Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a touch-screen application for people with dementia

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BSc Hons, MSc

Thesis submitted to the University of Nottingham for the Degree of Doctor of Philosophy

August, 2020

“Nothing in life is to be feared, it is only to be understood.

Now is the time to understand more, so we may fear less.”

– Marie Skłodowska-Curie

Abstract

Introduction: people with dementia may benefit from technology to enhance their quality of life (QoL), reduce social isolation and potentially improve cognition. Adapting existing interventions to digital platforms is a promising approach with prospective benefits. Group Cognitive Stimulation Therapy (CST) for people with dementia can benefit cognition and QoL. Individual CST (iCST) is delivered by a carer at home and can improve the relationship quality between the person with dementia and carer, and the QoL of carers. Given the lack of technological resources for the mental stimulation and engagement of people with dementia, there are potential benefits of combining iCST with touch-screen technology, which include improving global accessibility to iCST.

Aims: to develop and evaluate a touch-screen version of iCST, and examine its potential for implementation internationally.

Methods: this study employed a mixed methods approach to the development and evaluation of a novel iCST app. Development included a narrative synthesis systematic review supported by the Medical Research Council (MRC) Framework and the Centre for eHealth Research (CeHRes) roadmap, and following principles of action research and the agile approach to software development. Forty-one people with dementia and carers were involved in patient and public involvement (PPI) consultation meetings, focus groups, individual interviews, and usability questionnaires. Evaluation included a two-arm, feasibility randomised controlled trial (RCT) (n = 43) to investigate the usability of the iCST app, and feasibility of conducting a large-scale RCT. Three dyads participated in semi-structured, post-trial interviews. Feasibility of cultural adaptation and implementation internationally was investigated in Indonesia where 39 people with dementia, carers, and healthcare professionals participated in focus groups and a stakeholder meeting.

Results: the systematic review led to best practice guidelines on how to optimise involvement of people with dementia in technology development. These guidelines informed the development of the iCST app through three iterative prototypes. The idea of an iCST app was well received in PPI consultation meetings, and feedback indicated that the design and navigation of the prototypes were appropriate. A need for a wider range of more relevant activities was identified in the focus groups and interviews. The third prototype of the iCST app was used for the feasibility RCT. Carers using the iCST app rated their QoL better at follow-up 2 (FU2) compared to the treatment as usual (TAU) control group (EQ-5D, MD = 6.34, 95% CI = .92 – 11.76, p = .02). No other significant differences were found. The exploratory work in Indonesia indicated that it is feasible to implement the iCST app given appropriate cultural adaptation and provided that logistical barriers to accessibility have been overcome.

Conclusions: this is the first study to develop and evaluate an interactive, touch-screen version of iCST. Findings indicate certain modifications to the trial components including increased recruitment capacity and sample size, and an augmented version of the iCST app. Expansion of the iCST app is needed as most participants completed the activities more quickly than anticipated and therefore, did not receive the recommended dose. Given these adaptations to the study design, it is recommended to conduct a large-scale RCT to investigate formal effectiveness.

Funding

This research was funded by the Horizon 2020 Marie Skłodowska-Curie Actions - Innovative Training Networks in 2015 [grant number 676265].

Disclaimer

The views expressed are mine and those of the authors who I have collaborated with, and not necessarily those of the National Health Service (NHS), the funder, or the University of Nottingham.

Declaration

No part of this thesis has been submitted in support of an application for any other academic degree or qualification at the University of Nottingham, or at any other academic institution.

Acknowledgements

This project would not have been possible without funding from the European Union's Horizon 2020 Marie Skłodowska-Curie Actions. I feel both lucky and grateful to have been part of such a unique and exciting training network, which stimulated my growth beyond the PhD.

My sincerest gratitude goes to my supervisory team. Thank you Professor Martin Orrell. It is because of your willingness to create opportunities for me, and your constant belief, support and drive for pursuing high quality research that I was able to step out of my comfort zone, and that I now feel especially proud of this piece of work and can cherish my time in Nottingham. I would also like to thank Professor Justine Schneider, your compassion, reassurances, and excellent critiques were absolutely key in fully embracing and improving my research. Thank you Dr. Lauren Yates for being my iCST 'life line'. Your advice, particularly during the early stages, was paramount for me to better understand my project.

To the Nottingham team: Aline Cavalcanti Barroso, Dr. Déborah Oliveira, Dr. Orii McDermott, and Ann Gibbons, thank you for your collective support and uplifting words at all times, it has truly made all the difference. Thank you Rebecca Griffiths, for your indispensable contributions and company during the qualitative study.

I would like to thank the entire INDUCT consortium for the insightful collaborations. I am particularly grateful to Professor Anne Margriet Pot for setting me on the research path in the first place, and for continuing to be part of my journey by sharing invaluable pieces of advice. Thank you to Eumedianet for bringing our vision for Thinkability to life, and to the teams at INTRAS and Alzheimer Indonesia for hosting me during my unforgettable secondments.

My warmest thanks goes out to all the research participants who generously gave their time to help create Thinkability with their ideas and feedback. Working with

you has given me some of the fondest memories. Thank you also to all the staff at the CRN and the NHS study sites in Nottingham, Lincoln, Leicester and Derby for all your hard work and dedication to the study. I am also grateful to my internal and external examiners for their valued insights and feedback through which I was able to better my work.

My PhD experience in Nottingham has been enriched by the friends I have made along the way and their support. A special thank you to Dr. Jack Tomlin, future Dr. Shazmin Majid, and Dr. Joseph Dib, for the companionship and 'banter' as we say in the UK. I owe my thanks also to my friends back home in Amsterdam who came to visit or cheered me on from overseas, and were more than happy to proofread the thesis. A heartfelt thank you to Reva Efe, who always kept in touch to see how things were progressing and to provide some extra motivation whenever needed.

Lastly, I would not have had the confidence to undertake and complete this PhD had it not been for the boundless love and support from my family. To my grandmothers, I know that I have made you especially proud by doing this PhD since we always wanted to have a doctor in the family! Pa, thank you for setting a fine example of what it means to work hard, and for your kind and calm encouragement throughout. Ma, there are not enough words to describe how much your presence has meant to me, you have truly been my rock throughout this experience. Thank you for all the little things that eventually proved to be the biggest help. To my sister, Jasdeep Rai, thank you for always believing in me and supporting my decisions. I aimed to adopt many of your qualities such as strength, courage, perseverance, and kindness while undertaking this PhD. You are and always will be my leading example.

