be recruited from adverts posted on relevant social media sites including professional online forums. Participants expressing an interest in the study will be sent an information sheet and consent form by email from the researchers work email address. Potential participants will be able to email or phone (via a university-allocated mobile phone) the researcher to ask any questions about the research. Consent forms can be returned by email or by post to the researcher's university address. Fifteen participants will be recruited and a minimum of two focus groups will be conducted. The literature indicates that this should result in optimal data saturation whilst allowing for some attrition during the research. Everything will be done to recruit this number of participants however, if it is not possible, guidance and literature indicates that a minimum of eight people is required to obtain useful data for research of this design. Specifically, this research will uses a question route containing scripted questions, is interested in participant's experiences, will recruit participants with some homogeneity in terms of professional context and will not undertake very fine grained analysis. A minimum of eight should therefore obtain sufficient data to successfully in answer the research question (Guest, Namey & McKenna, 2017).

Once recruitment is complete, participants will be sent the tool and associated guidance by email with a reminder of the study aims. They will have eight weeks to trial the tool with approximately three clients. Clients will eligible if they have an acquired brain injury and they are medically stable. Where possible and known, the injury will have affected the frontal lobe. Capacity assessments will relate to whether the person can consent to staying in hospital or a care home for the purpose of receiving care or treatment. The care or treatment will entail restrictions that may amount to a deprivation of liberty. Participants have the right to refuse a capacity assessment. Moreover, participants will be asked to seek a client's verbal consent to including the tool as part of their professional guidance / support documentation. Clients will be offered the option of looking through the tool as part of this process or will have the opportunity to ask that a nominated person, for example, a family member look over it for, or with, them. Consent will be recorded in clinical notes. If they refuse consent the tool will not be used as part of their assessment. During the trail period, participants will be contacted twice from a work email address held by the researcher to remind them that they can seek support or ask questions about using the tool at any time. Following this, participants will be invited to attend a focus group to talk about their experiences. They will have at least one months notice of the focus group arrangements.

Where possible groups will be made up of four or five participants to balance the need to obtain both rich and interactive data. Where this is not feasible groups of between two and six will be held as this represents the minimum recommended number to achieve useful interactive data (Morgan, 2013). These will last for one and a half hours and be audio recorded. Where required, individual interviews will take place over an hour and also be recorded. Recordings will be transcribed verbatim in preparation for analysis.

Participants will have the opportunity to comment on initial themes and quotes, if they want to, before the final write up. These will be sent via email and participants will have two weeks to send any comments they might have.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
A small group of adults living with the effects of a brain injury were approached to provide informal feedback about the design of the study, including ideas about how the tool could be used and the questions asked in discussions. These adults shared several ideas that have been incorporated into the design. For example, they suggested that participants be asked how they thought clients and their families responded to conversations related to the assessment tool. This will be included in the question route. The adults consulted have agreed to provide ideas about the dissemination plan before it is finalised. They have asked for feedback about the findings and this has been agreed.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A16. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [x] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [x] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 110	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Participants will be health staff who are already undertaking complex capacity assessments or who will be required to undertake complex assessments when legal reforms are introduced (Deprivation of Liberty Safeguards: Code of Practice, 2008).

Health staff will include anyone who regularly completes capacity assessments in relation to hospital stays for adults over 18 with an acquired brain injury prior to making an application under the Deprivation of Liberty Safeguards (DoLS). This is likely to include doctors, senior nurses, clinical psychologists and ward managers. They may also include DoLS professionals, namely DoLS Assessors who who undertake capacity assessments in relation to hospital and care home stays as part of DoLS applications. These are typically psychiatrists who have undertaken an additional period of study.

Eligible participants will be completing assessments with medically stable patients (in practice this is likely to be on specialist brain injury units) or in a care home (for example in specialist care homes for people with alcohol related brain damage). They will trial the tool with any client or patient who has experienced an acquired brain injury and who is over 18-years-old and who is subject to restrictive care practices. Where possible, and where known, the brain injury will include injury to the frontal lobe.

A17-2. Please list the principal exclusion criteria (list the most important, max 6000 characters).

Professionals undertaking any decision other than that relating to hospital or care home stays that involve restrictive care practices. Those who are unlikely to be undertaking these capacity assessments as part of either the Deprivation of Liberty Safeguards (DoLS) process prior to legal changes or the Liberty Protection Safeguards (LPS) after the Mental Capacity Act (MCA) Amendment bill comes into force will also be excluded. Professionals who are unable to speak English or feel that their language or sensory abilities would prevent them from taking part will also be excluded.
Professionals working with any client under 18 will be excluded. Those who are unlikely to be able to try out the tool with anyone over the trial period will also be excluded as will anyone who knows they will be unable to attend a focus group in any circumstances prior to recruitment.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Reading of advert or invitation to participate	1	0	5	Participant. Participant's workplace
Reading of participant information sheet	1	0	10	Participant. Participant's workplace.
Providing consent to participate	1	0	5	Participant. Participant's workplace.
Reviewing the tool and associated guidance in preparation for trying the tool with clients. Seeking clarification and guidance from the researcher and supervisors where necessary.	1	0	30	Participant and Chief Investigator (trainee Clinical Psychologist). Participant's workplace.
Using the tool with at least three clients as part of a capacity assessment	1	0	90	Participant. Participant's workplace.
Reading email from Chief Investigator offering support whilst the tool is tried out in practice	1	0	5	Participant. Participant's workplace.
Participating in a focus group or interview	1	0	90	Chief Investigator. Location

				and date convenient to the participants.
Reading of debrief sheet	1	0	5	Participant. Address selected for focus group or interview.
Reviewing initial themes arising from analysis and providing feedback (participant can select not to do this if preferred).	1	0	30	Participant. Participant's workplace.

A21. How long do you expect each participant to be in the study in total?

Participants may be in the study for a maximum of twelve months from recruitment to receiving the study outcomes. They will be required to familiarise themselves with the tool and try it with around three clients, which should take approximately two hours. This is flexible however, depending on how the participant chooses to use the tool in their practice.
Participants will attend a focus group that will last for 90 minutes or an interview lasting 60 minutes. Participants will have the option of reviewing initial themes arising from the data and providing their feedback. This may take approximately 30 minutes.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Health professionals are busy, with limited time in their schedule to support research. Whilst this study will endeavour to keep the added demands of participation in this research to a minimum, (both to participants, clients and employing organisations) participants will be required to try a new and unfamiliar tool in their practice and attend a focus group. Both of which will create some demand on their time. However, it is not anticipated that this will be overly-burdensome and participants will be able to contact the researcher to ask questions at any point in the study.

The research question is, in part, concerned with understanding how the tool best works for practitioners. Accordingly, there will be no expectation that the tool will be used in a way that constitutes a significant deviation from practice as usual. Instead, the tool will be promoted as a practical aide memoire of factors to be considered in complex assessments. The tool can be completed as a formal document where this is felt to be helpful by participants or used to structure notes. Otherwise it can be act as a mental checklist prior to, and during, conversations. The tool asks that decision makers triangulate information gained from client interviews with professional assessments or family report. However, this is not beyond the existing legal requirement and should not require more than a brief conversation or reading of a report. To encourage participation, participants will be made aware that they will have free access to the tool after the study is complete and will be entered into a prize draw of £50 to acknowledge their contribution. Local organisations and team managers have indicated that they would be happy to lend their support for the project, which would include providing relevant support to participants to take part where needed.

The literature indicates that professionals can feel a sense of obligation to participate in research (Graham, Grewal, & Lewis, 2007). Full and informed consent will therefore be sought, which will include giving adequate time to think about whether people want to be involved and to ask questions. It will also be made clear in the information sheet, and in verbal discussions, that deciding not to participate will not affect their work or employment in any way.

It is not anticipated that participants will experience discomfort or harm as a result of taking part in this study. Questions asked will not be intentionally sensitive or distressing. However, the process of sharing experiences might elicit discomfort if, for example, using the tool was experienced as challenging or if it highlighted areas of practice where improvements could be made. To minimise and manage any distress or discomfort the researcher will provide email and telephone contact details that participants will be encouraged to use if they have any questions or concerns during the study. Where necessary, advice will be sought from supervisors about how best to support participants. During discussions, the researcher will utilise clinical skills to contain difficult emotions and to ensure discussions remain constructive. Debrief sheets will contain information about occupation health services and relevant support charities and, where needed, professionals will be encouraged to seek support from their GP or work supervisor. Regular meetings will also be held between the researcher and academic supervisors to discuss any practical or ethical concerns.

Participants who attend a focus group can withdraw their participation any time leading up to the focus group. After participating in the focus group they can withdraw their data from the final write up within two weeks of contributing to

the discussion. Participants who contribute their views as part of an individual interview will be able to withdraw their participation up-to two weeks after the interview.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◯ Yes ◉ No

A24. What is the potential for benefit to research participants?

It is hypothesised that the tool will provide useful psychological information and a more structured approach to assessments, which should increase the likelihood of sound decision making and confidence on the part of decision makers. The potential benefits for participants therefore include increased self-efficacy in this aspect of their practice and a supportive structure within which they can gather comprehensive assessment data in complex circumstances. It is anticipated that the clients of participants will experience a more comprehensive quality of care and additional safeguards to their wellbeing.

It is hoped that the results of the study will help organisations, research funding bodies and policy makers to better understand how to support professionals when undertaking complex assessments and make informed decisions about whether to undertake wider research on this tool.

A26. What are the potential risks for the researchers themselves? *(if any)*

It is not expected that there will be any risks to the researcher or the assistant psychologist supporting the focus group. Nevertheless, the Lancaster University Lone Working Policy will be adhered to throughout this project. Namely, the chief investigator will ensure that any venue identified for a focus group or interview conforms to the Health and Safety at Work Act 1974 and the Management of Health and Safety at Work Regulations 1999 by undertaking a sufficient risk assessment of the safety and security of the premises and local area. The lone working electronic system Skyguard, employed by the Clinical Psychology programme team, will also be utilised for the research and the assistant psychologist supporting the focus group.

Any situation where lone working is inadvisable will be avoided, such as the use of confined spaces, and a project supervisor will be contacted in the unlikely instance of discussions or interviews taking place away from a hospital site. A university email and mobile phone will be used when communicating with participants.

If any information is shared that could cause distress to the participant or researcher academic supervision will be used to discuss this. The assistant psychologist supporting the focus group will have the option of talking to the researcher about any issues raised by the project who will seek advice from their supervisors where required.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The researcher will contact local NHS Trust neuro-rehabilitation units, rehabilitation wards, and DoLS assessors across the [redacted] to identify unit, service managers or professionals with the authority to agree to members of their service, in principle, participating in the study. They will be contacted by the researcher from a work email and, where possible, by phone and with their agreement sent the research advert. It is envisaged that these health leads will forward the advert to people in their service who might be eligible to participate. The advert will include the researcher's work contact details and people will be encouraged to contact the researcher to express an interest in participating.
The same advert will be posted on appropriate social media sites including professional discussion forums. Namely, Facebook, Twitter and the online health and care forum The Knowledge Hub. Adverts will be posted from accounts set up specifically for the research and not sent from the researcher's personal accounts. Once potential participants have expressed an interest in participating they will be sent the study information sheet and consent form.

As part of the consultation undertaken on the research design, connections were made with some service managers and independent professionals who have already expressed an interest in supporting the study. Service managers will be send the advert to be forwarded to potential participants and independent professionals will be sent the information sheet and consent form.
No personal data other than the participants workplace or working email address will be known or used before they have consented to taking part in the study. Email addresses and names will only be known to the researcher.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
No. Participants will either respond to the advert directly to the researcher or they will already be known to the researcher because of a previous expression of interest in supporting the study.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

An advert has been devised for the study that will be posted on the website Knowledge Hub (www.khub.net) an information sharing platform for public service professionals. It may also be shared via Facebook (www.facebook.com) and Twitter (Twitter.com) communication platforms from accounts set up specifically for the researcher. The researcher will not use their personal accounts or page for this purpose.
The advert will also be sent to, and shared via, service managers with their consent to be shared with professionals in their service who might be eligible to participate.

A29. How and by whom will potential participants first be approached?

Participants will be recruited in three ways. Independent professionals who have already expressed an interest in supporting the research as part of the design consultation will be approached by the research through a work email. The email will include the information sheet and consent form for their consideration.
Local service managers who have also expressed an interest in support the research will be contacted in the same way. The email will include the advert.
The third route will be to advertise on social media platforms. Where necessary, Facebook, The Knowledge Hub (an online forum for health and care professionals) and/or Twitter will be used and advertisements will be send from an account operated by the researcher and set up specifically for the research - and not from the researcher's personal accounts or pages.
People responding to the advert will initiate contact with the researcher to express their interest in participating.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All participants will be provided with an information sheet and a consent form for the study from the researcher's academic email account to their workplace email. Consent forms can be completed and posted to the researcher at the University or emailed to the researcher's academic email address. Where consent forms are sent via email, the email will be treated as a proxy for a written signature if the person has no email signature they can use. In these instances the email and the consent form will be saved securely. Only the researcher will have access to these. Once the research is complete and the prescribed time as passed, members of the Doctorate in Clinical Psychology programme team will access them in order to permanently delete these documents from the servers. At no time will

the field supervisor have access to this data.

Full and informed consent will achieved by providing adequate time to think about whether people want to be involved and to ask questions. It will also be made clear in the information sheet, and in verbal discussions, that deciding not to participate will not affect their work or employment in any way. It is envisaged that these measures will prevent participants feeling pressured or coerced into consenting to participate.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◯ Yes ◉ No

If No, how will it be recorded?

Some consent forms may be signed in writing by participants if that is their preference. Alternatively, participants can choose to return their completed form by email which will act as a signature if they do not have an electronic signature that they can add to the document. These emails will be saved alongside the person's consent form on secure university servers.

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will be given as long as they require to decide on whether they would like to participate or until recruitment ends.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

As per the exclusion criteria, professionals who are unable to speak English or feel that their language or sensory abilities would prevent them from taking part will be excluded from taking part.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◯ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◯ The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◯ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

Confidentiality will be maintained during the project and after submission. Transcripts will be anonymised and the researcher will provide participants will a detailed summary of confidentiality before each group discussion or interview. Data confidentiality will be maintained by storing all documents electronically (including consent forms, demographic data and all other personal information) using assignment ID numbers, which will be saved separately to audio files or demographic data. Documents, audio recordings and transcripts will be stored and saved electronically onto Lancaster University's encrypted network. These are backed up on the University's Virtual Private Network (VPN). Audio recordings will be transcribed anonymously using participant ID numbers. This will be done on the researcher's personal laptop using password protection and encryption, accessed via the VPN. Audio recordings will be destroyed when the research is submitted for examination.

On completion of the research, research data will be stored electronically on Lancaster University's encrypted network for ten years. The Clinical Psychology programme team at Lancaster University will be responsible for storing and deleting the data after the student has submitted the thesis and completed the course. Confidential personal data (with the exception of consent forms) will be destroyed once the study is complete. Consent forms will retained electronically for three months, separate to the research data. Participants will be made aware that direct quotes will be used in the final report and that every effort will be made to ensure that information used is not identifiable. Participants will be sent provisional themes and quotes selected to illustrate them for comment and a copy of the final report where requested.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Confidentiality of the data will be maintained by storing identifiable documents electronically using participant ID numbers. These documents will be stored separately to audio files. Documents, audio files and interview transcripts will be stored and transferred electronically on Lancaster University's encrypted network. Anonymised typed copies of interviews containing participant ID numbers will be analysed on the researcher's personal laptop using password protection and encryption. Confidential personal data will be destroyed after the study is complete. Scanned or typed copies of notes taken during focus groups will be kept for ten years as described above. Paper copies will be destroyed after this.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

The chief investigator and researcher will be comply with the EU General Data Protection Regulation (GDPR) and the UK Data Protection Act (2018) in order to ensure that personal data is kept confidential.