Thank you God for seeing me through this transformative journey and for all these wonderful people who I could lean on along the way.

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List of abbreviations

ACCEPT	Acceptance Checklist for Clinical Effectiveness Pilot Trials
AChEIs	Acetylcholinesterase Inhibitors
ADAS-Cog	Alzheimer's Disease Assessment Scale - Cognitive Subscale
AD	Alzheimer's Disease
AT	Assistive Technology
ADCS-ADL	Alzheimer's Disease Cooperative Study - Activities of Daily Living
AE	Adverse Event
ANCOVA	Analysis of Covariance
App	Application
BADLS	Bristol Activities of Daily Living Scale
BPSD	Behavioural and Psychological Symptoms of Dementia
CASP	Critical Appraisal Skills Programme
CeHRes	Centre for eHealth Research
CI	Chief Investigator overall
CMHT	Community Mental Health Team
CONSORT	Consolidated Standards of Reporting Trials
CRN	Clinical Research Network
CSDD	Cornell Scale for Depression in Dementia
CST	Cognitive Stimulation Therapy
CUA	Questionnaire of Usability and Acceptability
CUSE	Computer User Self-Efficacy
DEMQoL	Dementia Quality of Life Scale
DHFT	Derbyshire Healthcare NHS Foundation Trust

DLB	Dementia with Lewy Bodies
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
EQ-5D	Euro-Quality of Life five dimensions
FTD	Frontotemporal Dementia
FU1	Follow-up 1 (5 weeks)
FU2	Follow-up 2 (11 weeks)
GB	Great Britain
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GDS-15	Geriatric Depression Scale - 15
GP	General Practitioner
GPS	Global Positioning System
HADS	Hospital Anxiety and Depression Scale
HRA	Health Research Authority
H&S	Health and Safety
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th Revision
iCST	Individual Cognitive Stimulation Therapy
ICT	Information and Communication Technologies
JDR	Join Dementia Research
IMH	Institute of Mental Health
INDUCT	Interdisciplinary Network for Dementia Using Current Technology
LMIC	Low and Middle Income Countries
LPT	Leicestershire Partnership NHS Trust
LPFT	Lincolnshire Partnership NHS Foundation Trust

MCST	Maintenance Cognitive Stimulation Therapy
MMSE	Mini Mental State Examination
MoCA	Montreal Cognitive Assessment
MRC	Medical Research Council
NHFT	Nottinghamshire Healthcare NHS Foundation Trust
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPI	Neuropsychiatric Inventory
PC	Personal Computer
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PROSPERO	Prospective Register of Systematic Reviews
QAO	Quality Assurance Officer
QCPR	Quality of the Carer Patient Relationship
QoL	Quality of Life
QoL-AD	Quality of Life in Alzheimer's Disease
RCT	Randomised Controlled Trial
RDO	Research Delivery Officer
REC	Research Ethics Committee
R&D	Research and Development department
SAE	Serious Adverse Event
SF-12	Short Form (12) Health Survey
SUS	System Usability Scale
TAU	Treatment as Usual
UK	United Kingdom

VaD	Vascular Dementia
VRF	Virtual Reality Forest
WHO	World Health Organisation

Contributors' references in this thesis

ACB	Aline Cavalcanti Barroso (PhD student, University of Nottingham)
HR	Harleen Rai
IT	Imelda Theresia (member of research and scientific division, Alzheimer Indonesia)
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LY	Dr. Lauren Yates (research associate, University College London)
MO	Prof. Martin Orrell (chief investigator and supervisor, University of Nottingham)
PT	Patricia Tumbelaka (executive director, Alzheimer Indonesia)
RG	Rebecca Griffiths (MSc student, University of Nottingham)
TS	Tara Puspitarini Sani (research and scientific division coordinator, Alzheimer Indonesia)
VP	Virginia Geraldine Hanny Prasetya (BSc student, Atma Jaya Catholic University)

List of publications

PhD publications

Rai, H., Yates, L. A., & Orrell, M. (2018). Cognitive Stimulation Therapy for dementia. *Clinics in Geriatric Medicine, 34*(4), 653-665. https://doi.org/10.1016/j.cger.2018.06.010. See Chapter 2.

Rai, H. K., Cavalcanti Barroso, A., Yates, L., Schneider, J., & Orrell, M. (2020). Involvement of people with dementia in the development of technology-based interventions: A narrative synthesis review and best practice guidelines. *JMIR, 22*(12). https://doi.org/10.2196/17531. See Chapter 3.

Rai, H. K., Schneider, J., & Orrell, M. (2020). An individual Cognitive Stimulation Therapy app for people with dementia: Development and usability study of Thinkability. *JMIR Aging, 3*(2). http://doi.org/10.2196/17105. See Chapter 4.

Rai, H. K., Griffiths, R., Yates, L., Schneider, J., & Orrell, M. (2020). Field-testing an iCST touch-screen application with people with dementia and carers: A mixed method study. *Aging & Mental Health*, 1-11. https://doi.org/10.1080/13607863.2020.1783515. See Chapter 5.

Rai, H. K., Schneider, J., & Orrell, M. An individual Cognitive Stimulation Therapy app for people with dementia and carers: Protocol for a feasibility randomised controlled trial. *JMIR Research Protocols* (forthcoming). http://doi.org/10.2196/24628. See Chapter 6.

Rai, H. K., Schneider, J., & Orrell, M. A feasibility study of a randomised controlled trial to examine the individual Cognitive Stimulation Therapy application (iCST app) for people with dementia (in process of submission). See Chapter 6.

Rai, H. K., Prasetya, V. G. H., Sani, T. P., Theresia, I., Tumbelaka, P., Turana, Y., Schneider, J., & Orrell, M. Exploring the feasibility of an individual Cognitive Stimulation Therapy (iCST) application and related technology for use by people with dementia and carers in Indonesia. *Dementia* (under review). See Chapter 7.

Non PhD publications

Cavalcanti Barroso, A., Rai, H. K., Sousa, L., Orrell, M., & Schneider, J. (2020). Participatory visual arts activities for people with dementia: A review. *Perspectives in Public Health*, 1-10. https://doi.org/10.1177/1757913920948916.

Rai, H. K., Somoza, L. C., Guzmán, J. M. T., Franco, M., & Orrell, M. Exploring the needs and preferences of people with dementia for new cognitive stimulation technologies: A focus group study (in process of submission).