Once recruitment is complete, participants will be assigned a participant identification (ID) number and will be sent a short form (excel sheet) on which to complete demographic data and to record days and times that might be suitable for them to attend a focus group. The form will ask them to record their role, whether they undertake assessments in hospitals, care homes or both and the number of years of experience they have had in this area of work. This should be returned to the researcher by email. Demographic data will be compiled onto one excel spreadsheet and saved onto the secure University network. At which point, emails and individual demographic sheets returned by participants will be deleted. The document that lists the ID number assigned to each participant will be kept separate from other documents and password protected. The excel database and any other anonymised document, including the transcript, will only use the person's ID number.

Interviews will be transcribed anonymously. Original recordings will be taken using a microphone and the researcher's personal laptop or, in the case of individual interviews using a recording devise. They will be transferred immediately from the researcher's personal laptop or the recording devise via the University's VPN and saved using the University's encrypted network. Where this is not possible, the recording will be transferred onto an encrypted memory stick using password protection and saved as soon as possible onto the University's encrypted network. In the meantime the encrypted memory stick will be stored securely in a locked cabinet. In the case of individual interviews, recording devises will be kept in a locked cabinet in the researchers home until they can be stored on the the University's network. This will be done within one week. File copies of audio recordings will be deleted once the project has been submitted and examined. Other research data will be retained for up to ten years as electronic documents on Lancaster University's encrypted network. The Clinical Psychology programme team at Lancaster University will be responsible for deleting the data after ten years once the thesis has been submitted and the researcher has completed the course.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Basic demographic information will be stored on an anonymised spreadsheet using participant ID numbers. Client names and corresponding ID numbers will be saved separately, and securely, on university secure servers. Groups discussions or individual interviews stored on the University's network will only be accessible to the researcher and academic supervisory team. Before this, if the researcher needs to save audio files onto an encrypted memory stick or retain interviews on a recording devise, they will be stored securely in a locked cabinet in the researcher's own home and transferred to the University Network as soon as possible. Only the researcher will access this. The academic supervisors will have access to recordings and to anonymised transcripts to ensure the thoroughness and trustworthiness of the analysis process. During the study, names of participants will only be accessed by the researcher and the focus group moderation assistant and only the researcher will have access to participant contact details.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Transcribed, anonymous data saved and password protected on the University network will be analysed either on University computers or the researcher's personal laptop using the password protection and encryption and via the University's VPN. Transcripts and results of the analysis will be accessed and reviewed by academic supervisors using Lancaster University computers.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/initials	Surname
	Dr	Guillermo	Perez Algorta
Post	Lecturer		
Qualifications	[redacted]		
Work Address			

[redacted]

Post Code
Work Email
Work Telephone
Fax

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ◉ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

On completion of the research project, research data and consent forms will be stored electronically on Lancaster's University's encrypted network for ten years. The Clinical Psychology programme team will be responsible for deleting the data once the thesis has been submitted and the researcher has completed the course.
Personal data other than consent forms will be destroyed after the study is complete. Original audio recordings will be deleted from the encrypted memory stick (if used) as quickly as possible onto the University's encrypted network, otherwise it will be saved directly onto it using the researcher's personal computer via the VPN once interviews or discussions are complete. Electronic copies of audio files will be deleted once the project has been submitted and examined.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ○ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Professionals are being asked to give time out of busy working lives to try the tool and attend either a 90 minute focus group or 60 minute interview. This is consistent with feasibility research but more than many qualitative studies and it was judged important to acknowledge this.
Therefore, participants will have free access to the tool once the study is complete and will be entered into a £50 prize draw after contributing their views. It will be made clear that inclusion in the draw is only dependent on their attending a group or interview and not dependent on the views they choose to share. The draw will be made by a member of the University research team not involved in the study who will select a piece of paper at random on which the a participants ID number will be written.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◉ Yes ○ No

If yes, please give details including the amount of any monetary payment or the basis on which this will be calculated:
Neither the Chief Investigator or researcher has not had any personal involvement in the organisations sponsoring or funding the research that might give rise to a conflict of interest.
However, the field supervisor, Dr Janice Mackenzie, designed the tool that we hope to study in this research. Further, it can not be guaranteed that participants will not have had personal contact with Dr Mackenzie in their working practice. As such, Dr Mackenzie will not be made aware of the names of any participants and will only have access to research data once it has been anonymised and organised into themes.

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
The intention will be to publish the results of the research in a public journal. The chief investigator is not aware of any public database on which it would be suitable to register the study.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

A summary of the results of the research will be provided to participants and they will be made that they can request a copy of the research section of the thesis. Verbal feedback of the results will probably be shared with stakeholders and a summary of results will also be made available to them. Feedback will be given at professional networking and development events and to other researchers were appropriate.

A62. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Every effort will be made to ensure that quotations or discussion extracts used from audio data does not identify participants or their clients/patients. This will be made explicit to participants in the information sheet.

A63. Will you inform participants of the results?

(●) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
A summary of the results will be provided to participants and they will be made aware that they can request a copy of the research section of the thesis.

C. Scientific and Statistical Review

A64. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi-centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The project was reviewed by the researcher's academic and field supervisors, including the chief investigator, and feedback provided. The research proposal was anonymously peer-reviewed by the research team at Lancaster University's Doctorate in Clinical Psychology programme and approved.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A68. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	15
Total international sample size (including UK):	15
Total in European Economic Area:	15

Further details:
It is expected that the study will involve two focus groups of participants comprising six in each. An additional three people will be recruited to allow for any attrition during the project. The study will recruit a sample of senior hospital or DoLS assessors who meet the inclusion criteria using a purposive sampling method.

A69. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Morgan (2010) recommends approximately six participants per group across two or more groups for topics that are sensitive or complex in nature, with an additional 20% to provide for attrition during the study. As such, 15 participants will be recruited.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Theoretical thematic analysis (TA) will be used to code and organise the data into themes. Braun and Clarke (2006) describe TA as a method for identifying, analysing and reporting patterns in qualitative data. It has been successfully used in health research in the service of interpreting the experience of health professionals (Fugard & Potts, 2015). Furthermore, TA is independent of theory and epistemology and therefore provides a flexible system that can be applied across qualitative methods. This makes it a suitable analytical tool to synthesis and make sense of information shared in the focus groups, individual interview data (where taken) and ideas and notes arising from discussions held by the focus group moderation team.

Non-verbal communication expressed in a focus group setting can be analysed and used to answer research questions alongside words (Braun & Clarke, 2006; Gorden, 1975). However, given the time and resource constraints inherent in this study and the experience level of the researcher only obvious non-verbal communication such as audible sighs or loud comments will be included in this analysis. The researcher will familiarise themselves with the content of the data through repeated reading and reflection and codes will be assigned. Codes will be drawn together and compared, examining how they relate to variation between participants and across groups (Kitzinger & Barbour, 1999). Themes will then be developed and refined through supervision and through feedback from participants.

Bhaskar's (2016) four planes of social being model, rooted in critical realism epistemology, will be used to help frame, organise and understand the themes that emerge from the data. This model assumes that there are four aspects of human life; our lives in relation to the natural world, our experiences in the context of open social structures, ourselves in interpersonal relations with others and our inner being (Bhaskar, 2016). These last three planes will support data analysis by scaffolding the researcher's reflections on how organisational systems, professional relationships and inner experiences might have influenced the degree to which the tool was perceived as useful. For transparency of interpretation and data integrity any assumptions held by the researcher or decisions made during the analysis will be recorded in a reflective journal will be kept and discussed within supervision (Braun and Clarke 2013). For transparency of interpretation and data integrity any assumptions held by the researcher or decisions made during the analysis will be recorded in a reflective journal will be kept and discussed within supervision (Braun and Clarke 2013).

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Suzanne	Hodge
Post	Lecturer		
Qualifications			
Employer	Lancaster University		
Work Address	[redacted]		
Post Code			
Telephone			
Fax			
Mobile			
Work Email			

Title	Forename/initials	Surname
Dr	Anna	Duxbury

Post
Qualifications
Employer
Work Address

[redacted]

Post Code
Telephone
Fax
Mobile
Work Email

Title	Forename/initials	Surname
Dr	Janice	Mackenzie

Post
Qualifications
Employer
Work Address

[redacted]

Post Code
Telephone
Fax
Mobile
Work Email

A84. Details of research sponsor(s)

A84-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation Lancaster University

Given name [redacted]

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title Forename/initials Surname [redacted]

Organisation

Address [redacted]

Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A89-1. How long do you expect the study to last in the UK?

Planned start date: 17/02/2020
Planned end date: 02/09/2020
Total duration:
Years: 0 Months: 6 Days: 15

A71-1. Is this study?

◯ Single centre
◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?
◯ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England 4
☐ NHS organisations in Wales
☐ NHS organisations in Scotland
☐ HSC organisations in Northern Ireland
☐ GP practices in England
☐ GP practices in Wales
☐ GP practices in Scotland
☐ GP practices in Northern Ireland
☐ Joint health and social care agencies (eg community mental health teams)

- [ ] Local authorities
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas
- [ ] Independent (private or voluntary sector) organisations
- [ ] Educational establishments
- [ ] Independent research units
- [ ] Other (give details)

Total UK sites in study: 4

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The research supervisor and research director for Lancaster University's Clinical Psychology Doctoral programme will monitor the conduct of the research. The Principal Investigator at each site will also be responsible for ensuring the professional and ethical conduct of the research. Academic researchers will review all aspects of the final report in addition to providing feedback on initial codes and themes as part of the analysis.
Participants will be made aware that if they have any complaints, concerns or issues with the research then they can contact the research director for the Doctorate in Clinical Psychology programme at Lancaster University.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: In this question 'NHS indemnity schemes' include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (NHS sponsors only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

Lancaster University's legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University's legal liability cover will apply

Please enclose a copy of relevant documents.

A78-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1	(●) NHS/HSC Site ( ) Non-NHS/HSC Site Organisation name: [redacted] Address: Post Code: Country:	Forename: Emma Middle name: Louise Family name: Fowler Email: e.l.fowler@lancaster.ac.uk Qualification (MD...): BA, MEd Country: UNITED KINGDOM
IN2	(●) NHS/HSC Site ( ) Non-NHS/HSC Site Organisation name: [redacted] Address: Post Code: Country:	Forename: Emma Middle name: Louise Family name: Fowler Email: e.l.fowler@lancaster.ac.uk Qualification (MD...): BA, MEd Country: UNITED KINGDOM
IN3	(●) NHS/HSC Site ( ) Non-NHS/HSC Site Organisation name: [redacted] Address: Post Code:	Forename: Emma Middle name: Louise Family name: Fowler Email: e.l.fowler@lancaster.ac.uk Qualification (MD...): BA, MEd Country: UNITED KINGDOM

Country ENGLAND

IN4

NHS/HSC Site

Non-NHS/HSC Site

Organisation name

Address

Post Code

Country

[redacted]

Forename Emma

Middle name Louise

Family name Fowler

Email e.l.fowler@lancaster.ac.uk

Qualification (MD...) BA, MEd

Country UNITED KINGDOM

IN8

NHS/HSC Site

Non-NHS/HSC Site

Organisation name

Address

Post Code

Country

[redacted]

Forename Emma

Middle name Louise

Family name Fowler

Email e.l.fowler@lancaster.ac.uk

Qualification (MD...) BA, MEd

Country UNITED KINGDOM

IN9

NHS/HSC Site

Non-NHS/HSC Site

Organisation name

Address

Post Code

Country

[redacted]

Forename Emma

Middle name Louise

Family name Fowler

Email e.l.fowler@lancaster.ac.uk

Qualification (MD...) BA, MEd

Country UNITED KINGDOM

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.
10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

Information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr. Guillermo Perez Algorta on 03/03/2020 13:09.

Job Title/Post:	Lecturer
Organisation:	Lancaster University
Email:	[redacted]

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at sponsorship@lancaster.ac.uk on 03/03/2020 11:38.

Job Title/Post:	Head of Research Quality and Policy
Organisation:	Lancaster University
Email:	[redacted]

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Suzanne Hodge on 03/03/2020 13:55.

Job Title/Post:

Organisation:

Email:

Academic supervisor 2

This section was signed electronically by Dr Anna Duxbury on 03/03/2020 14:13.

Job Title/Post: Clinical Psychologist/ Clinical Tutor

Organisation: Lancaster University

Email: [redacted]

Academic supervisor 3

This section was signed electronically by Dr. Guillermo Perez Algorta on 03/03/2020 13:10.

Job Title/Post: Lecturer

Organisation: Lancaster University

Email: [redacted]

Doctorate in Clinical Psychology | Lancaster University

Research protocol

Research title:

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study

Applicant: Emma Fowler, Trainee Clinical Psychologist, Lancaster University.
Supervisors:
Primary research supervisor and Chief Investigator: Dr Guillermo Perez Algorta, [redacted]

Academic supervisors: Dr Suzanne Hodge [redacted]
and
Dr Anna Duxbury, [redacted]

Field supervisor: Dr Janice Mackenzie, Consultant Clinical Neuropsychologist, [redacted]

Introduction

The Mental Capacity Act 2005 (MCA) states that a person lacks capacity to make a specific decision if they have a mental impairment and are unable to make the decision at the time it needs to be made (Mental Capacity Act: Code of Practice, 2005). In order to be deemed unable to make a decision, there must be a reasonable belief that the person is unable to understand information relevant to the decision, to retain it, to use and weigh the information or be unable to communicate their decision (Mental Capacity Act: Code of

Practice, 2005). People who undertake assessments under the Act are called decision makers (Mental Capacity Act: Code of Practice, 2005).

Professional issues relating to capacity assessment

Recent scrutiny of formal capacity assessments has highlighted that assessments are often of poor quality, are insufficiently thorough and frequently do not comply with statutory requirements (National Institute for Health and Care Excellence, 2014). Whilst guidelines recommend that health and care professionals receive sufficient support to undertake assessments that are commensurate with their role, such support is rarely adequate and can lead to professionals experiencing reduced self-efficacy in this area of practice (Mental Capacity Act: Code of Practice, 2005; National Institute for Health and Care Excellence, 2018).

Some people who lack capacity and who are being accommodated in hospital or in a care home have considerable restrictions imposed on their liberty for the purpose of receiving care or treatment (Deprivation of Liberty Safeguards: Code of Practice, 2008). To date, such circumstances have required independent assessment (including a capacity assessment) by Deprivation of Liberty Safeguards (DoLS) assessors (Deprivation of Liberty Safeguards: Code of Practice, 2008).

An amendment to the Mental Capacity Act 2005 passed into law in 2019 will require hospitals, in most instances, to assess someone's capacity to consent to care regimes that amount to a deprivation of their liberty themselves as part of an internal process to determine whether the patient's care is lawful (Mental Capacity (Amendment) Act, 2019). There will be a requirement for many health providers (including NHS hospitals) to establish processes that amount to peer review in which someone with relevant knowledge and experience within the organisation reviews the capacity assessment completed and decides whether there is sufficient evidence to support the conclusions reached (Mental Capacity (Amendment) Act, 2019). Until the changes come into force (the exact date is, as yet, unclear) the existing arrangements will apply, in that independent Deprivation of Liberty Safeguards assessors, commissioned by a relevant local authority, will undertake capacity assessments in hospital settings where the circumstances include restrictions that may amount to a deprivation of liberty (Deprivation of Liberty Safeguards: Code of Practice, 2008).

Capacity assessments in the context of complex psychological and neuropsychological difficulties

Challenges in the assessment of capacity in practice are exemplified when assessing the capacity of people with reduced insight and difficulties with executive function (British

Psychological Society, 2018a). Psychological insight (or awareness) can be defined as an understanding of an impairment and of how it has affected relationships and/or functioning in daily life (Markova & Berrios, 1992). Reduced insight is a recognised sequela of many cognitive impairments including traumatic brain injuries (TBIs), alcohol-related dementia and some strokes, with some clients experiencing a complete absence of insight, known as anosognosia (Ownsworth, McFarland, & McYoung, 2000; Vuilleumier, 2004). Crosson et al. (1989) were the first to propose a multi-dimensional model of insight, which describes three interdependent and hierarchical levels. The three levels are described as: Intellectual awareness, or the ability to acknowledge that a specific function is impaired; emergent awareness, an ability to recognise difficulties as they occur and to monitor performance and, finally, anticipatory awareness, where someone has sufficient foresight to anticipate problems resulting from functional deficits (Crosson et al., 1989).

The causes of insight difficulties are only partially understood (Belchev et al., 2017). There is broad agreement that both organic and psychological factors play a role, albeit there is no unifying theory of how these processes might interact to predict problems in insight (Belchev et al., 2017; Bivona, Ciurli, Barba, Onder, & Azicnuda, 2008). For instance, damage to the frontal lobe, or to fronto-temporal-parietal circuits in the right hemisphere of the brain, has been found to correlate with insight problems and psychological processes, including defence mechanisms such as denial (employed to prevent the recognition of distressing aspects of the self) have also been identified as playing a role in some instances (Belchev et al., 2017; Moro, Pernigo, Zapparoli, Cordioli, & Aglioti, 2011; Vallar & Ronchi, 2006; Vuilleumier, 2004).

Beyond these difficulties, it can be a complex task to synthesise legal principles of assessment with neuropsychological knowledge and translate these ideas into real client contexts (George & Gilbert, 2018). For example, questions still remain about whether the concept of being able to "use" information as part of the decision making process in law is compatible with psychological theories of insight (Dunn, 2013; Mental Capacity Act: Code of Practice, 2005).

Undertaking remote capacity assessments related to care and treatment arrangements as part of a DoLS application in the context of a global health crisis

In March 2020 the United Kingdom (UK) government implemented a range of measures to respond to a global health pandemic caused by the virus COVID-19 Corona virus, to protect the health of citizens and manage statutory resources (Office, 2020). Many services and organisations have taken the decision to undertake desktop, or remote, capacity

assessments in order to avoid face-to-face visits with clients and patients in vulnerable groups in circumstances where this would jeopardise their health or that of the public (Mithran, 2020; The Hon. Mr Justice Hayden, 2020). The strong message from the government and judiciary is that remote assessments are acceptable in sub-optimal conditions (Department of Health and Social Care, 2020). In the midst of the current crisis there is little research or practice guidance available for capacity decision makers who will be expected to radically change their practice by either interviewing clients or patients via video conferencing or phone or, in some instances, by gathering evidence from third parties who know the person well (The Hon. Mr Justice Hayden, 2020).

At the time of this study additional formal guidance is expected from the Department of Health and Social Care (Ruck Keane & Scott, 2020). In the interim two key guidance documents have been made available to professionals and organisations involved in DoLS assessments that have a very broad scope (Department of Health and Social Care, 2020; HM Government, 2020). A clear message is that the Mental Capacity Act and Deprivation of Liberty duties apply during the pandemic (HM Government, 2020) and that the ethical principles of minimising harm and accountability, particularly in relation to transparency as to how decisions are being made, are amongst the values to be foregrounded during this time (Department of Health and Social Care, 2020). In the meantime, health and care services are having to create processes at speed to respond to discharge their responsibilities as best they can in the circumstances (Mithran, 2020; Ruck Keane & Scott, 2020). For instance, local authority managers and legal professionals are recommending that, where necessary, other sources of evidence be drawn on when making decisions about the person's capacity to consent to their care and treatment arrangements (Ruck Keane & Scott, 2020).

In crisis situations there is often insufficient time to abide by usual decision-making processes (Sayegh, Anthony, & Perrewé, 2004). The quality of the decisions made by professionals have been theorised as influenced by a range of psychological, personal and environmental factors including: Experience in the role; the quality and clarity of the guidance or information available; the extent to which the crisis creates significant negative or threatening emotion in the individual and degree of existing professional self-efficacy and tacit knowledge possessed by the professional in their role (Agor, 1986; Buttriss, 2015; Elbanna & Fadol, 2016; Gist & Mitchell, 1992; Hadley, Pittinsky, Sommer, & Zhu, 2011; Khatri & Ng, 2000; O'reilly, Lain, Sheehan, Smale, & Stuart, 2011; Sweeny, 2008). In a research context, a model by Seyegh, Anthony and Perrewe (2004) brings these elements together and predicts that positive and structured organisational support, tacit knowledge,

self-efficacy and a perception of a crisis as, to a degree, an opportunity to find innovative solutions can combine to improve the quality of decision-making and professional judgement in crisis circumstances. Accordingly, their model will frame this research.

A new tool to support remote capacity assessments in relation to care arrangements

A capacity tool in the form of a semi-structured interview has been developed to support professionals undertaking capacity assessments (Mackenzie, Lincoln & Newby, 2008) and this has been adapted to assess capacity remotely with people who have complex cognitive difficulties in relation to hospital or care home stays that involve restrictive care or treatment arrangements. The tool has been developed from post-doctoral research work undertaken in a stroke populations and has been revised in line with feedback from experienced professionals working across health and care services over the last decade (personal communication with Dr Mackenzie, May 2019).

The tool is underpinned both by legal requirements and neuropsychological theory. For instance, the tool assumes that some difficulties in decision making ability in complex presentations can be explained by reduced insight and limited executive function and therefore includes questions designed to gather evidence to establish the presence of these factors are impacting on the person's capacity. It is accompanied by written guidance that outlines threshold levels of understanding required to make a capacity decision about hospital or care home stays and provides ideas for how to use in practice.

Most professionals are required to record assessments on prescribed organisational or legal capacity assessment documentation. Accordingly, whilst the tool includes all aspects of the two-stage legal test of capacity and can be used as a template to record formal assessments, it is anticipated that its primary value will be as a supplement to current practice. The tool aims to address challenges in practice by providing awareness of salient information, improved accuracy of professional judgements and a supportive structure

The aim of the research, therefore, is to establish the feasibility of using an assessment tool to support remote capacity assessments with people with a cognitive or psychological impairment in the context of admission to hospital or a care home in circumstances where restrictions are in place. The research will answer the following question:

Is a tool designed to support remote capacity assessments with people with a psychological or cognitive impairment around their admission to hospital or a care home experienced as practical, acceptable and useful by decision makers?

Method

Design

Information is required to determine whether it will be beneficial to professionals to roll-out this capacity assessment tool as part of larger-scale research. As such, a feasibility approach will be taken in this study (Bowen et al., 2009). A qualitative design will be employed using focus group methodology.

Focus groups can facilitate the development of participant views through interaction, which can enrich their, and our, understanding of the topic (Krueger, 2009). Interaction in groups has been posited as encouraging autonomous and communicative reflexivity between people and it is this reflexivity that can facilitate the elaboration of ideas between people (Archer, 2000). Morgan (2010) found that focus groups can create a sense of cohesion and belonging between participants; creating a space that feels safe to share views and opinions. This can be especially useful in exploratory research as it allows for the examination of opinion in greater depth through interaction and discussion (Frey & Fontana, 1993). A criticism of focus groups is that there can be a lack of internal consistency in the data arising from group interaction, such as participants changing their minds (Onwuegbuzie, Dickinson, Leech, & Zoran, 2009). Krueger (1998a) has argued, however, that this is a misunderstanding of the value of focus group methodology and that the development of ideas provides valuable data to researchers.

From a pragmatic perspective it might not be possible for some participants to attend a focus group given they are likely to be busy professionals working in different localities. Further, changes in how health and care workers undertake their duties has meant that may professionals are working remotely (Office., 2020). Whilst every effort will be made to arrange face-to-face groups at a time and date that suit participants, other provisions will be made to accommodate practical and national considerations that might affect this plan.

Where needed, online web conference technology will be used to facilitate synchronous group discussion. Web conferencing can provide the scope to hold shared, real-time discussion during which rich interaction data can still be obtained as participants have the option of both seeing and hearing each other (Tuttas, 2015). There appears to be no theoretical literature relating to group size in these circumstances. However, researchers have found that discussions amongst professionals can work in smaller groups as they often seem able to talk more freely and limiting group size in this context to five people can make managing technical challenges easier (Finch & Lewis, 2003; Tuttas, 2015).

Provision will also be made to undertake individual interviews either in person, where possible, via web conferencing or over the telephone. There is evidence of this approach being undertaken successfully in other research and it should ensure that a variety of viewpoints are captured in instances where it is not possible for certain roles to be represented in a group (Lambert & Loiselle, 2008; Pamphilon, 1999). It will also provide an alternative option for professionals who might prefer not participate in online conferencing or for whom it is not possible. Focus groups and individual interviews are methods that are theory-independent and can therefore both be informed by the critical realism paradigm underpinning this study (Alderson, 2016). Both methods can also lend themselves to thematic analysis as an analytic technique, which should allow for data synthesis without compromising the trustworthiness of the analysis (Lambert & Loiselle, 2008).

Participants will have one week after receiving an email or advert to decide whether to participate in the study. Once recruited, participants will have six weeks to trial the tool. The timeframe was decided on after conducting a scoping exercise with potential participants in health and care settings. They confirmed that they would typically undertake at least three assessments over this period. In order to ensure data is obtained from participants who have had a good opportunity to use the tool, participants will be asked to use it with approximately three clients. However, this will not be prescriptive as participants might have important contributions to make about the tool regardless of the number of times it has been tried. During this time, participants will be able to contact the researcher to clarify aspects of the tool or to ask practical questions about it. Moreover, participant will be contacted twice throughout the trial period to act as prompt to ask any questions that participants might have about the tool. This will happen after one week and then again four weeks into the trial. There is a possibility that this could influence whether the tool is used. However, the email will be clear that the purpose of the contact is to encourage questions. To prevent any interactions between the researcher and participants from influencing results it will made clear that questions or queries should relate to practical aspects of the tool. During this time focus groups will also be arranged in accordance with preferences expressed by clients wherever possible.

Where possible, participants will be contacted at a six, and then again at 12, month interval following the study to establish whether the inclusion of the tool had an impact on client/patient care or outcomes. This will be done by email. DoLS assessments are typically discrete pieces of work that do not require the same assessor to have continued contact or input into the person's care. Further, this research is being undertaken as part of a

professional qualification that will be complete after the study has been assessed. Therefore, follow-up might not be practically feasible. In these instances, additional research studies will be considered that include a longitudinal element.

Fifteen participants will be recruited and a minimum of two focus groups will be conducted. The literature indicates that this should result in optimal data saturation whilst allowing for some attrition during the research. Everything will be done to recruit this number of participants however, if it is not possible, guidance and literature indicates that a minimum of eight people is required to obtain useful data for research of this design (Guest, Bunce, & Johnson, 2006). Specifically, this research will uses a question route containing scripted questions, is interested in participant's experiences, will recruit participants with some homogeneity in terms of professional context and will not undertake very fine grained analysis (Guest et al., 2006). A minimum of eight should therefore obtain sufficient data to successfully in answer the research question. Where possible groups will be made up of four or five participants to balance the need to obtain both rich and interactive data. Where this is not feasible groups of between two and six will be held as this represents the minimum recommended number to achieve useful interactive data (Morgan, Ataie, Carder, & Hoffman, 2013). Where groups are conducted online, there will be a maximum of three people per group to facilitate useful discussion (Finch & Lewis, 2003; Tuttas, 2015).

The researcher will make arrangements for focus groups or interviews, honouring the preferences of participants wherever possible, and notify participants of the date, day and time of the focus group by email, follow-up phone call or text between work phones. Text notifications or reminders has been found to be particularly effective when interacting remotely with participants (Tuttas, 2015). This will be done no later than one month before the focus group is due to take place and a reminder will be given the day before the group or interview. A scoping exercise has indicated that many health rehabilitation professionals attend the Greater Manchester Operational Delivery Network (ODN) meetings that take place at regular intervals throughout the year (gmnrodn.org.uk) or participate in local specialist interest groups that also meet regularly. There is an indication that professionals who oversee these forums may be able to host focus groups as part of regular scheduled meetings. Support for travel including reimbursement of public transport costs or mileage claims will be provided by the University.

Where the participant is not able to attend a focus group, arrangements will be made to conduct an individual interview at a mutually convenient time and date. Everyone taking part will be offered the chance to participate in a group. In the unlikely event of it not being

possible to arrange any groups, individual interviews will be undertaken with all participants. The researcher will undertake all individual interviews and facilitate all groups. As with focus group discussions participants will be able to have a break or stop individual interview at any time. They will be provided with the same information as focus group participants after the interview, including the debrief sheet.

Groups will last approximately one hour and be facilitated by a focus group moderation team comprising the researcher (who will act as the facilitator) and an assistant psychologist who has expressed an interest in supporting the research. An hour is the least amount of time recommended for a focus group and has been selected to minimise the demand on participant time when they are already experiencing additional practical and psychological pressures (Morgan & Bottorff, 2010). The assistant psychologist will have been provided with some informal training in undertaking this role by the researcher. This will include information and tips on moderating focus groups learned from previous experience in undertaking focus groups as part of a previous academic assignment and from independent study. The researcher will go over the content of this informal training with supervisors beforehand. The assistant psychologist's role will be to take brief notes of what is said in the groups alongside their observations of any notable or obvious group dynamics or non-verbal communication.

A question route has been developed for the focus groups, informed by the research question and comprising 11 questions, in line with focus group best practice recommendations (Krueger, 2009). A question route is preferred over a topic guide as it is more structured and systematic and, therefore, likely to result in more comparable data across groups and individual interviews where required (Krueger, 2009). If there is an indication during data collection that some questions are not working well, for example if a question results in silence within a group or irrelevant talk, they will be reviewed in supervision. The question route includes introductory questions, key questions and ending questions. As recommended, they will all be uni-dimensional, with no synonyms, and positive questions will be placed before negative questions (Freeman, 2006; Krueger, 1998b). The question route includes options in the script so it can be adapted to either face-to-face on web-based discussions (Tuttas, 2015).

Data will be collected across multiple sources and will comprise:

- Recordings of the group that will be transcribed by the researcher
- Field notes taken by the moderation team that will include the assistant psychologist's

reflections on the group, notes made by the researcher from the moderation debrief meeting and any additional participant comments shared at the end of the group

- Researcher's reflective journal

An individual interview schedule has also been developed comprising 10 questions. The questions reflect the same topic areas as the question route but the wording, introduction and summary has been designed to reflect individual discussions. Both the group question route and individual interview schedule will be tested for simplicity, clarity and directness both with the research team and potential participants or non-researchers. Questions will be revised as needed.

Stakeholders have been consulted on the research design. This has included people who have a cognitive impairment and who live in a specialist care home. Each person had experience of having their capacity assessed. There was no evidence to suggest that these stakeholders lacked the capacity to consent to being consulted about the research and so capacity, in line with legislation, was assumed. Other stakeholders consulted have included safeguarding leads and managers in relevant statutory services, local professional development networks and professionals who undertake complex assessments. In response to feedback, changes have been made to the setting in which data will be collected to include care homes and to the capacity tool (which includes some additional guidance).

Participants

NHS-employed participants will be recruited from NHS Trusts across the [redacted] Independent professionals will be recruited from adverts posted on relevant social media sites including professional online forums. DoLS Best Interest Assessors will also be recruited from local authority DoLS teams via local managers. Where online forums and social media is used, the student will create an account specifically for the research and not use their personal account. Participants expressing an interest in the study will be sent an information sheet and consent form by email from the researcher's work email address. Potential participants will be able to email or phone (via a university-allocated mobile phone) the researcher to ask any questions about the research. Consent forms can be returned by email or by post to the researcher's university address. Fifteen participants will be recruited and a minimum of two focus groups will be conducted. The literature indicates that this should result in optimal data saturation whilst allowing for some attrition during the research. Everything will be done to recruit this number of participants however, if it is not possible,

guidance and literature indicates that a minimum of eight people is required to obtain useful data for research of this design. As discussed, smaller groups will be held where groups are conducted via web-based conferencing.