Woods, B., Rai, H. K., Elliott, E., Aguirre, E., Spector, A., & Orrell, M. Cognitive stimulation to improve cognitive functioning in people with dementia. *Cochrane Database of Systematic Reviews* 2020 (in process of submission).

Statement of contribution

Preliminary work

My first tasks included getting familiar with the CST and iCST materials such as the manuals, the iCST DVD, and LY's thesis. I also reviewed the current evidence-base behind the various forms of CST leading to a literature review. In addition, I obtained NHS REC & HRA approval for the project in its entirety.

Systematic review

I developed the research question in collaboration with MO based on a topic which would assist the development of the iCST app i.e. involving people with dementia in developing technology. I conducted the searches and removal of duplicates independently and then collaborated with ACB for screening for eligibility and additionally with LY and JS for data extraction. Finally, I presented the best practice guidelines at two PPI consultation meetings.

Development of the iCST app

I conducted the three development sprints which included:

- Regular meetings with Eumedianet (software development company) with support from JS.
- Conducted the three PPI consultation meetings.
- Organisation, recruitment, and eligibility screening for focus groups and interviews.
- Conducted four focus groups with support from RG, and five individual interviews. During these activities I also guided participants through the consent process.
- Transcription and coding of data from the focus groups and interviews and application of thematic analysis in collaboration with RG.

- Led the exploratory study in Indonesia in terms of designing the study in collaboration with MO, obtained ethical approval from the Division of Psychiatry and Applied Psychology at the University, presented at a stakeholder meeting with TS, assisted PT and IT in conducting four focus groups, undertook coding and thematic analysis of the data with support from VP.

Evaluation of the iCST app

During the feasibility trial, I managed the study in its entirety with support from MO, and acted as an unblind researcher at the Nottingham site and at the remaining sites where necessary. As such, I conducted the following tasks:

- Drafted all study-related documents including a detailed trial manual.
- Set-up for four study sites: trained researchers in use of the iCST app, its installation and providing carer support, and supplied the necessary materials to conduct the study e.g. assessment packs, vouchers for participants.
- Supported recruitment by visiting support groups, memory clinics, and disseminating the study through media outlets.
- Performed randomisations using Sealed Envelope and allocation disclosure to participants, conducted iCST app installations and weekly telephone calls.
- Performed data pick-up from every site, and subsequent data audit, input and analysis.
- Conducted, transcribed, and reviewed the data of semi-structured interviews with three dyads from the experimental group upon completion of the study.

- Liaised with Eumedianet to release Thinkability on the Apple and Google Play stores.

Training

Throughout my PhD, I completed training as part of INDUCT which included, but was not limited to, five, one-week schools and two international secondments. I spent three months at Fundación INTRAS in Zamora, Spain which is a day centre for older adults with memory problems, and two months at the Indonesian Alzheimer's association in Jakarta, Indonesia.

Other work based on the iCST app development

Results from the focus groups and interviews in the UK concerning the qualitative impact of the iCST app are included in RG's MSc thesis.

Chapter 1 – Introduction

Dementia poses a significant public health challenge considering its increasing global prevalence and multi-level impact on the individual, society and economy. People with dementia often require care and support in managing the symptoms of dementia as they can face difficulties with staying mentally stimulated and engaged. Additionally, dementia care can have a big impact on families with the majority of the care and support provided by unpaid or informal carers which can lead to increased burden and decreased quality of life (QoL). This thesis was written up during the COVID-19 pandemic in 2020 which further exacerbated the impact of dementia. Given the risks of contracting the virus in social gatherings, many services for people with dementia had to be suspended. Older people in particular were having to take shielding measures which left many people with dementia and carers at home without support. Therefore, there is a need to explore more resources for people with dementia that can help manage the symptoms but can be done from the safety of their homes. This thesis sets out to develop and evaluate a touch-screen application (app) for people with dementia to promote mental stimulation, QoL, and communication.

1.1. Dementia

1.1.1. Epidemiology of dementia

The development of dementia is associated with older age and, as the average life expectancy has increased universally over the past century, the prevalence of dementia has increased as well. In 2015, it was estimated that 46.8 million older people were living with dementia worldwide (Prince et al., 2015). Western Europe has the second largest population of people with dementia overall after Asia. In the United Kingdom (UK), over 885,000 people are living with dementia (Wittenberg, Hu, Barraza-Araiza, & Rehill, 2019). The Medical Research Council

Cognitive Function and Ageing Study II including 2500 participants aged 65 years and older, has identified the existence of a cohort effect in the prevalence of dementia. The investigators concluded that populations from later generations have a lower risk for dementia than those from earlier generations (Matthews et al., 2013). This may be due to improved lifestyle choices (e.g. reduction in smoking). Indeed, there is some strong evidence suggesting possible causal relationships between dementia and several modifiable risk factors such as higher levels of education, improved cardiovascular health and other lifestyle behaviours such as physical exercise and diet (Prince, Albanese, Guerchet, & Prina, 2014). However, despite the encouraging findings and the focus on risk reduction, the worldwide prevalence of dementia is expected to increase to 74.7 million by 2030, and even to 131.5 million by 2050. Thus, dementia is very much regarded as a public health priority on a national and international level (Prince et al., 2015).

1.1.2. Definition of dementia

Dementia is a progressive condition which, in most cases, leads to a gradual decline in cognitive functioning, activities of daily living, and social participation, all of which have a significant impact on the QoL of people with dementia and their carers (National Institute for Health and Care Excellence, 2018). According to the International Statistical Classification of Diseases and Related Health Problems (ICD-10) of the World Health Organisation (WHO), dementia is defined as a syndrome due to a disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple, higher level cortical functions including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement (World Health Organisation, 1992). These cognitive deficits can lead to deterioration compared to the person's previous level of functioning and can negatively affect social and occupational functioning. The

symptoms must typically occur for a period of at least six months in order to formally give the diagnosis.

1.1.3. Sub-types of dementia

Alzheimer's disease (AD) is the most prevalent sub-type of dementia (Figure 1.1). In the UK, AD accounts for roughly 62% of all cases of dementia. The early characteristic symptoms of AD consist of impaired memory, depression, and apathy (Prince, Knapp, et al., 2014). Vascular dementia (VaD) is the second most prevalent sub-type of dementia. A total of 17% of the cases in the UK are accounted for by VaD. The symptomology is relatively similar to that of AD however, people with VaD can experience less impairment in their memory but increased physical frailty and fluctuations in their mood (Alzheimer's Disease International, 2009).