Eligible participants will be Deprivation of Liberty Safeguards (DoLS) assessors who currently undertake capacity assessments about care arrangements in relation to DoLS applications (Mental Capacity (Amendment) Act, 2019). These assessors will continue to undertake some complex assessments (the majority of which will be in care homes) when legal reforms are introduced under their new title of Approved Mental Capacity Practitioners (AMCPs) (Mental Capacity (Amendment) Act, 2019). Current DoLS professionals have undertaken an additional period of study following professional qualification and include psychiatrists.

Participants will be recruited from across [redacted] region. This will include Greater Manchester and Liverpool. Independent professionals and DoLS assessors working with local council teams will be recruited from across England. There will be three different routes for recruitment. Some professionals will be contacted directly via a work email. This will be where the person has previously expressed an interest in participating, either via the researcher or field supervisor, and where managerial or organisational approval is not required (for example where they are independent DoLS assessors). The email will include an information sheet and a consent form. Some recruitment will be undertaken through local Trusts or local authorities where managers have expressed a willingness to be contacted and are prepared to cascade the research advert and information sheet to relevant professionals. Thirdly, advertisements will be posted on Twitter and will briefly explain the study and which will invite potential participants to contact the research to express an interest or enquire further. Adverts will be posted from an account set up specifically for the research and not from the researcher's personal account. Professionals interested in participating will be encouraged to contact the researcher via their university email or university-allocate mobile phone.

Many participants, like doctors working as DoLS Mental Health Assessors or independent DoLS assessors will have the autonomy to decide whether to participate and to trial the tool in their practice. Otherwise, recruitment through line management structures will ensure that people have organisational support for their involvement in the study should they wish to participate.

Procedure

All participants will be provided with an information sheet and a consent form for the study. Consent forms can be posted to the researcher at the University (where this is acceptable under any existing public health measures during the COVID-19 pandemic) or emailed to the researcher via a work address. Where consent forms are sent via email, the email will be treated as a proxy for a written signature if the person has no email signature that they can use. In these instances, the email and the consent form will be saved as password protected documents onto encrypted University servers. Consent forms and related documents will only be accessed by the researcher or a member of the Doctorate in Psychology programme team for the purpose of deleting files once the specified time for retaining the documents has lapsed.

Once recruitment is complete, participants will be assigned a participant identification (ID) number and will be sent a short form (excel sheet) on which to complete demographic data and to record days and times that might be suitable for them to attend a focus group or participate in an interview either in person (where acceptable under existing public health measures) or online. The form will ask them to record their role, whether they undertake assessments in hospitals, care homes or both and the number of years of experience they have had in this area of work. In addition, the form will ask them to indicate if they have the necessary equipment to participate in a web-based discussion (desktop or laptop computer and adequate microphone and web camera facilities) and whether they feel they have the skills to participate in an web-based group. Where appropriate support will be offered to help the participate feel confident in accessing and using the required technology. This should be returned to the researcher by email.

Demographic data will be compiled onto one excel spreadsheet and saved onto the secure University network. At which point, emails and individual demographic sheets returned by participants will be deleted. The document that lists the ID number assigned to each participant will be kept separate from other documents and password protected. The excel database and any other anonymised document, including the transcript, will only use the person's ID number.

Participants will also be sent the capacity tool and associated written guidance via email. The email will include a reminder (taken from the information sheet) about the time period for trialling the tool, who the tool should be used with and in which settings it should

be used. Participants will be encouraged to direct any clarification or practical questions, raised either by them or the person completing the remote checklist, about the tool to the researcher at any time during the trial period by email. Participants will then trial the tool for six weeks with, where possible, around three clients. If participants ask questions about the tool during the trial period on their behalf, or that of the person completing the tool on their behalf, the researcher will contact the field supervisor for assistance in answering the query.

Participants will also be sent a client/frontline worker consent form to enable formal consent of a client and, where necessary, the frontline worker caring for the person. If the person lacks capacity in relation to deciding whether to consent to the tool it will not be used. Participants can email the form directly to the client and/or to a work email address for them to physically or electronically signed and placed into confidential records.

Participants will advised to ask the frontline worker to make arrangements for reasonable support to be provided to help the person understand the consent form. This might include ensuring that they have their glasses or reading it out loud. If the person consents, the form can be retained by them or in their client records at their discretion. This is outlined on the consent form. As with participants, frontline workers and clients/patients can ask questions and the participant can return to the researcher to have these answered. People completing the tool, as well as client/patient, will be offered the option of looking through the tool as part of this process. If the person completing the form on the decision-maker's behalf, or the client, refuses their consent the tool will not be used as part of their assessment. Neither researcher or supervisors will be aware of the identity of any frontline worker or client involved in the process of trialling the tool as they are not study participants.

Focus group and individual interview discussions will be audio recorded using a sufficiently sensitive microphone or recording equipment. For face-to-face focus groups this will be a large microphone borrowed from the University and connected to the researcher's own laptop. Whilst the laptop will be used for recording, no audio files will be saved onto the laptop. The file will be directly saved onto University systems using virtual private network (VPN) technology. If this is not possible, the audio file will be saved directly onto an encrypted memory stick and transferred to secure university systems as soon as possible.

For web-based focus groups Microsoft Teams software will be used as the University has full access to security features that include encryption of data in transit and at rest, the option of storing files in SharePoint backed up by SharePoint encryption and the facility for the researcher to be the only member of the groups to record the discussion. To protect the

rights and privacy of participants they will be reminded that online discussions will be audio recorded and told when this begins.

Regardless of the method of group data collection, a digital voice recorder will also be used to record the discussion as a back-up and participants will be made aware of this in the information sheet and before the discussion. If this is not required it will be deleted immediately following the discussion. All recordings will be uploaded onto University secure services and deleted from the recorded, devise or application.

For individual interviews a digital voice recorder will be used to record the interview. The recording will be uploaded onto University secure servers as soon as possible and the recording deleted from the digital voice recorder. Where it is not possible to immediately upload the recording, the voice recorded will be kept in a locked cabinet at the researchers own home and transferred to University systems as soon as possible. Alternatively, the interview will take place using web-based conferencing exactly as described above for group discussions. This might be required if public health measures prohibit face-to-face discussions or if it is the preference of the participant.

Both group discussions and individual interviews will include an introduction during which confidentiality expectations will be explained and the research aims restated. A copy of the tool, associated guidance and the information sheet will be made available either physically or re-sent by email where needed. Participants will also be reminded that they cannot withdraw their contribution after the group, or the individual interview, has taken place.

For face-to-face groups participants will be invited to come along up to thirty minutes before a focus group is scheduled to begin. As outlined, it is anticipated that groups will take place at the end of existing meetings organised by local health networks or special interest groups. These meetings usually take place within health premises (offices or hospitals). If DoLS assessors have been recruited they will have the option of attending these groups. The researcher is aware that DoLS assessors often have their own peer support networks. Accordingly, groups will be arranged to tag onto these meetings where necessary and possible. It is expected that meetings will take place within working hours. If they take place either on private premises or outside working hours University lone working procedures will be followed, which includes the use of Skyguard reporting technology. Refreshments will be provided by the researcher at focus groups and participants will have the opportunity to ask any questions they might have about the group informally with the researcher before discussions begin. Each participant will have a name card or badge on which their first name

will be written. The researcher and the assistant psychologist supporting the group will know the ID number for each participant. During the course of the discussion, the assistant psychologist will take notes of the first few words said by participants each time they speak and will use their ID number against these notes. This will help the researcher to understand who contributed what when transcribing the audio recording.

During the group, participants will be made aware that they can ask for a short break or withdraw from the discussion if they experience any discomfort or distress. The researcher will also stay alert to any potential discomfort being experienced in the group and initiate a break if that is felt to be appropriate. During a break the researcher will talk privately to any participant who may be experiencing distress to agree, together, how to proceed. The assistant psychologist will note key points of the discussion which will be summarised during the last few minutes of each group for verification and initial feedback. For web-based groups participants will be informed that they can mute their video recorder or their microphone at any time in order to have a break from active participation or to ensure their own privacy. They will be asked in their email invitation that they ensure, as far as possible, that they have access to a private space when participating in the online discussion and informed that they can use other aspects of Team functionality as required including the "blurred background" feature.

At the end of the group participants will be thanked for their involvement and told approximately when they will be contacted with a summary of the themes arising from the analysis for their comments and feedback, should they wish to provide any. This will be done within one month of the discussion taking place. It will be made clear that they do not have to provide feedback. Participants will also receive a debrief sheet containing support information and the researcher will remain behind after the group talk to participants about further support if needed. Participants who have been involved in an individual interview will be reminded that they have up-to two weeks following the interview to withdraw from the study. Focus group participants will have two weeks to withdraw their permission for the data to be included in the write up. This will have been made explicit in the information sheet. Participants will be reimbursed for travel expenses where necessary from the research budget up to a maximum of twenty pounds (in line with University policy). Participants will be made aware of reimbursement procedures via email prior to groups or interviews taking place.

The researcher and assistant psychologist will meet for approximately fifteen minutes after each group to have a short debrief. This time will be used to explore any comments of

particular interest or possible themes arising from the discussion as well as ideas about how to ensure later groups are as productive and useful as possible. These ideas will be recorded in the notes already taken during the discussion by the assistant psychologist. All notes made during and after the group will be anonymous and will not include participant names or any other identifying details other than their assignment number. Where needed, this discussion will be used to explore anything that might have caused the assistant psychologist discomfort or distress and to agree on how best to ensure their wellbeing. Advice will be sought from supervisors if required.

For online groups, segments of audio recordings might be shared with an academic supervisor for the same purpose; for example to explore any aspects of the discussion that might be unclear, of particular interest or useful to hold in mind for later discussions.

Data transfer and storage

The chief investigator will be comply with the EU General Data Protection Regulation (GDPR) and the UK Data Protection Act (2018) in order to ensure that personal data is kept confidential. Consent forms will be scanned or saved onto the secure University network within one week of receipt and emails or paper copies will be disposed of appropriately, for example via University confidential waste. If a consent form has been completed electronically but does not include an electronic signature, the email will be saved securely with the consent form. Assignment ID numbers allocated to participants will be saved separate from the demographic data and from the transcripts of audio files to ensure confidentiality.

At the end of each focus group the assistant psychologist will give all the paper notes made to the researcher. These will be scanned or typed onto the University network within one week and destroyed via confidential waste. Audio files will be saved onto secure University networks and deleted from either the encrypted memory stick (if used for face-to-face focus groups), digital recording devise or Microsoft Teams encrypted software as soon as the file is transferred and within a minimum of one week. The encrypted memory stick and/or digital voice recording will be kept in locked cabinet in the researcher's own home if there is a delay between taking a recording and uploading it to University servers. Recordings will be transcribed using the researcher's personal laptop via the University's Virtual Private Network (VPN). Transcriptions will be anonymised, removing any references identifiers like names, places or organisations. Sections of audio file might be played to the academic supervisor for, for example, advice about how to improve interviewing technique or group

management. In these instances, recordings will be listened to in a private space at the University.

All documents will be password protected including notes, audio files, consent forms and transcripts. They will be saved on the University network for ten years. Confidential, personal data will be destroyed after the study is complete. The Doctorate in Psychology programme will be responsible for storing and deleting the data once the researcher has submitted the thesis and completed the course.

Proposed analysis

There is no clear epistemology associated with focus group methods (Wilkinson, 1999). Further, focus group analytic techniques are rarely discussed in detail and, to date, no framework exists to describe the range of techniques that might available to focus group researchers (Onwuegbuzie et al., 2009; Webb & Kevern, 2001). Consequently, the researcher has decided to take a critical realist position in relation to the research. Critical realism (CR) has been praised as a comprehensive and internally consistent philosophical framework (Gorski, 2013). This position complements the assumptions inherent in this study, namely that real phenomena exist in the world (e.g. mental impairment) that can be partially understood through empirical enquiry (Alderson, 2016). Further, CR theorises the existence of indirect or unseen contextual forces that have a reciprocal influence on agents and which are often only visible in their effects (Bhaskar, 2016). This concept is pertinent to the study aims, which is interested in the practical value of the tool as a way of adhering to legislative requirements in practice in the context of a global pandemic and national public health restrictions and its feasibility in a health and care context.

Theoretical thematic analysis (TA) will be used to code and organise the data into themes. Braun and Clarke (2006) describe TA as a method for identifying, analysing and reporting patterns in qualitative data. It has been successfully used in health research in the service of interpreting the experience of health professionals (Fugard & Potts, 2015). Furthermore, TA is independent of theory and epistemology and therefore provides a flexible system that can be applied across qualitative methods and can involve critical realist concepts at the broader analytical level (Braun & Clarke, 2006). This makes it a suitable analytical tool to synthesis and make sense of information shared in the focus groups, individual interview data and ideas and notes arising from discussions held by the focus group moderation team.

Non-verbal communication expressed in a focus group setting can be analysed and used to answer research questions alongside words (Braun & Clarke, 2006; Gorden, 1975). However, such communication is not relevant to the research question in this instance and, as such, this data will not be recorded and analysed. The researcher will familiarise themselves with the content of the data through repeated reading and reflection and codes will be assigned. Codes will be drawn together and compared, examining how they relate to variation between participants and across groups (Kitzinger & Barbour, 1999). Themes will then be developed and refined through supervision and through feedback from participants.

Bhaskar's (2016) four planes of social being model, rooted in critical realism epistemology, will be used to help frame, organise and understand the themes that emerge from the data. This model assumes that there are four aspects of human life; our lives in relation to the natural world, our experiences in the context of open social structures, ourselves in interpersonal relations with others and our inner being (Bhaskar, 2016). These last three planes will support data analysis by scaffolding the researcher's reflections on how organisational systems, professional relationships and inner experiences might have influenced the degree to which the tool was perceived as useful. For transparency of interpretation and data integrity any assumptions held by the researcher or decisions made during the analysis will be recorded in a reflective journal will be kept and discussed within supervision (Braun & Clarke, 2013).

Risks and service related issues

NHS and DOLS professionals are busy, with limited time in their schedule, particularly in the current context of a global pandemic, to support research. Whilst this study will endeavour to keep the added demands of participation in this research to a minimum, (both to participants, professionals completing the tool on behalf of participants, clients/ patients and employing organisations) participants, people completing the tool on their behalf or discussing it with them, will be required to try a new and unfamiliar tool in their practice and, in the case of participants, attend a focus group. Both of which will create some demand on their time. However, it is not anticipated that this will be overly-burdensome and participants will be able to contact the researcher to ask questions, on their or another's behalf, at any point in the study. As outlined, plans are in place to arrange groups as adjuncts to existing meetings wherever possible or undertake groups or interviews via web-based conferencing software.

The research question is, in part, concerned with understanding how the tool best works for practitioners where they have no choice but to undertake an assessment remotely. Accordingly, the tool will be promoted as a practical aide memoire of factors to be considered in remote assessments or as a useful way to gather relevant information via a proxy such as a care home manager or nurse. Otherwise it can act as a mental checklist prior to, and during, conversations. Whilst there might be some additional work involved in using the tool this needs to be balanced with the benefits that the tool might offer.

From personal communication with professionals working in practice at this difficult time, there is little formal support or guidance about how to undertake assessments remotely whilst at the same time an expectation that harm to clients/patients is minimised, which includes the up-holding of human rights to liberty and private and family life despite exceptional pressures brought about by the Covid-19 pandemic (Coronavirus Act 2020). At present, approximately ten thousand vulnerable people a week are dying as a result of this virus in care homes and many more in hospital settings (Altmann, 2020; Triggle, 2020). Whilst their physical health is of paramount importance their legal right to autonomy or care in their best interests as an individual has never been so starkly highlighted (Allen & Ruck Keane, 2020).

It is hoped that timely research to support professionals working in these circumstances through the provision of this tool will provide a valuable opportunity to contribute to safety and wellbeing of clients and professional (British Psychological Society, 2018b)

When using technology to support data collection a range of difficulties can be experienced including a lack of suitably equipment, limited technological skills on the part of the researcher or participants, breaches of security or feelings of intimidation on the part of participants (Hollander, 2004; Hydén & Bülow, 2003; Stover & Goodman, 2012). To address these considerations, the researcher will ensure that they are familiar and fluent in Microsoft Teams software, that practice groups are held with colleagues or supervisors beforehand, that support is offered to participants in using the software, that a password is used for online focus groups that are sent out in the email invitation and the day before, that will only permit participants to attend the discussions, the researcher will log into the group at least 15 minutes before to ensure help can be offered in a timely way to participants and participants will be asked to logon to the group at least five minutes before the official start of the discussion. Alternative means of interview will be offered including individual

interviews in person, over the web or over the telephone. Research indicates that these measures are all useful in addressing the barriers described (Tuttas, 2015).

Local health and care organisations and team managers have indicated that they would be happy to lend their support for the project, which would include providing relevant support to participants to take part where needed. Some participants might not be able to trial the tool with the optimal number of three clients in the six-week trial period. Participants will still have the opportunity to share their views in a group or individual interview irrespective of the number of times they have used the tool as their feedback is still likely to be of some value to the study. Four (20%) participants beyond the recommended number will be recruited to accommodate any attrition.

As a student, the researcher has limited experience undertaking empirical research using qualitative methods. As such, they will prioritise the development of research competencies in these methods of qualitative data collection and analysis.

Ethical issues pertinent to the study

Ethical considerations will be held in mind throughout the study by the researcher. The literature indicates that professionals can feel a sense of obligation to participate in research (Graham, Grewal, & Lewis, 2007). Full and informed consent will therefore be sought, which will include giving adequate time to think about whether people want to be involved and to ask questions. Participants will be given as much time as they need or until recruitment is complete. It will also be made clear in the information sheet, and in verbal discussions, that deciding not to participate will not affect their work or employment in any way. It is not anticipated that participants will require any additional cover from managers or colleagues in order to participate or that participation will disrupt service provision.

Whilst formal consent will be sought from anyone completing the tool on the decision-makers behalf, and from clients to use the tool as part of their assessment, they will not be directly participating in the study. This presents the risks of client voices, or those of health and care staff indirectly involved, being silenced or minimised and the potential for discomfort or distress through, for example, being involved in a capacity assessment, or DoLS process, which takes slightly longer than standard practice. An important benefit of an extended assessment period, however, might be that decision makers gather more useful and detailed information that facilitates a more informed and accurate decision. Clients, or those completing the tool on participants behalf, have the right to refuse to use the tool, the right to refuse an assessment (in the case of clients/patients), or to having the tool used as part of their

assessment, and professionals will be encouraged to prioritise client and colleague wellbeing over research aims if there is any indication that using the tool is contra-indicated.

To promote informed consent and protect clients' rights they will be asked if they would like a trusted person (e.g. family member) to look over the tool with them or talk to them about the proposed use of the tool with the support of the participant or their colleague completing the checklist. To provide space for client voices to be included in the research, clients living at a care home specialising in alcohol related brain injury have agreed to act as consultants to the research. They have provided their thoughts on the research design and will be consulted on other aspects of the study including dissemination. It is hypothesised that the tool will provide useful psychological information and a more structured approach to assessments, which should increase the likelihood of sound decision making and confidence on the part of decision makers and therefore additional safeguards and quality of care for clients in a time of a global health crisis.

It will not be possible to ensure that all participants have not had personal contact with the field supervisor (who is also the developer of the tool). As such, to protect confidentiality and to reduce bias in the study, the field supervisor will not have access to the names of participants and will only see data once it has been anonymised and coded into themes. Participants will have the right to withdraw their participation up-to two weeks after interview (in the case of individual interviews) or to withdraw their data from the final write up (in the case of focus group participants).

Attention will be paid to the removal of names, dates, locations and organisations in the transcription of the data and audio recordings will be deleted once the thesis has been submitted and assessed. Consideration will be given to the selection of quotes or conversation extracts to ensure that they are anonymous. Participant assignment numbers will be used instead of names. Recruitment sites, organisations or places will be disguised and the professional role of the participant will not be reported if this is likely to risk identification (for example where only one DoLS MHA is recruited to the study). Quotes from participants will be used in academic submissions and any subsequent publications. Participants will be made aware of this and informed that that every effort will be made to ensure that information in the report cannot identify participants.

In line with The British Psychological Society's code of ethics, consideration has been given to whether this tool, as an addition to existing practice, is adequately supported by the evidence (British Psychological Society, 2006). The literature, indicates that professionals outside Clinical Psychology often have limited psychological knowledge about

how damage to the brain can affect decision making, which can affect the accuracy of some complex capacity decisions, putting clients at risk (British Psychological Society, 2018a; George & Gilbert, 2018). This tool includes questions, ideas and prompts to address this knowledge gap. Further, the structure and content of the tool is informed by an earlier, published, iteration of the document (Mackenzie et al., 2008) by current neuropsychological theory, relevant case law and Court of Protection guidance

Participants might disclose examples of poor practice or safeguarding concerns during the course of the research. These issues may present a risk to confidentiality as they may need to be shared or reported to ensure client wellbeing. The procedures that the researcher or supervisors will follow in these instances will be made clear in written information and reiterated verbally before discussions. Reporting of poor practice or safeguarding concerns will take place in line with University policies and procedures as well as relevant organisational procedures. Concerns will be discussed with participants wherever possible and, if necessary and required, advice will be sought from supervisors.

It is not anticipated that participants will experience discomfort or harm as a result of taking part in this study. Questions asked will not be intentionally sensitive or distressing. However, the process of sharing experiences might elicit discomfort if, for example, using the tool was experienced as challenging or if it highlighted areas of practice where improvements could be made. To minimise and manage any distress or discomfort the researcher will provide email and telephone contact details that participants will be encouraged to use if they, or any colleague completing the tool on their behalf, have any questions or concerns during the study. Where necessary, advice will be sought from supervisors about how best to support participants. During discussions, the researcher will utilise clinical skills to contain difficult emotions and to ensure discussions remain constructive. Debrief sheets will contain information about occupation health services and relevant support charities and, where needed, professionals will be encouraged to seek support from their GP or work supervisor. Participants will be encouraged to share debrief sheets with anyone who has completed the tool on their behalf as appropriate. This will be done via participants to protect the anonymity of these professionals. Regular meetings will also be held between the researcher and academic supervisors to discuss any practical or ethical concerns.

It is not expected that there will be any risks to the researcher or the assistant psychologist supporting the focus groups. The researcher will endeavor to undertake face-to-face groups and interviews on NHS premises and in the rare situation of this not being

possible the University lone worker policy will be followed. A university email and mobile phone will be used when communicating with participants. If any information is shared that could cause distress to the participant or researcher academic supervision will be used to discuss this. The assistant psychologist supporting any face-to-face focus group will have the option of talking to the researcher about any issues raised by the project who will seek advice from academic supervisors where required.

Dissemination

For additional rigor in dissemination the impact and communication tool developed by the Economic and Social Research Council will be used to document the final plan devised with stakeholders and to outline the justification for planned actions (Economic and Social Research Council, 2019).

Sponsorship and monitoring

This study is being sponsored and by Lancaster University and adherence to ethical principles, practice and approved protocols will be monitored by this institution.

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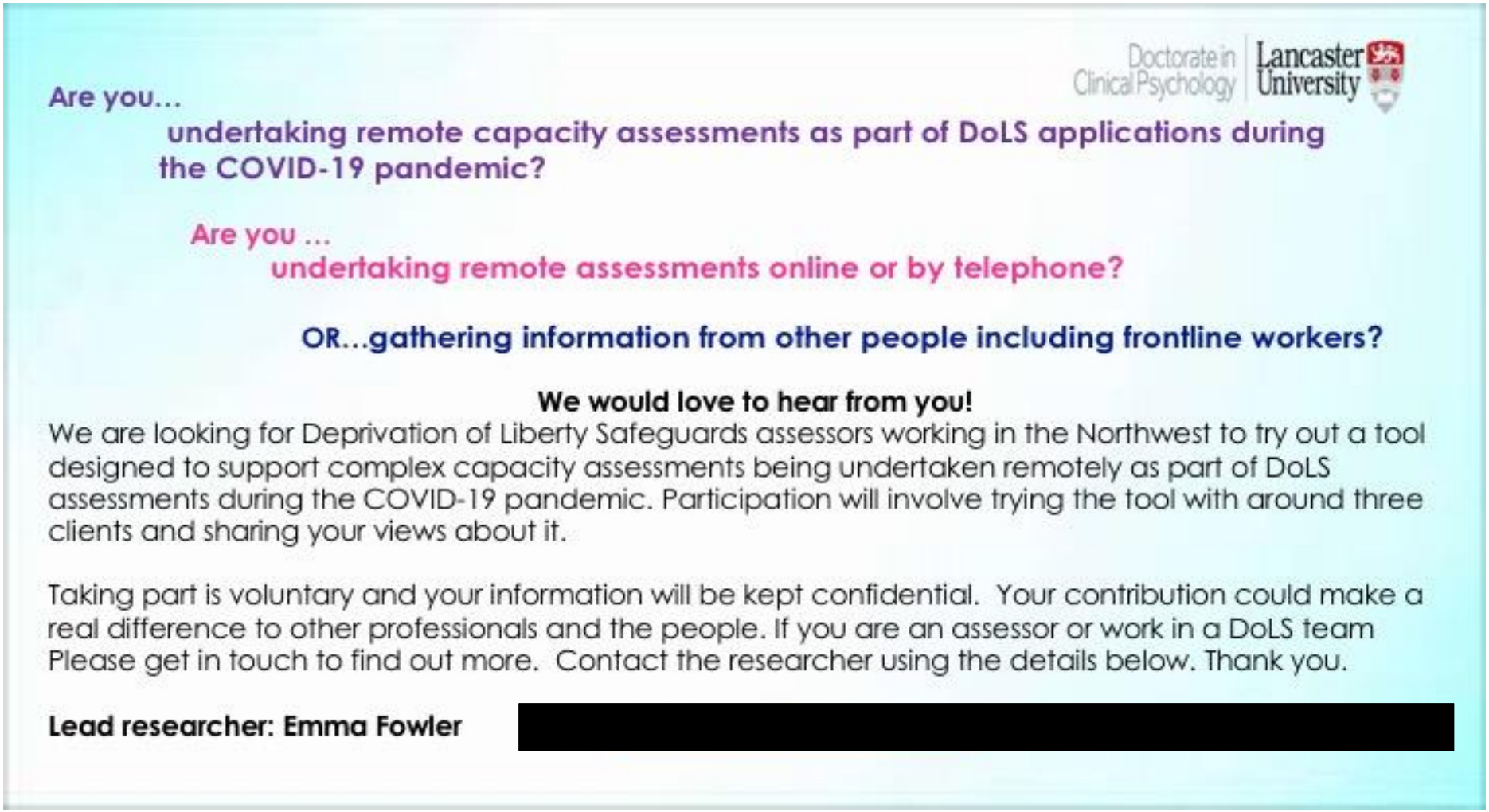
Appendix 4-A

Research Advertisement



Appendix 4-B

Participant Information Sheet

(Version 3, 18th April 2020)

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Doctorate in Clinical Psychology | Lancaster University ¶

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Participant Information Sheet¶

¶

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study¶

¶

My name is Emma Fowler and I am conducting this research as a Doctoral student on the Clinical Psychology course at Lancaster University, Lancaster, United Kingdom.¶

¶

What is the study about?¶

The purpose of this study is to evaluate whether professionals in health and care services experience a tool designed to support remote assessments of capacity in the context of a global health crisis as useful, acceptable and practical.¶

¶

Why have I been approached?¶

You have been approached because you are a Deprivation of Liberty Safeguards (DoLS) assessor and your role involves undertaking remote capacity assessments as part of necessary measures that have been put in place to protect clients as a result of the COVID-19 pandemic.¶

¶

Do I have to take part?¶

No. It is up to you to decide whether to participate in this study. If you would like to participate, you can send a completed consent form back to me by email or post within one week of receipt of the study information. If you decide you do not want to participate in this study, it will not prejudice your work or employment in any way. ¶

¶

The aim of this study is to evaluate the feasibility of rolling-out a capacity tool as part of wider research and not about individual performance management.¶

¶

What will I be asked to do if I take part?¶

If you consent to take part, you will be asked to provide basic demographic details. ¶

¶

You will be sent a copy of the capacity tool, which is a type of semi-structured interview checklist, and associated guidance and asked to familiarise yourself with it before trying it out. If you have any questions or want to talk about the tool, you will be able to contact the researcher at any point during the research. ¶

¶ 1

¶

The tool is designed to be used flexibly as part of a remote, or desktop, capacity assessment. For example, you might decide to ask someone directly caring for the person to complete the tool with them and talk to you about the information they gathered afterwards. Another option might be to use it as the basis for an conversation with a frontline worker to give you a better sense of the person's abilities.

It is designed to support your practice by encouraging the collation of, and reflection on, psychological issues that might be relevant when working remotely with clients with complex presentations. It is not intended to replace official guidance or prescribed documentation.

You will be asked to use the tool with approximately three people for whom a DoLS application or review has been sought by a hospital or care home. You will have six weeks to try out the tool. You will then be asked to share your experiences of using the tool in a focus group.

The group will last for around 60 minutes and will take place via face-to-face or online meetings if social distancing measures continue. An audio or audio-visual recording of the discussion will be taken that will be transcribed verbatim by the researcher. If you are unable to attend a group, it might be possible for an individual interview to be arranged.

We may contact you again over the year following your use of the tool, at around six and 12 monthly-intervals, to identify whether the use of the tool had any sustained impact on client outcomes. However, we understand that DoLS assessments are typically discrete pieces of work and this information might not be available.

Once the data has been analysed, you will have the opportunity, if you wish, to comment on initial themes arising from the data and review the quotes selected to illustrate them.

Will my data be Identifiable?

Attention will be paid to the removal of names, dates, locations and organisations in the transcription of the data. You will be assigned a participant identification (ID) number at the beginning of the research that will be used as a proxy for your name in the transcription. Only the researcher and assistant psychologist supporting focus groups will know your ID number. Recruitment sites, organisations or places will be disguised and the professional role of the participant will not be reported if this is likely to risk identification.

Limits to confidentiality

Some of what you share may be used as a quote in the academic submission and any subsequent publications. As such, confidentiality cannot be guaranteed. However, full consideration will be given to the selection of quotes or conversation extracts to ensure that

¶

they are anonymous and that there is no reference to your name, client information, where you work or your organisation. ¶

¶

If you share information about a client that makes me think that you, the client or someone else, is at significant risk of harm, I will have to share this information with an academic supervisor and act in line with the safeguarding requirements. If you share information that is indicative of poor practice that presents a risk to client care I will discuss this with you. In some instances, I might need to seek advice but I will always try to talk to you about this first. ¶

¶

Are there any risks? ¶

Trying out the tool and attending a focus group will require some investment of your time. To minimise the impact of this we will do everything possible to arrange focus groups at times that are convenient for you. ¶

¶

The tool was designed by Dr Janice Mackenzie, Consultant Clinical Neuropsychologist, who is also acting as a supervisor in this research. It is possible that some participants may have had personal contact with Dr Mackenzie. To protect your anonymity, Dr Mackenzie will not know the names of anyone participating in this study and will only have access to the research data once it has been organised into themes and fully anonymised. ¶

¶

We ask that you seek formal consent from clients and to use the tool. You will be sent a consent form that can be forwarded to them by email. Frontline workers might be required to help with this process; for example by printing the form. We also ask that you seek formal consent from a relevant frontline worker if they are providing information about capacity or completing the tool with the person. This can be done on the same form. These can be kept in client records. ¶

¶

In line with good practice, client wellbeing should be prioritised over research aims and the tool should not be used if there is any indication that it may be unhelpful, or cause distress. ¶

¶

If you consent to participating in this research, you will be able to withdraw from the study at any time and ask that your data not be included in the final report up to two-weeks after the focus group. If you participate in a focus group it will not be possible removed your data from anonymised transcripts as it will form part of the discussion held in the group. ¶

¶

Information about data transfer and storage ¶

Data transfer, for example of recordings, will be done using encrypted equipment once files or documents have been password protected. The University will retain electronic versions of all documents including participant signed consent forms, demographic information, discussion/ interview recordings, focus group notes and transcripts on secure University

¶ 3

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servers. Recordings and any other personal data will be deleted from University secure servers once the thesis has been submitted and assessed.