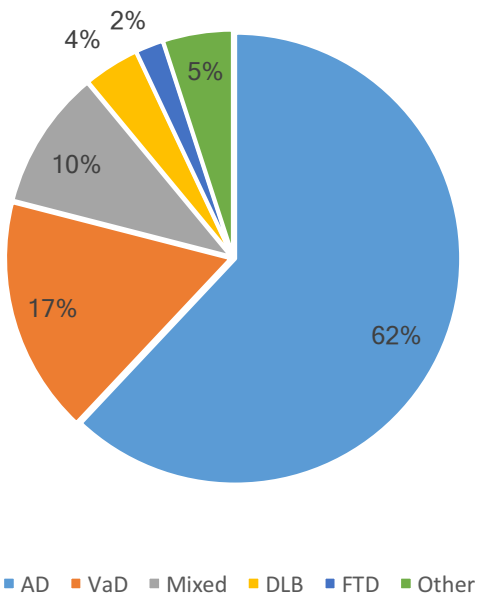


Figure 1.1. Distribution of dementia sub-types in the UK (Prince, Knapp, et al., 2014).

The overlap between the sub-types of dementia are often not very distinct and it is not uncommon for different sub-types to present a mixed clinical picture: roughly

10% of the cases in the UK can be attributed to mixed dementia (Prince, Knapp, et al., 2014). Other less common sub-types of dementia include dementia with Lewy bodies (DLB), which accounts for four percent of the cases, and frontotemporal dementia (FTD) which accounts for two percent of the cases.

1.1.4. Symptoms of dementia

1.1.4.1. Cognitive symptoms

The manifestation of cognitive symptoms varies by individual and can depend on the sub-type of dementia, however, memory impairment is often the first symptom reported by people with dementia and it is also the most common cognitive symptom (Albert, 2011). Dementia primarily affects explicit memory which is made up of an episodic and semantic subset. Impairment in the episodic memory causes difficulties in learning and retaining new information. People with dementia often have less difficulty with remembering events from the past. Semantic memory refers to the storage and retrieval of information relating to the meaning of words, concepts, and facts (Albert, 2011). Impairment in semantic memory can result in difficulties with language functioning. Other common cognitive symptoms in dementia include aphasia (language disturbances such as word finding), apraxia (impaired ability to carry out motor activities despite an intact motor function), agnosia (failure to identify or recognise objects despite an intact sensory function), and executive dysfunction (disturbances in planning, organising, sequencing, and abstracting) (American Psychiatric Assocation, 1994).

1.1.4.2. Non-cognitive symptoms

The non-cognitive symptoms of dementia, also referred to as behavioural and psychological symptoms of dementia (BPSD), can consist of agitation, aberrant motor behaviour, anxiety, elation, irritability, depression, apathy, disinhibition, delusions, hallucinations, and sleep or appetite changes (Cerejeira, Lagarto, &

Mukaetova-Ladinska, 2012). The manifestation of BPSD will vary between individuals considering the type and stage of dementia, and both psychological and environmental factors. Roughly 90% of the people with dementia experience BPSD, which can lead to early institutionalisation, inappropriate use of medication (e.g. overuse), and increased healthcare costs (Cerejeira et al., 2012). Expert advice advocates an individualised treatment plan which carefully combines psychological treatments and pharmacological treatments (if necessary) to manage the BPSD (Cerejeira et al., 2012; Tible, Riese, Savaskan, & von Gunten, 2017).

1.1.5. Impact of dementia

1.1.5.1. Societal and economic impact

There is a large economic impact of dementia as, in 2019, it was estimated that £34.7 billion was spent on dementia care in the UK on a yearly basis (Wittenberg et al., 2019). A total of £15.7 billion is spent on social care (e.g. support with daily activities for the person with dementia), unpaid or informal carers of people with dementia pick up £13.9 billion of the total costs, and £4.9 billion is spent on healthcare costs. Furthermore, dementia is a leading cause of disability and dependence for people aged 60 and over (Alzheimer's Disease International, 2009). It accounts for 13.1% of the total years lived with a disability, second only to visual impairment, among 12 other chronic diseases. Generally, dementia also reduces the life expectancy however, compared to other chronic diseases, it contributes only to 0.9% of years of life lost (Prince et al., 2015). Thus, dementia contributes more to disability than it does to mortality. Since prioritisation is generally given to chronic diseases that lead to higher mortality, diseases such as cancer and heart disease attract greater health spending and research investment than dementia (Alzheimer's Disease International, 2009). Despite this, dementia does pose a great societal challenge because of the disability burden and the

WHO has put together a global action plan on the public health response to dementia in order to reduce its global impact. This includes seven action areas ranging from dementia awareness to research and innovation to better understand dementia (World Health Organisation, 2017).

1.1.5.2. Individual impact

Both the cognitive and non-cognitive symptoms of dementia can lead to a significant amount of distress for the person with dementia and can lead to burden for the carer. Moreover, in a global survey among 2068 people with dementia, respondents mentioned social isolation and avoidance as consequences of experiencing stigma caused by poor understanding and awareness (Batsch & Mittelman, 2012). However, a small study by Katsuno (2005) found that, although people reported their psychological and social wellbeing to be affected by stigma, the majority of people with early-stage dementia (n = 21) reported their QoL as 'good'. This means that dementia does not necessarily lead to a decreased QoL and that this will depend on the individual.

While there can be some positive aspects of caring, such as a sense of fulfilment or companionship, carers of people with dementia are also very likely to experience strain (Alzheimer's Disease International, 2009; World Health Organisation, 2012). Carers of people with dementia generally provide intensive and extensive care which can have consequences for both their physical and mental health (Alzheimer's Research UK, 2015). Carers self-report a poorer QoL than non-carers, and also experience worse health outcomes including higher levels of stress hormones, greater cognitive decline, and an impaired immunity response (World Health Organisation, 2012).

1.1.6. Psychosocial interventions

Generally, the use of drug treatments such as acetylcholinesterase inhibitors (AChEIs) (e.g. donepezil, galantamine, rivastigmine) is recommended as they can achieve modest improvements in the cognitive function of people with moderate to severe dementia (National Institute for Health and Care Excellence, 2018). However, they can have potential drawbacks including the limited effectiveness of some AChEIs on certain types of dementia (e.g. vascular dementia) and their side effects, making them unsuitable for some people (O'Brien et al., 2017). Over the last 25 years there has been an advance in the development and implementation of psychosocial interventions as a different means to supporting people with dementia. A recent synthesis of systematic reviews adopts the following definition of psychosocial interventions: those physical, cognitive or social activities that may maintain or improve functioning, interpersonal relationships and well-being in people with dementia (McDermott et al., 2019; Moniz-Cook, Vernooij-Dassen, Woods, Orrell, & INTERDEM Network, 2011). Interventions include cognitive stimulation, cognitive rehabilitation, cognitive training, and reminiscence therapy.

1.1.6.1. Cognitive stimulation

Cognitive stimulation is aimed at the general improvement of cognitive and social functioning through engaging in reality orientation, activities, games and discussions while prioritising information-processing rather than knowledge (National Institute for Health and Care Excellence, 2018). It can be administered in a group setting by professionals or by carers who have received the necessary training. Findings from a study by Quayhagen et al. (2000) suggest that an eight-week, carer-delivered cognitive stimulation programme improved the memory, verbal fluency, and problem-solving abilities of people with dementia, and led to a reduction in depressive symptoms among spousal carers. Milders, Bell, Lorimer, MacEwan, and McBain (2013) also found benefits of a carer-delivered cognitive stimulation programme in terms of verbal fluency for people with dementia

however, they did not find any improvements for the carer. A Cochrane review found that the benefits of cognitive stimulation on the cognition of people with mild to moderate dementia are similar to those of medication (Woods, Aguirre, Spector, & Orrell, 2012). In order to offer cognitive stimulation in a standardised manner, researchers in the UK developed Cognitive Stimulation Therapy (CST): a manualised, psychological treatment for people with dementia. CST is delivered both nationally and internationally given its benefits on the cognition and QoL of people with dementia (Spector et al., 2003). It is available in both a group and individualised format (iCST) of which the latter is delivered by informal carers. Chapter 2 provides a detailed overview of the current literature and evidence surrounding CST.

1.1.6.2. Cognitive training

Cognitive training involves guided practice on a set of standard tasks designed to reflect specific cognitive functions such as memory, attention, or problem-solving (National Institute for Health and Care Excellence, 2018). Depending on the individual's ability, the tasks can have a range of difficulty levels. However, evidence on the effectiveness of cognitive training is inconsistent (Kallio, Ohman, Kautiainen, Hietanen, & Pitkala, 2017) and there seem to be no benefits for the person with dementia. In addition, the National Institute for Health and Care Excellence (NICE) guidelines do not recommend offering cognitive training in order to treat symptoms of dementia (National Institute for Health and Care Excellence, 2018).

1.1.6.3. Cognitive rehabilitation

Where cognitive stimulation is aimed at the general enhancement of cognition and social functioning, cognitive rehabilitation adopts a more individualised approach in which the emphasis is not so much on improving cognition as it is on improving

functioning for specific tasks and supporting independence (Clare & Woods, 2004; National Institute for Health and Care Excellence, 2018). Cognitive rehabilitation allows people with dementia and their families to work together with healthcare professionals to identify problems and develop functional goals that are relevant to the person with dementia, and to come up with strategies together to achieve these. Goals can be changed and adjusted depending on their need and relevance. There is no assumption that changes in one context can be generalised to other contexts. There is limited evidence on the effectiveness of paper-based cognitive rehabilitation.

1.1.6.4. Reminiscence therapy

Reminiscence therapy involves the discussion of past activities, events, and experiences with other people (Woods, O'Philbin, Farrell, Spector, & Orrell, 2018). Prompts like photographs and music can be used to evoke memories and stimulate conversation. A recent Cochrane review including 22 randomised controlled trials (RCTs) found the effects of reminiscence therapy to be inconsistent and small in size depending on the modality and setting of the intervention (Woods et al., 2018). For instance, individual reminiscence therapy was associated with benefits for cognition and mood whereas group reminiscence therapy and a community setting were associated with improvements in communication. Differences across the various studies made accurate comparisons and evaluation of the effects more challenging.

1.2. Role of technology for people with dementia

1.2.1. General use of technology

1.2.1.1. Healthy older people

The use of technology has increased among the general and older populations. An example of this phenomenon is the percentage of adults accessing the internet on a daily basis in Great Britain (GB), which has more than doubled from 35% in 2006 to 86% in 2018 (Office for National Statistics, 2018). Households with one adult aged 65 years or older have seen the largest growth in internet access from 36% in 2012 to 59% in 2018, and again to 80% in 2020 (Figure 1.2). However, these households still have the lowest proportion of internet access compared to any other household (Office for National Statistics, 2020).

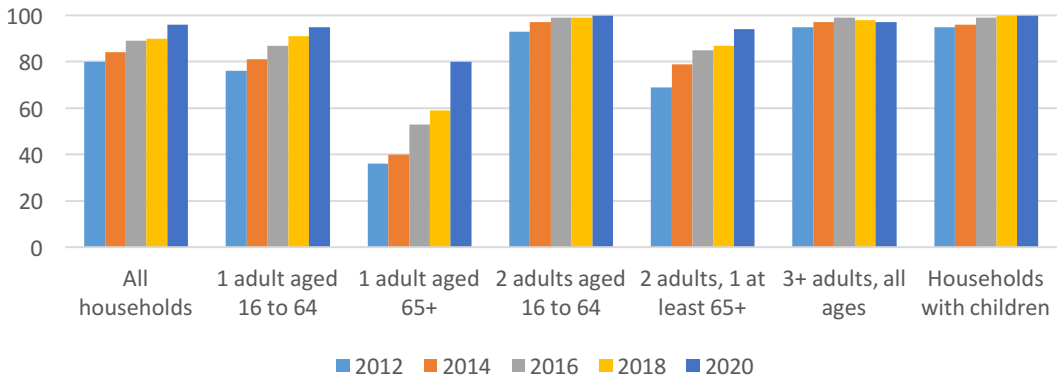


Figure 1.2. Internet connection from 2012 to 2020 by composition of households in Great Britain (Office for National Statistics, 2020).

This disparity in access to internet or information and communication technologies (ICT) in general within society is often referred to as the 'digital divide'. Older people report various barriers such as costs, lack of interest and awareness, and inappropriate designs to using technology, which can add to this divide (Delello & McWhorter, 2017). In addition, older people may feel less confident when it comes to using novel technologies which can partly be due to successes and/or failures in past experiences. On the other hand, use of technology on a day-to-day basis does come with several advantages such as ease of communication and transportation. Indeed, a small study within a residential care setting concluded

that the frequent use of touch-screen tablets (iPads) over the course of six weeks had the potential to decrease social isolation by connecting people with online communities and/or staying in touch with family members and friends (Delello & McWhorter, 2017). Furthermore, results from the English Longitudinal Study of Ageing, including a sample of 2314 participants aged over 50, suggest that digital literacy has a positive impact on overall life satisfaction (Quintana, Cervantes, Saez, & Isasi, 2018).