The Doctorate in Clinical Psychology Team at Lancaster University will store electronic data on University secure servers for ten years.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

What will happen to the results?

The results will be submitted as part of my doctoral thesis at Lancaster University. The report may be submitted for publication in an academic or professional journal. In addition, it will be discussed at the thesis presentation day at Lancaster University and might be discussed at conferences, special interest groups or other relevant public presentations.

Are there any benefits to taking part?

Yes. We think that the tool will provide you with a useful, structured supplement to assessments during a time when normal practice and avenues for information gathering have been curtailed. In turn we hope that using the tool will enhance care and help to uphold peoples' legal and human rights. You will have free access to the tool after the study is complete to acknowledge your contribution to the study.

Your feedback on the feasibility of using the tool in practice will help us decide whether it would be useful to share the tool more widely, undertake larger-scale research and understand which professional or client/patient groups the tool might benefit the most.

Who has reviewed the project?

This study has been reviewed by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University and has received NHS research governance approval.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

Emma Fowler, Trainee Clinical Psychologist

[redacted]

Supervised by:

Dr Guillermo Perez Algorta, Faculty of Health and Medicine, Lancaster University. Email: [redacted]

Dr Suzanne Hodge, Faculty of Health and Medicine, Lancaster University. Email: [redacted]

Dr Anna Duxbury, Faculty of Health and Medicine, Lancaster University. Email: [redacted]

Dr Janice Mackenzie, Consultant Clinical Neuropsychologist, [redacted]

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Professor Bill Sellwood, [redacted]

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Roger Pickup, Associate Dean for Research, [redacted]

Thank you for taking the time to read this information sheet.

Resources in the event of distress

Should you feel distressed, either as a result of taking part or in the future, please contact your manager or supervisor in the first instance. The following resources may also be of assistance:

Occupational Health Services: Contact your employing organisation for more information about occupational health support.

Your GP or local primary health care service

Samaritans: The Samaritans can provide emotional support and a safe place to talk.

They can be contacted by phone on 116 123 or by email at jo@samaritans.org

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Appendix 4-C

Participant Consent Form

Doctorate in Clinical Psychology | Lancaster University

Participant Consent Form

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A Feasibility study

We are asking if you would like to take part in a study that will evaluate whether DoLS assessors experience a tool designed to support remote assessments of capacity as useful, acceptable and practical.

Before you consent to participating, we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions before signing the consent form please speak to the researcher, Emma Fowler, Trainee Clinical Psychologist, at Tel: [redacted]

	Initial here
1. I confirm that I have read the information sheet (version 4, 18.04.2020) and fully understand what is expected of me within this study **(please initial in the box)**	
2. I confirm that I have had the opportunity to ask any questions and to have them answered	
3. I understand that I do not have to participate in this study	
4. I understand that I will be asked to try out a capacity tool with approx. three clients	
5. I consent to taking part in a focus group or interview	
6. I understand that participation will involve asking clients and, where necessary, frontline staff to complete a consent form that they will keep in their own or in client records.	
7. I understand that my views will be recorded and typed up verbatim into an anonymised transcript	
8. I understand that I can withdraw my data from the final report up-to two weeks after the focus group. I understand that anonymised focus group transcript data cannot be withdrawn as it forms part of the discussion that took place. I understand that all individual interview data can be withdrawn up-to two weeks after the interview.	
9. I understand that any information I give will remain confidential and anonymous unless it is believed that there is a risk of harm to myself or others, in which case the researcher will need to share this information with research supervisors	
10. I understand that the researcher will discuss data with academic supervisors as needed	
11. I consent to the researcher sharing initial themes from focus group notes via email	
12. I understand that the results and written report will be submitted as part of a doctoral thesis and may be published	
13. I consent to information and quotes I might share being used in reports, conferences, training events and other relevant public presentations	
14. I consent to the Clinical Doctorate in Psychology team at Lancaster University keeping audio transcripts, notes and other documentation that does not contain personal data for ten years after the study has finished	
15. I understand that the researcher might get in touch six months, and again at 12 months, after using this tool to try and identify whether the tool impacted on client outcomes	
16. I consent to take part in the above study	

Name of Participant_____ **Signature**_____ **Date**_____

Name of Researcher_____ **Signature**_____ **Date**_____

One copy of this consent form should be retained by the participant and one copy by the University.

Appendix 4-D

Combined Client and Worker Consent Form

(Version 1, 18th April 2020)

Doctorate in Clinical Psychology | Lancaster University

Client and Frontline Worker Consent Form

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A Feasibility study

My name is Emma Fowler and I am doing some research for my University course. I am training to be a Clinical Psychologist at Lancaster University.

Someone working with you has asked you to complete this consent form because you are staying in a hospital or care home. Someone called a "Deprivation of Liberty (DoLS) assessor" has been asked to find out what you know about your care or treatment. They want to find out if you agree to staying in the hospital or the care home.

I am asking your assessor to include our questions and ideas in their assessment. I have called this a capacity assessment tool. Someone involved in your care (a frontline worker at the hospital or care home) might complete the tool with you on behalf of the assessor. They will sign this form too. I hope that it will help the assessor to make the best decision they can, even though they cannot meet you face-to-face.

If you have any questions before signing this consent form please speak to the person that has given you this form. Where needed, the DoLS assessor can ask the researcher for more information to answer your question.

	Client Initials	Worker Initials
1. I have had the opportunity to ask any questions and to have them answered	☐	☐
2. I understand that I do not have to agree to the tool being used as part of a conversation with me about this hospital or care home stay	☐	☐
3. I understand that I do not have to agree to the tool being completed remotely on the DoLS assessors behalf	☐	☐
4. I understand that the DoLS assessor will talk to the researcher about their experience of using the assessment tool with me	☐	☐
5. I understand that any information I give will be confidential and anonymous unless someone thinks that there is a risk of harm to me or someone else. In these situations the concerns will need to share this information with other professionals to keep everyone safe	☐	☐
6. I understand that the DoLS assessor might get in touch with the hospital or care home six months, and again at 12 months, after using this tool to help the researcher find out if the tool had any impact on care.	☐	☐
7. I consent to taking part in this study	☐	☐

Name of client_____ **Signature**_____ **Date**_____

Name of frontline worker_____ **Signature**_____ **Date**_____

Please keep this consent form safe in your records or in your hospital or care home records. Please keep this consent form for one year from the date it is signed. After this you can destroy it or the hospital /care home can destroy it in their confidential waste.

Appendix 4-E

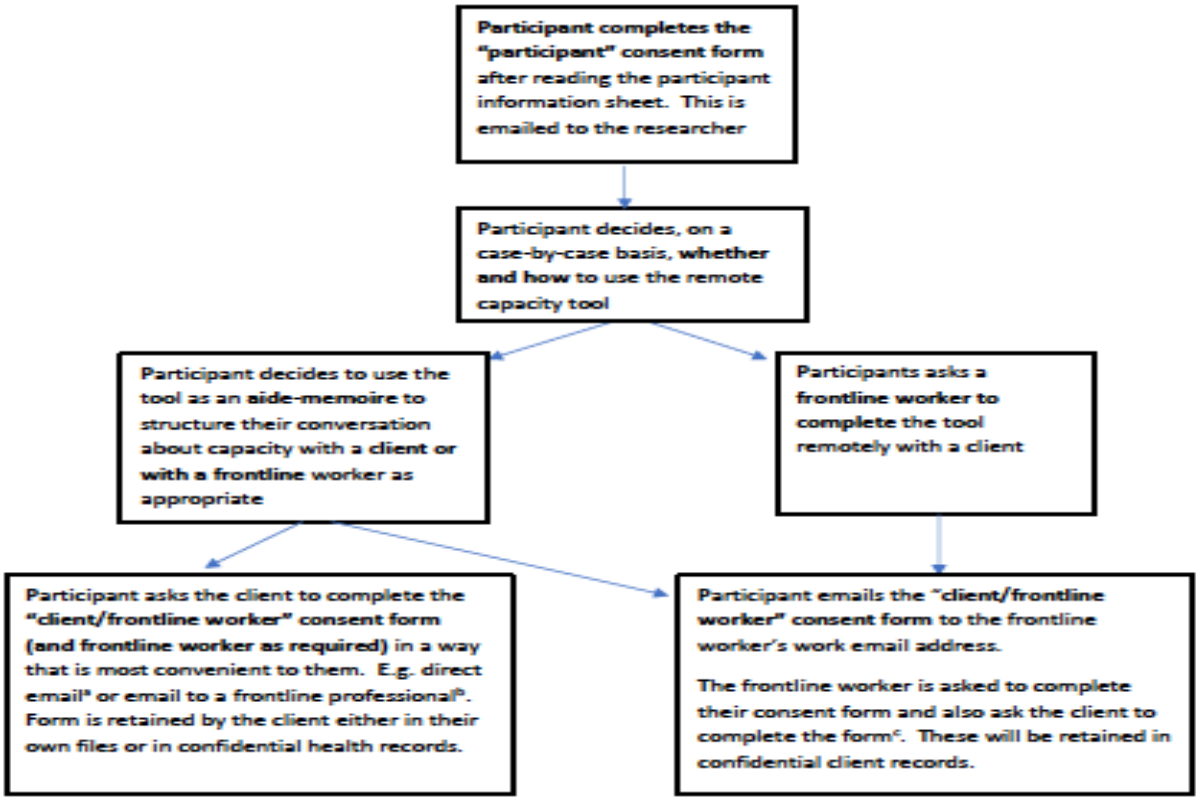
Consent Process Flowchart

IRAS: 272214 V.1.0 18.04.2020

Doctorate in Clinical Psychology | Lancaster University

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study

Consent process flowchart



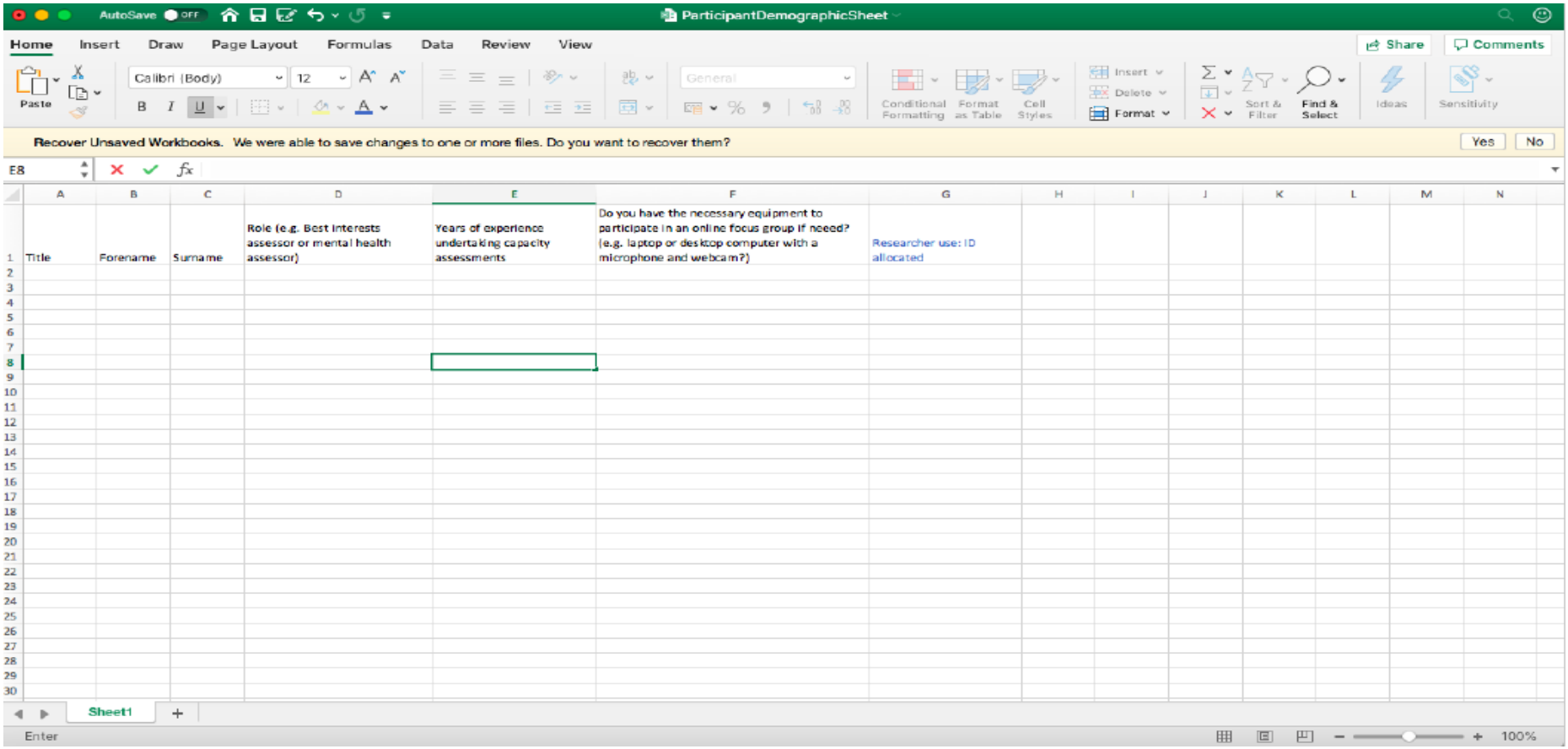
[a] An email inbox of the client's choosing. The participant will check that it is only accessible to trusted people (e.g. their own inbox or that of a family member).

[b] Emails to frontline workers will only be sent to professional inboxes either their own or an organisational inbox. Emails will not reference the clients name.

[c] Either the participant or frontline worker will offer the client basic support in completing the "client" consent form as needed. This might include reading the consent form aloud or checking they have they're glasses available when they read it.

Appendix 4-F

Demographic Information Sheet (Version 2, 18th April 2020)



Appendix 4-G

Remote Assessment Tool to Consent to Care Arrangements (Version 2, 18th April 2020)

Doctorate in Clinical Psychology | Lancaster University

Remote Assessment of Capacity to Consent to Care or Treatment Arrangements as part of a Deprivation of Liberty Safeguards (DoLS) authorisation application

(Developed by Dr Janice Mackenzie, Consultant Clinical Neuropsychologist)

Name of person requiring assessment: _____ **Date:** _____

Name and job title of staff member discussing capacity assessment: _____

This **remote working checklist is intended for use in situations where a capacity assessment is being done remotely as a result of specific measures in place to protect the person /patient.** Please use this flexibly as befits your circumstances. For instance, you might decide to ask the care providers to complete it with the person face-to-face if this is feasible. At which point, it could be used as the basis for a conversation about the evidence they have gathered. Alternatively, you may want to use it to guide your discussion with the care provider, ticking each question as you discuss them.

Decision-makers will still be responsible for making the final decision about the person's capacity based on evidence gathered using all practicable steps available.

Remote assessment checklist

This checklist can be completed by someone who knows the person/patient in circumstances where the person responsible for the capacity assessment (e.g. the Deprivation of Liberty Assessor) is doing a **remote assessment as part of a DoLS authorisation application.**

If you are a staff member completing it for a DoLS assessor, try to get the best information you can, whilst enhancing the person's capacity, and share what you find with the DoLS assessor. You can use the notes column to record what the person/patient said and continue on an additional sheet if necessary.

How did you enhance the person's capacity before and during the capacity assessment?

_____

_____

_____

Before completing the checklist, **write down the main problems** over the page that you/people involved in the person's life think the person/patient has that could put him/her at risk if he/she left the hospital or care home.

(Examples of issues to think about: Getting in and out of bed, washing and dressing, going to the toilet, eating and drinking, buying and preparing food, taking medication, doing housework, community mobility and transport – e.g., getting to shops and appointments, road safety

awareness, vulnerability, risk to self and others – e.g., anger management problems or challenging behaviour)

Main problems

1.....

2.....

3.....

4.....

Any others?.....

	Questions to explore with the person / patient	Yes	No	Not sure	Notes (e.g. what the person said or observations of behaviour) – continue on another page if required
1	Does the person know where they are and what type of place they are in? *(Give options if necessary, e.g., is it a care home, a hospital, or a hotel? Provide the answer if the person is incorrect)*				
2	Does the person know why they are there? (Note response) *(If necessary, provide the answer for them.)*				
3	Has the person noticed any physical problems they might be having? (Note responses) *(Prompt as needed: e.g. any problems with legs/walking, arms, vision, washing and dressing, going to the toilet, eating and drinking?)*				

	Questions to explore with the person / patient	**Yes**	**No**	**Not sure**	**Notes**
4	Have they noticed any changes to their memory, their attention or their problem-solving skills? (Note responses)				
5	Have they noticed any changes to their mood, personality or their relationships with other people? (Note responses)				
6	Go through the problems you've listed at the top of this checklist with the person, explaining that these are things the staff / their family have noticed. Does the person think they are having problems with these things? (Note responses)				
7	If the person agrees that they are having some problems: Does the person think these problems would affect them if they left hospital or the care home now? How?				
8	Describe the treatment and care plan to the person. *(e.g. help with washing and dressing / going to the toilet, physiotherapy to help them walk, OT to help them relearn kitchen tasks etc)*				

	Do they think they need this help?				
	Questions to explore with the person / patient	**Yes**	**No**	**Not sure**	**Notes**
9	Describe to the person the restrictions you will use to provide treatment and/or care or to keep them safe. *(e.g. locked door, supervision from staff, being escorted when leaving the ward/home, no access to their medication)* Do they think they need these restrictions? If not, why not?				
10	Does the person think that they would need help/care/support if they left the care home/hospital now? (What would they need help with, how often, for how long and who would provide this help?)				
11	Does the person think that there would be any problems if they were to leave and live without support at this moment?				

Share the options below with the person. If there are more than three you can add them to the bottom of the table. Ask them about the reasons to say yes / good things about each option and the reasons to say no / problems / risks of each option.

	Reasons to say yes to this option (from the person's perspective)	Reasons to say no to this option (from the person's perspective)
Option 1: Stay in hospital or care home under the existing or planned restrictions that are specific to their care and/or treatment *(e.g. not managing their own medication or not going out alone)*		
Option 2: Stay in the hospital or care home with the general restrictions of the hospital or care home *(e.g. asking or buzzing to have the main door unlocked, no direct access to the kitchen or restricted visiting times)*		
Option 3: No restrictions *(e.g. going out without telling staff or leaving completely if you want to and living somewhere else)*		

	Questions to explore with the person / patient	Yes	No	Not sure	Notes (e.g. what the person said or observations of behaviour) – continue on another page if required
12	Which of the options discussed with the person would be their choice? Why?				
13	Does the person think that their choice would affect anyone else? If so, whom? How would it affect them? *(e.g. those expected to provide the care)*				
14	When you tell the person that you think they would be at risk leaving hospital/ the care home now due to (the problems you listed), do they believe you? If not, why not?				

Additional notes……

……

……

……

……

……

Thank you for your help if you have completed this on behalf of the DoLS assessor

For the decision maker: Decision regarding the person's capacity

Can the person:

1. Understand the relevant information in relation to his/her own circumstances? YES / NO
2. Retain the relevant information? YES / NO
3. Use and weigh up the relevant information to arrive at an informed choice? YES / NO
4. Communicate that choice? YES / NO

Does the person have the capacity to make a decision about care and treatment arrangements at this point in time?

YES / NO

Signed:

Designation:

Appendix 4-H

Guidance to Accompany Capacity Tool for Decision-Makers (Version 2, 18th April 2020)

Doctorate in Clinical Psychology | Lancaster University

Threshold for understanding the relevant information in order to have the capacity to make a decision regarding admission to hospital or a care home for care and treatment in the context of a remote assessment using the Remote Assessment Checklist

Introduction:

This guidance can be shared with the person completing the Checklist or used as a prompt for the decision-maker.

The decision-maker (e.g. the DoLS assessor) should ensure everyone knows what is, and is not, required of them. If the person completing the Checklist is not making the final decision about capacity, then explain this clearly. Make sure the person completing the Checklist is familiar with it and happy to use it.

As the Checklist will be used as part of a research project, whoever is completing the Checklist will need to consent the client/patient. This will usually mean asking the client/patient if they are happy for the Checklist to be used as part of their assessment. Possible pros and cons to be discussed are that it may take a bit longer but it may result in a more comprehensive assessment. If the client refuses, or lacks capacity to consent, it should not be used.

Providing the relevant information to the client/patient:

Please make sure that the person undertaking the Remote Assessment Checklist (e.g. member of the care team) has provided as much relevant information as possible to the client/patient in a way that they can understand before the Checklist is completed. Where possible, help them to consider how information might be individualised for the client/patient. The examples below are to help you think what might be required, rather than to be used for everyone.

Remember ways to enhance someone's capacity:

- Resources that might help the person to understand, remember, use and weigh the relevant information: Timelines, scan results, pictures, easy-read information leaflets, decision trees, bullet points of the relevant information
- Dealing with potential barriers to communication: hearing aids are in place and are working, facilitating lip reading, glasses on, minimising background noises and distractions, good practice in the use of interpreters
- Ways to reduce anxiety: support from familiar people, reassurance, private environments

¶

What the person needs to understand in order to make an informed decision:¶

1. The person needs to understand: ¶
   a. Roughly where they are (i.e., in hospital or in a care home – they don't have to know the name) ¶
   b. Why they are here (e.g., for treatment of continence problems, rehabilitation of walking, help to 'get back to normal', to learn to do things for themselves again, rehabilitation after a brain injury, to be 'looked after' or supported) ¶
   - This addresses 'why the decision needs to be made' ¶
   - It doesn't matter if they are not sure of the cause of their problems ¶

   ¶
2. The person needs to understand: ¶
   a. What the proposed care and treatment will be in general terms (e.g., hoist transfers, assistance with washing and dressing, rehabilitation for physical and/or cognitive problems etc.) ¶
   b. Why they need this care and treatment (e.g., 'because I can't walk' or 'I can't do it myself') ¶
   c. The good things/benefits of this care and treatment (e.g., they will receive the care that they need, the rehab will hopefully help them to improve, they will be safe) ¶
   d. Potential downsides of this care and treatment (e.g., they won't be with their family or in their own house, they will be restricted in what they can do and eat, they have to share a room with other people) ¶
   e. The good things/benefits if they did not receive this care and treatment and left hospital (e.g., being at home and with their family, having less restrictions on them, having more privacy) ¶
   f. The potential downsides and general risks if they did not receive this care and treatment and left hospital (e.g., being unable to look after themselves, being unable to get out of bed, the possibility of being knocked down by a car, the possibility of ending up back in hospital through another injury or illness due to their care needs not being met, not improving as much as they might have due to the lack of rehabilitation) ¶
   g. Their care needs on discharge and how these realistically would be met if they want to leave hospital or the care home (e.g. not saying that their family will do it all when they all work full-time) ¶

   ¶
3. The person needs to understand: ¶
   a. The restrictions that are inherent in the environment (e.g., locked doors, staff keeping a note of where they are) ¶
   b. The restrictions that they might be subject to personally due to the care and treatment provided (e.g., 1:1 supervision, accompanied visits off the ward or out of the care home) ¶
   c. The consequences of the restrictions (e.g., not being allowed off the ward or out of the care home by themselves, someone being with them all of the time) ¶

¶

¶

Remembering the relevant information:¶

- Ongoing decisions such as admission for care and treatment require the person to be able to retain the relevant information over time, not just in the short assessment period, so that they can use the information in the next week or month.¶
- This requires carryover between assessment sessions (it is always better to do more than one assessment session for this reason and for others, such as slow processing speed, unless it is obvious that the person does or does not have the capacity to make the decision).¶
- For example, if the person needs to stay in hospital for treatment and rehabilitation and she would be at risk if she self-discharged then she needs to be able to remember this for the whole of the admission and not just for 10 minutes with prompting during the assessment. It is the same for staying in a care home for support and care.¶

¶

Remote assessments:¶

It might not be possible for the decision-maker to achieve the same amount or quality of evidence when undertaking an assessment remotely as they might have obtained face-to-face with the client/patient. However, it is hoped that the Remote Assessment Checklist will be of value in unusual contexts such as the current Covid-19 pandemic where official guidance has included instructions that visits to clients/patients should only happen when necessary (Judiciary of England and Wales, March 2020). In these instances, decision-makers should be clear about the basis for their assessments in their notes (Judiciary of England and Wales, March 2020). Noting the questions asked or the tools used along with the decision on capacity would be good practice.¶

¶

Dr Janice Mackenzie¶
Consultant Clinical Neuropsychologist¶
April 2020¶
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Appendix 4-I

Question Route for Focus Groups (Version 2, 18th April 2020)

¶

Doctorate in Clinical Psychology | Lancaster University ¶

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study¶

Question route ¶

Introduction (information in brackets relates to face-to-face or online groups only to be read out where relevant) ¶

Welcome to our focus group and thank you for agreeing to contribute to the group discussion. My name is Emma Fowler and I'm the principle researcher. (Gemma Barlow (Assistant Psychologist) will be helping me to facilitate our discussion). We want to hear from you about your experience of using the capacity tool. We will use your feedback to help determine whether it is feasible to undertake larger scale research on the tool. (You have been provided with a copy of the tool today to remind you of its content and layout). You were chosen because you undertake capacity assessments as part of your role. ¶

We will be asking about aspects of the tool you found useful and perhaps less useful. We will ask about whether the tool impacted on your practice. We will also ask about how this tool might be rolled out to other services in the future. There are no wrong answers. We are interested in differing perspectives so please feel free to share your experience even if these differs from other people's in the group. We are just as interested in any challenges you experienced in using the tool as well as positive experiences. ¶

Before we begin I'd like to suggest some things that should help to make the discussion more productive. Please speak up as clearly as you can to ensure that your point is heard. Please try and talk one person at a time. For confidentiality we ask that you only refer to each other using first names and try to avoid using the names of anyone you work with or specific organisations. ((Name of AP) will make non-verbatim, anonymised notes of ideas that seem significant). The discussion will be recorded (AV recorded if web-based conference). I will also be using a dictaphone devise as a back-up recording. This will be deleted straight away if not needed. Only my academic supervisors and I will hear (see) the recording or see the anonymised transcript. I will type up an anonymised transcript from the recording as soon as possible. The recording, transcript and notes taken during the group will be stored securely using password protected and encrypted software on University systems. ¶

I will be using anonymised quotes to illustrate findings. I will share the quotes I intend to use and themes arising from the discussions with you before finalising the report. You are invited to share your comments on this with me by email or on the phone. If you share anything today that suggests that you or someone else is at risk or in danger, I will need to act on that information as outlined in the information sheet. (I have made copies of the information sheet available today). Does any one have any questions about any of this? ¶

¶

I'll be asking questions and listening. (I will write the question in the comment box as well as asking it verbally). I will not be part of the discussion but I want you to feel able to talk to each other. It is typical for some people to share more within a group but we would like to hear from everyone. As such, I may need to move the discussion along at times or ask other people to talk if you have already shared a lot of information. (You have a name card in front of you to help you to remember each other's names). (You have the option to mute your microphone or camera at any time and you can share your thoughts via microphone only if you prefer). We will be finished by…. Towards the end I/we will share what we think some of the main points were and you can tell us/me if I/we have missed anything or misunderstood a point. Let's find out a bit more about each other…

1. Could you briefly tell the group your name and your role? *(opening question to warm the context)*

2. What did you think about the tool?

3. In what circumstances did you use the tool?

4. How did you use this tool? *(prompt where needed e.g. asking someone to complete it for you, as a basis for discussion with another professional or something else?)*

Before we talk about the tool any more we would like you to make a brief mental note of a question or section that you found useful and one which was least useful. (We have provided a copy of the tool as a reminder of the content if needed).

5. What section of the tool, if any, did you find most useful when doing your remote assessment?
   Follow up question if needed: "what made this section useful?"

6. What section of the tool, if any, did you find least useful when doing your remote assessment?

7. If I asked the client or the member of staff that completed the remote checklist (on your behalf) how they experienced the tool – what might they say?

8. Do you think that using the tool made a difference to your practice?
   (This question speaks to knowledge awareness and decision accuracy so follow-up questions will be asked in these areas where required)

9. How could this tool be best used in services in the future?
   (This question speaks to how, who and in what setting the tool could be most useful)

10. If we did further research on this tool how would we know if it had improved professional practice?

¶

¶

¶

11. Finally, if you were responsible for implementing this tool with professionals, what key point would you stress to sell it?¶

Summary¶

Thank you for sharing your views today, your contribution is much appreciated. From what I/we have heard the following ideas have been discussed today (verbally list them). Do these ideas or themes reflect what you think is important for me/us to know about the tool? If not, could you briefly say what might be inaccurate or missing?¶

I will now (hand / email out to you) a debrief sheet with information about sources of support should you need them. You can expect to receive a summary of the themes by (X date—within one month of the focus group). Please do contact me if you have any questions following the focus group. As outlined in the information sheet you have up to two weeks to withdraw your data from the final write up should you wish to. Once all the groups and interviews have taken place we will undertake the prize draw and notify the winner by email. Thank you again.¶

¶

If not already discussed as part of the previous question.¶

Question included following consultation with service-users.¶

¶

Appendix 4-J

Individual Interview Schedule (Version 2, 18th April 2020)

¶

Doctorate in Clinical Psychology | Lancaster University ¶

Using an assessment tool to support capacity assessments undertaken remotely in the context of a global health crisis: A feasibility study ¶

Individual interview schedule ¶

Introduction (information in brackets relates to face-to-face or online groups only to be read out where relevant) ¶

Thank you for agreeing to this interview, I really appreciated you giving your time to share your views. I want to hear about your experience of using this capacity tool. Your feedback will help to determine whether it is feasible to undertake larger scale research on the tool. You were chosen because you undertake capacity assessments as part of your role. ¶

I will be asking about aspects of the tool you found useful and perhaps less useful. I will ask about whether the tool impacted on your practice. I will also ask about how this tool might be rolled out to other services in the future. There are no wrong answers so please feel free to share your experience. I am just as interested in any challenges you experienced in using the tool as well as positive experiences. ¶

Before we begin I would like to reiterate some things that were outlined in the information sheet. For confidentiality we ask that you try to avoid using the names of anyone you work with or specific organisations. Our discussion will be recorded (AV recorded if web-based conference and I will also be using a dictaphone device as a back-up recording if web conferencing. This will be deleted straight away if not needed). Only my academic supervisors and I will hear/ see the recording or see the anonymised transcript. I will type up the transcript from the recording as soon as possible. The recording and transcript will be stored securely using password protected and encrypted software on University systems. ¶

I will be using anonymised quotes to illustrate findings. I will share the quotes I intend to use and themes arising from all of the interviews and groups discussions with you before finalising the report. Please do share your comments on this with me by email or telephone. If you share anything today that suggests that you or someone else is at risk or in danger, I will need to act on that information in-line with University and (name of employing organisations) procedures (I have brought along a copy of the information sheet that you can read over or take away if you want to). Do you have any questions about any of this? ¶

I may need to move our discussion along at times to ensure that I get your thoughts on each area for discussion. We will be finished by… (I've brought along a copy of the tool that you are welcome to use as a reminder of the content and layout if needed during our discussion). ¶

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1. What did you think about the tool? ¶

¶

2. In what circumstances did you use the tool? ¶

¶

3. How did you use this tool? *(prompt where needed e.g. asking someone to complete it for you, as a basis for discussion with another professional or something else?)* ¶

¶

4. What section of the tool, if any, did you find most useful when doing your remote assessment? ¶

Follow up question if needed: "what made this section useful?" ¶

¶

5. What section of the tool, if any, did you find least useful when doing your remote assessment? ¶

¶

6. If I asked the client, or the member of staff that completed the remote checklist (on your behalf), how they experienced the tool – what might they say? ¶

¶

7. Do you think that using the tool made a difference to your practice? ¶

¶

8. How could this tool be best used in statutory services in the future? ¶

(This question speaks how, who and in what setting the tool could be most useful) ¶

¶

9. If we did further research on this tool how would we know if it had improved professional practice? ¶

¶

10. Finally, if you were responsible for implementing this tool with professionals, what key point would you stress to sell it? ¶

Summary ¶

Thank you for sharing your views today, your contribution is much appreciated. ¶

(I would like to give you a copy of/ email a copy of) the debrief sheet that contains information about sources of additional support should you need it. You can expect to receive a summary of the themes by (X date – within one month of the focus group). Please do contact me if you have any questions after this interview. As outlined in the information sheet you have up-to two weeks after this interview to withdraw your participation should you wish to. Once all the groups and interviews have taken place we will undertake the prize draw and notify the winner by email. Thank you again. ¶

¶

If not already discussed as part of the previous question)

Question included following consultation with service-users) ¶

¶

Appendix 4-K

Participant Debrief Sheet (Version 2, 18th April 2020)

Doctorate in Clinical Psychology | Lancaster University

Participant debrief sheet

Thank you for giving your time to take part in this research.