The beneficial effects of using technology on cognition have been the subject of research as well. A large-scale study conducted by Tun and Lachman (2010) assessed the frequency of computer-use among participants between the age of 32 and 84 years in relation to cognition. The results showed that a higher frequency of computer activity (e.g. for internet, email) was associated with better cognitive performance across adulthood into old age (Tun & Lachman, 2010). A cohort study where 5506 community-dwelling men aged 69 to 87 years were followed up to 8.5 years, showed that computerised cognitive leisure activities are associated with a lower risk of receiving a diagnosis of dementia (Almeida et al., 2012). In addition, another study found that use of internet/email may reduce cognitive decline in older adults (Xavier et al., 2014). Some studies have yielded conflicting results which could perhaps be attributed to different platform choices for training and use (personal computer (PC) vs. touch-screen tablet). For instance, an RCT including 191 healthy older adults indicated that intensive interaction with a PC did not show any effects on the main cognitive domains. The intervention consisted of brief training and use of a PC over 12 months (Slegers, van Boxtel, & Jolles, 2009). In contrast, another study with a smaller sample size suggests that healthy older people trained to use the iPad for three months showed improvement in certain cognitive domains such as episodic memory and processing speed (Chan, Haber, Drew, & Park, 2016). Even though there are several studies which have

investigated the relationship between frequency of computer use and cognition among older people, the findings are not conclusive and more research is needed among older people with cognitive impairment in particular.

1.2.1.2. People with dementia

Roughly 42% of the people aged 65 and over use a tablet computer (e.g. an iPad) to access the internet, making it the most popular choice for older people in GB (Office for National Statistics, 2018). When accessing the internet 'on the go', 28% of the same age group use a mobile phone or a smart phone compared to 20% using a tablet computer. However, older people experienced their reduced speed of knowledge acquisition and memory difficulties as barriers in learning how to operate an iPad (Delello & McWhorter, 2017). Orpwood et al. (2009) explored the acceptability of several interfaces across various pieces of technology for people with dementia and found touch screens to be highly intuitive. Nordheim, Hamm, Kuhlmey, and Suhr (2015) found that nursing home residents living with dementia in Germany showed a high degree of acceptance of tablet computers over the course of three months. The most notable benefits were the easy handling of the tablet and the diversity of multifunctional apps. Nordheim et al. (2015) stress the need for further research and the development of specially adapted software. Lim, Wallace, Luszcz, and Reynolds (2013) examined whether 21 people with early-stage dementia in their home environment could use tablet computers (Apple iPads) independently. They found that 50% of participants were able to use the iPad independently and that this proved helpful to their carers. The acceptability of tablet computers among people with dementia may be dependent on the provision of more device features which enable communication (e.g. through social media), apps, and informal support (Lim et al., 2013). The findings from Lim et al. (2013) are further supported by a systematic review by Joddrell and Astell (2016) which examined the body of literature involving people with dementia and the use

of touch-screen technology in order to inform future research. The evidence suggests that people with dementia were able to use touch-screen technology independently. However, the researchers pointed out that this technology is primarily used to deliver assessments and screening tests, or provide an assistive function or cognitive rehabilitation (Joddrell & Astell, 2016). They have identified a need for more independent activities for entertainment and fun, and as a meaningful way to spend time. Indeed, Smith and Mountain (2012) also highlight that the most common unmet need for people with dementia is having an enjoyable activity to engage with regularly. The authors found a significant underrepresentation of apps specifically related to dementia or AD after performing a search of Apple's online app store. The existing apps are mostly used to support diagnosis and to identify symptoms and insufficient attention has been given to technologies that may enable more leisure activities. Authors stress that ICT has the potential to meet the aforementioned need of people with dementia. There is scope for more apps to promote QoL, and to stimulate meaningful and enjoyable activities for people with dementia (Smith & Mountain, 2012).

1.2.2. Technology-based interventions

Tyack and Camic (2017) reviewed an array of touch-screen interventions and concluded that they can have a wide range of benefits on the well-being of people with dementia in terms of mood, mental health, social relationships, and more. Moreover, these interventions can have a positive impact on the well-being of carers by decreasing their burden and improving the quality of the relationship with the person they are caring for by spending more time together. The authors identified several key aspects of interventions that contribute to their success. The interface should be kept simple, intuitive, aesthetically pleasant and error-free, with some guidance to the user on what to do. In terms of the content, it should be tailored where appropriate to the user and should include a slight challenge so

they are invited to apply more complex cognitive skills rather than simpler ones (Tyack & Camic, 2017).

Computerised cognitive interventions ('brain training') in particular are becoming more widely available for older people with cognitive impairment and they build on the notion that increased computer use may lead to improved cognitive abilities for healthy older people. In a recent systematic review, Garcia-Casal et al. (2017) concluded that computerised cognitive interventions led to significant improvements in cognition, depression and anxiety among people with dementia. Potentially, therefore, computerised cognitive interventions may have even more of an impact on cognition than non-computerised versions (Garcia-Casal et al., 2017). Tarraga et al. (2006) investigated 46 people with mild AD exposed to both a computerised, cognitive stimulation programme and a non-computerised, face-to-face cognitive stimulation programme delivered in groups. The control group consisted solely of the non-computerised, cognitive stimulation programme. The results showed that that the intervention group showed greater improvements in cognition after 24 weeks which suggests added benefits of a computerised cognitive stimulation programme (Tarraga et al., 2006). Another RCT has shown that there were no additional benefits of receiving computerised cognitive training on top of non-computerised cognitive training on cognitive functioning among people with dementia (Gaitan et al., 2013). Lastly, an RCT on the efficacy of computerised cognitive rehabilitation among people with AD found that it can be effective in slowing the progression of cognitive impairment (Galante, Venturini, & Fiaccadori, 2007). Technology also provides scope for delivering paper-based cognitive interventions online. For instance, in light of the COVID-19 pandemic where CST groups for people with dementia are unavailable, Cheung and Peri (2020) have been investigating the feasibility of virtual CST groups using Zoom: a

video conferencing software. This may support people with dementia to stay mentally stimulated and engaged in the safety of their homes.

The effects of computerised cognitive interventions among people with dementia are not conclusive with different types of interventions leading to different results. Furthermore, the field of computerised cognitive stimulation in particular is underdeveloped despite the potential of these interventions (Garcia-Casal et al., 2017). More research in the field is warranted as the existing evidence seems to be promising, there are minimal risks in engaging with computerised cognitive stimulation, and such interventions have the potential to be cost-effective.

1.3. Rationale for combining CST and technology

Over the course of the last decade, a strong evidence base has been developed supporting the effectiveness of cognitive stimulation in improving the cognitive functioning and QoL of people with dementia (see Chapter 2) (Spector et al., 2003; Woods et al., 2012). A further study investigated the development and evaluation of iCST which involved a carer (family member/friend) delivering the intervention at home. The results from a large-scale RCT including 356 participants of iCST, did not show similar improvements in the cognitive functioning of people with dementia to those demonstrated in group CST (Orrell et al., 2017). However, they indicated positive effects on the caregiving relationship and the QoL of carers, which suggests that the involvement of a family member/friend was a beneficial component of the intervention (see Chapter 2). Researchers stressed the need for more studies investigating the effectiveness of iCST but also encouraged the exploration of innovative approaches towards delivering iCST such as the use of a computerised platform. According to the researchers, a computerised platform could lead to different results as it may have the potential to increase fidelity to the intervention through monitoring progress on a device, and provides more scope

for different types of activities which can include media. Finally, the effects of cognitive stimulation can be maximised through the added use of computers as their content and platforms can be cognitively stimulating by themselves (Yates, Ziser, Spector, & Orrell, 2016).

The separate findings on the use of CST, iCST, and technology for people with dementia and carers are promising however, a computerised version of iCST has not been developed or evaluated. A computerised version of iCST which can be delivered at home via touch-screen tablets could combine the added value of technology use and the beneficial effects of iCST with the convenience and interactive features of touch-screen technology. The development of paper-based iCST was supported by a rigorous approach involving evidence-based frameworks and multiple research activities (see Chapter 2). It is hypothesized that a similar approach to the development of computerised iCST supported by evidence-based frameworks and stakeholder involvement will result in a well-designed and suitable intervention because an effective design process can contribute to the usefulness and usability of an intervention. Furthermore, it is hypothesized that computerised iCST will lead to better outcomes for people with dementia and carers compared to paper-based iCST because the benefits of computer use on cognitive functioning and QoL may add to the overall effectiveness of the intervention as a result of engaging with novel and stimulating activities, increased confidence, and feelings of empowerment. Figure 1.3 shows the logic model of a computerised version of iCST which describes how the intervention may lead to better outcomes than paper-based iCST. The key components of the intervention consist of iCST, the use of technology, and the involvement of a close family member or a friend/volunteer. These could lead to various key outcomes for the person with dementia e.g. improvements in cognitive functioning, QoL, and the relationship between the person with dementia and carer.

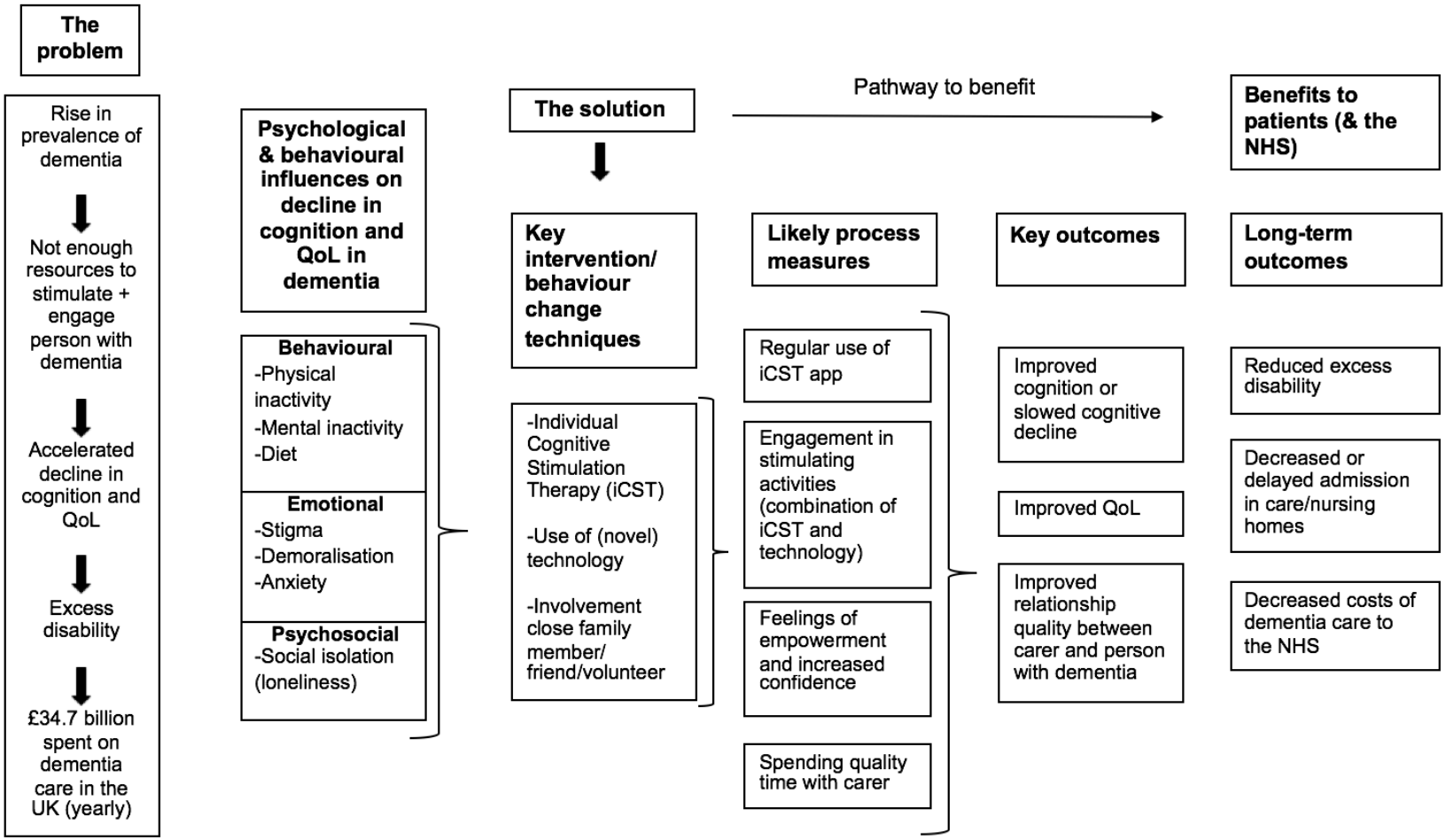


Figure 1.3. Developing an iCST app to improve cognition and QoL for people with dementia: Logic model for the intervention.