What happens next?

Emma will email you with a summary of initial themes arising from the data and the quotes that they intend to use in the research. Should you wish, you can email or telephone Emma with your comments and views on these themes.

Once the research is complete, you will also be emailed a summary of the written report for your information.

What happens if I feel I need support after the interview?

Support can be provided by your manager or by your GP. You can also seek support from your organisation's occupational health service where this applies. A list of occupational health service contact details are listed below. One of these services should be relevant to you. Alternatively, your organisation's intranet site should have more details on employee health and wellbeing services available to you.

Mind: Support for key workers

It is a difficult time for anyone involved in supporting vulnerable people and MIND have information on their website that provides ideas for coping with the challenges

https://www.mind.org.uk/information-support/coronavirus/coping-as-a-key-worker/

Samaritans

Support for anyone experiencing distress at any time

Phone: 116 123 (free 24-hour helpline)

Website: www.samaritans.org.uk

Support line

Provides a confidential telephone helpline, offering emotional support to any individual of any age on any issue.

www.supportline.org.uk Helpline: 01708 765200 E-mail: info@supportline.org.uk

Appendix 4-L

Lancaster University Research and Ethics Committee (REC) approval letter

Applicant: Emma Fowler
Supervisor: Guillermo Perez Algorta, Anna Duxbury, Suzanne Hodge
Department: Health Research
FHMREC Reference: FHMREC19090

29 April 2020

Dear Emma

Re: Using an assessment tool to support capacity assessments with people with an acquired brain injury in the context of admission to hospital or a care home: A feasibility study

Thank you for submitting your research ethics amendment application for the above project for review by the **Faculty of Health and Medicine Research Ethics Committee (FHMREC)**. The application was recommended for approval by FHMREC, and on behalf of the Chair of the Committee, I can confirm that approval has been granted for the amendment to this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer at the email address below (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information.

Tel:-
Emai[redacted]

Yours sincerely,

[redacted]

Research Ethics Officer, Secretary to FHMREC.

Appendix 4-M

Lancaster University COVID-19 Study Amendments Requirement Email

[redacted]

Hi Emma,

We try and work to the path of least resistance with IRAS applications so:

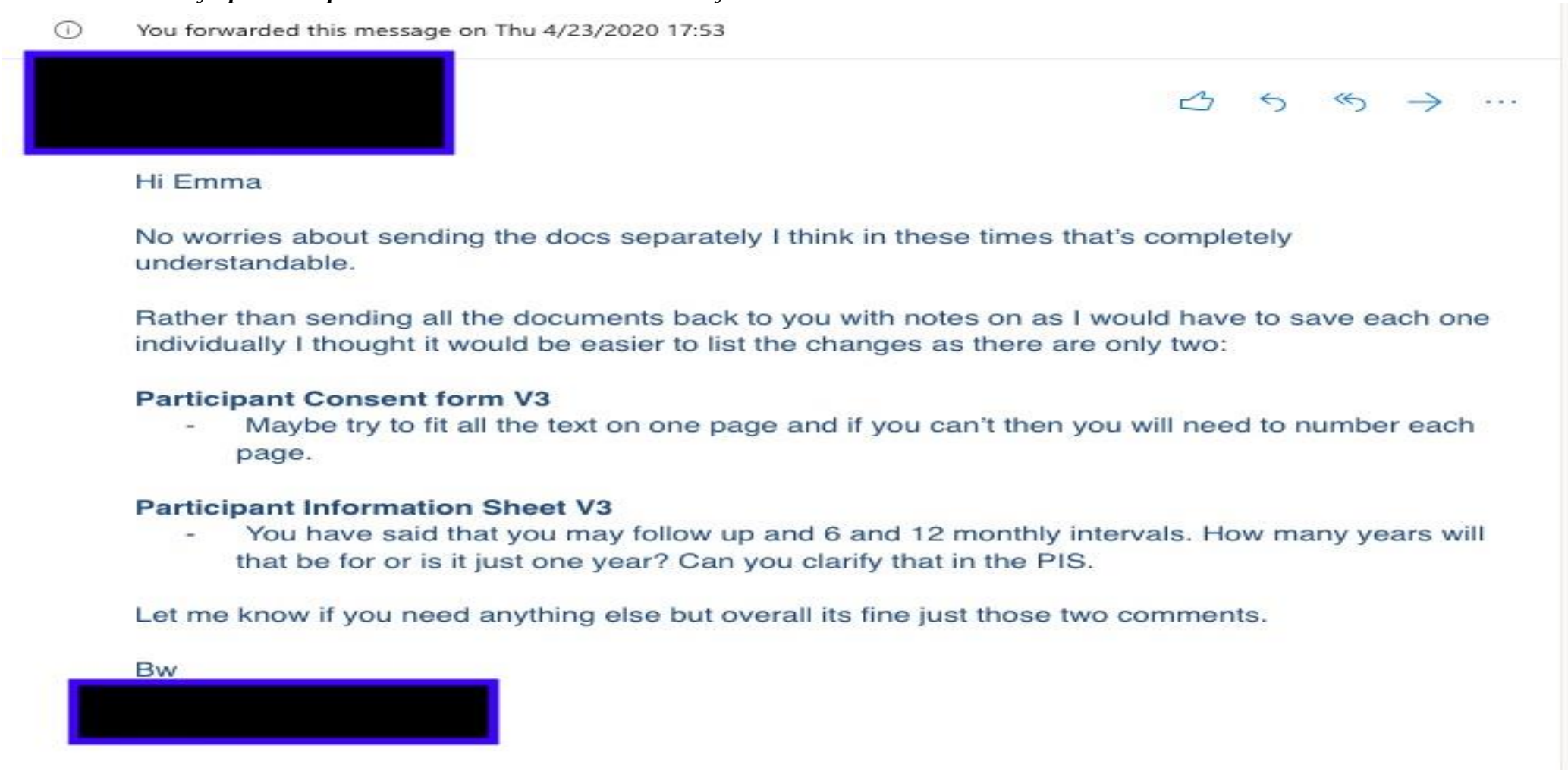
- If an NHS REC saw these amendments and approved them, it doesn't have to come back to FHM REC.
- Since the changes were not requested by your NHS REC, but were made by you in response to the current situation, it would be good if you could send your amended (approved) IRAS form to Chris Beckwith (cc'd) with the changes you made highlighted, to make sure that they are OK from a sponsor perspective. Usually amendments made that haven't been requested by the NHS REC should get sponsor approval but I can completely understand that researchers are needing to make amendments through the process at the moment – seeing a lot of this in FHM REC!
- Once Chris has confirmed that the changes are fine (and I imagine they will be if the NHS REC approved them) then all is in place and you can start.

Hope this is OK?

[redacted]

Appendix 4-N

Lancaster University Sponsorship Email in Relation to COVID-19 Study Amendments



You forwarded this message on Thu 4/23/2020 17:53

[redacted]

Hi Emma

No worries about sending the docs separately I think in these times that's completely understandable.

Rather than sending all the documents back to you with notes on as I would have to save each one individually I thought it would be easier to list the changes as there are only two:

Participant Consent form V3

- Maybe try to fit all the text on one page and if you can't then you will need to number each page.

Participant Information Sheet V3

- You have said that you may follow up and 6 and 12 monthly intervals. How many years will that be for or is it just one year? Can you clarify that in the PIS.

Let me know if you need anything else but overall its fine just those two comments.

Bw

[redacted]

Appendix 4-O

NHS Research Ethics Committee Favourable Opinion

NHS
Health Research Authority

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

22 April 2020

Dr Guillermo Perez Algorta
Doctorate in Clinical Psychology

[redacted]

Dear Dr Perez Algorta

Study title:	**Using an assessment tool to support capacity assessments with people with an acquired brain injury in the context of admission to hospital or a care home: A feasibility study**
REC reference:	**20/HRA/0857**
Protocol number:	**n/a**
IRAS project ID:	**272714**

Thank you for your letter of 20 April 2020, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC at a meeting held on 21 April 2020. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Recommendation

The Sub-Committee recommended that clauses 2 and 3 of the client worker combined consent form could be re-worded to make it clearer that participation in the study is voluntary.

This is a recommendation and does not have to be complied with and will not affect the Favourable Opinion of the REC.

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*

Copies of advertisement materials for research participants [EFThesisAdvertV.3.018.04.2020]	V.3.0	18 April 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [LancasterUniversityPublicLiabilityDoc1]	V.1.0	18 April 2020
Interview schedules or topic guides for participants [InterviewScheduleV.2.018.04.2020]	V.2.0	18 April 2020
Interview schedules or topic guides for participants [QuestionRouteForFocusGroupsV.2.018.04.2020]	V.2.0	18 April 2020
IRAS Application Form [IRAS_Form_10032020]		10 March 2020
Other [CapacityAssessmentTool]	V1.0	11 December 2019
Other [CVAnnaDuxburyV1.025.02.20]	V1.0	25 February 2020
Other [Suzanne Hodge CV (3rd Supervisor)]	V1.0	11 February 2020
Other [Emma Fowler (FHMREC19060) ethics approval]	V1.0	03 March 2020
Other [LancasterUniversityLiabilityInsuranceDoc2]	V.1.0	18 April 2020
Other [HRARECRecommendationsCompletedTablesV.1.018.04.2020]	V.1.0	18 April 2020
Other [RemoteAssessmentOfCapacityToolV.2.018.04.2020]	V.2.0	18 April 2020
Other [ThresholdsForUnderstandingV.2.018.04.2020]	V.2.0	18 April 2020
Other [ParticipantDebriefSheetV.2.018.04.2020]	V.2.0	18 April 2020
Other [ParticipantDemographicSheetV.2.018.04.2020]	V.2.0	18 April 2020
Participant consent form [ParticipantConsentFormV.3.018.04.2020]	V.3.0	18 April 2020
Participant consent form [ClientWorkerCombinedConsentFormV.1.018.04.2020]	V.1.0	18 April 2020
Participant consent form [ConsentProcessFlowchartV.1.018.04.2020]	V.1.0	18 April 2020
Participant information sheet (PIS) [ParticipantInformationSheetV.3.018.05.2020]	V.3.0	18 April 2020
Research protocol or project proposal [ResearchProtocolV.4.018.04.2020]	V.4.0	18 April 2020
Summary CV for Chief Investigator (CI) [CVGuillermoPerezAlgortaV1.013.01.2020]	V1.0	13 January 2020
Summary CV for student [EmmaFowlerCVV1.010.01.2020]	V1.0	10 January 2020
Summary CV for supervisor (student research) [CV of primary supervisor and chief investigator]	V1.0	13 January 2020

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 272714 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: [redacted]

Lead Nation England: approvals@hra.nhs.uk

London - Surrey Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 April 2020

Committee Members:

Name	Profession	Present	Notes
[redacted]			

Also in attendance:

Name	Position (or reason for attending)
[redacted]	

Appendix 4-P

Health Research Authority Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Guillermo Perez Algorta
[redacted]

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

22 April 2020

Dear Dr Perez Algorta

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Using an assessment tool to support capacity assessments with people with an acquired brain injury in the context of admission to hospital or a care home: A feasibility study**
IRAS project ID:	**272714**
Protocol number:	**n/a**
REC reference:	**20/HRA/0857**
Sponsor	**Lancaster University**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **272714**. Please quote this on all correspondence.

Yours sincerely,

[redacted]

Email: approvals@hra.nhs.uk

Copy to: [redacted]

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [EFThesisAdvertV.3.018.04.2020]	V.3.0	18 April 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [LancasterUniversityPublicLiabilityDoc1]	V.1.0	18 April 2020
Interview schedules or topic guides for participants [InterviewScheduleV.2.018.04.2020]	V.2.0	18 April 2020
Interview schedules or topic guides for participants [QuestionRouteForFocusGroupsV.2.018.04.2020]	V.2.0	18 April 2020
IRAS Application Form [IRAS_Form_10032020]		10 March 2020
Organisation Information Document [Organisation Information Document]	V1.0	20 January 2020
Other [CapacityAssessmentTool]	V1.0	11 December 2019
Other [CVAnnaDuxburyV1.025.02.20]	V1.0	25 February 2020
Other [Suzanne Hodge CV (3rd Supervisor)]	V1.0	11 February 2020
Other [Emma Fowler (FHMREC19060) ethics approval]	V1.0	03 March 2020
Other [LancasterUniversityLiabilityInsuranceDoc2]	V.1.0	18 April 2020
Other [HRARECRecommendationsCompletedTablesV.1.018.04.2020]	V.1.0	18 April 2020
Other [RemoteAssessmentOfCapacityToolV.2.018.04.2020]	V.2.0	18 April 2020
Other [ThresholdsForUnderstandingV.2.018.04.2020]	V.2.0	18 April 2020
Other [ParticipantDebriefSheetV.2.018.04.2020]	V.2.0	18 April 2020
Other [ParticipantDemographicSheetV.2.018.04.2020]	V.2.0	18 April 2020
Participant consent form [ParticipantConsentFormV.3.018.04.2020]	V.3.0	18 April 2020
Participant consent form [ClientWorkerCombinedConsentFormV.1.018.04.2020]	V.1.0	18 April 2020
Participant consent form [ConsentProcessFlowchartV.1.018.04.2020]	V.1.0	18 April 2020
Participant information sheet (PIS) [ParticipantInformationSheetV.3.018.05.2020]	V.3.0	18 April 2020
Research protocol or project proposal [ResearchProtocolV.4.018.04.2020]	V.4.0	18 April 2020
Schedule of Events or SoECAT [IRASScheduleOfEventsV1.011/12/2019]	V1.0	11 December 2019
Summary CV for Chief Investigator (CI) [CVGuillermoPerezAlgortaV1.013.01.2020]	V1.0	13 January 2020
Summary CV for student [EmmaFowlerCVV1.010.01.2020]	V1.0	10 January 2020
Summary CV for supervisor (student research) [CV of primary supervisor and chief investigator]	V1.0	13 January 2020

IRAS project ID	272714

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No external study funding has been sought.	A Principal Investigator should be appointed at study sites.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.