These changes may be attributed to several mechanisms. The mental stimulation provided by the activities included in iCST and the use of technology with its interactive features, can contribute to changes in cognition and QoL. Engaging in a novel platform and through it perhaps learning a new skill could lead to feelings of empowerment and a sense of mastery (Tyack & Camic, 2017). Lastly, having someone involved in the intervention could combat social isolation and feelings of loneliness which then could have a positive impact on the caregiving relationship. Tyack and Camic (2017) argue that a positive caregiving relationship may help to sustain the relationship for a longer time. This could then help the person with dementia remain at home longer as well with the support of the carer. In the long-term, regular use of computerised iCST could lead to reduced excess disability and therefore delayed admission to care/nursing homes and perhaps even reduced costs of dementia care to the National Health Service (NHS), if it is deemed to be cost-effective in the future. Overall, the development and evaluation of computerised iCST will add to the current knowledge of both CST and iCST which are non-computerised. For example, a computerised version of iCST would allow for improved monitoring of the adherence rates and therefore would allow for a better investigation of the effects of an iCST-based approach. It will also help fill the research gap in computerised cognitive stimulation (Garcia-Casal et al., 2017).

In terms of implementation, computerised iCST will complement traditional CST and iCST by making the therapies even more accessible since users of technology will be able to access it easily on their device. Computer tablets (thin, flat mobile computers with touch-screen technology) with internet coverage are making technology even more accessible for everyone, including people with dementia. Therefore, computerising iCST could lead to easier access for larger numbers of users of iCST, so benefitting more people with dementia or people at risk of

cognitive decline. Improved accessibility applies to potential users on a global scale as well considering both CST and iCST are being used internationally. Therefore, there is also a need to evaluate computerised iCST in a different cultural setting in order to understand how it may be used in other parts of the world. It is hypothesized that evaluating computerised iCST in a low income country such as Indonesia with an alternative cultural setting will provide evidence for its feasibility and applicability, and therefore contribute to its overall quality with a better understanding of different cultural needs which may support global accessibility to computerised iCST.

1.4. Summary

Dementia is increasingly treated as a public health priority considering its rise in global prevalence and the multi-level impact it has on the individual, economy, and society as whole. A variety of treatments exists in order to alleviate the burden of the condition and cognitive stimulation is the only psychosocial intervention with the most robust evidence. Current trends are shifting towards the benefits of technology and investigating how technology can be used to support people with dementia in their daily lives. More importantly, current psychosocial interventions are being offered on computerised platforms in order to provide the most optimal results. However, the current body of evidence suggests inconsistent results regarding the effectiveness of these interventions and there is a clear need for more meaningful and enjoyable technologies. Therefore, more research is necessary in order to better understand how technology can best benefit people with dementia and apply this knowledge in the development of meaningful technologies. The current gap in the availability of such technologies can be met by combining iCST with technology. This seems to be a promising approach due

to the potential of combined beneficial effects on cognition and QoL for people with dementia, added level of interactivity with the iCST content, and increased accessibility to iCST for users internationally.

1.5. Aim, objectives, and hypotheses

1.5.1. Aim

The overall aim of this PhD study is to develop and evaluate an interactive touch-screen version of iCST, and to examine its potential for implementation internationally.

1.5.2. Objectives

1) To develop an interactive (touch-screen) app as a mode of delivery of iCST for people with dementia and carers, which can be used on touch-screen tablets.

2) To evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a treatment as usual (TAU) control group.

3) To investigate the feasibility of adapting the iCST app for users in Indonesia according to their cultural context.

1.5.3. Hypotheses

1) A development approach supported by evidence-based frameworks and stakeholder involvement will result in a well-designed and suitable iCST app because an effective design process can contribute to the usefulness and usability of an intervention.

2) The iCST app will lead to better outcomes for people with dementia and carers compared to paper-based iCST because the benefits of computer use on cognitive functioning and QoL may add to the overall effectiveness of the intervention as a

result of engaging with novel and stimulating activities, increased confidence, and feelings of empowerment.

3) Evaluating the iCST app in Indonesia will provide evidence for its feasibility and applicability in an alternative cultural context, and therefore contribute to its overall quality with a better understanding of different cultural needs which may support global accessibility to the iCST app.

1.6. Overview and structure of the thesis

An overview of the thesis is provided in Figure 1.4. The thesis consists of two key components: (1) the development and (2) the evaluation of the iCST app. These components are preceded by a review of the literature and evidence behind CST and CST-based approaches in Chapter 2. Hereafter, development activities are outlined in Chapter 3, 4, 5, and 7, and evaluation work is described in Chapter 6.

Chapter 3 is a narrative synthesis systematic review, which aimed to appraise the methods used to involve people with dementia in developing technology-based interventions, and to create best practice guidelines based on the findings. This informed the development of the iCST app as outlined in Chapter 4 and Chapter 5. Chapter 4 provides an overview of the overall approach towards development including the relevant frameworks and the preliminary development activities. Chapter 5 details the results from a qualitative study in the UK during which people with dementia and carers tested a second prototype version of the iCST app. Chapter 6 includes the evaluation of the iCST app in terms of feasibility and acceptability, and describes the methods and results of a feasibility study for an RCT with people with dementia and carers in the UK. Chapter 7 details findings from a qualitative study where people with dementia, carers, and healthcare professionals in Indonesia shared their opinions on the iCST app and related

technology for people with dementia. The thesis concludes with Chapter 8, which discusses the findings and implications of the thesis in its entirety.

This project was completed as part of the Interdisciplinary Network for Dementia Using Current Technology (INDUCT) which received funding through the Horizon 2020 Marie Skłodowska-Curie Actions - Innovative Training Networks in 2015 (grant agreement number 676265). This multi-disciplinary, educational research framework set out to improve the care for and lives of people with dementia by developing a strong evidence-base surrounding technology. It also provided a comprehensive training programme for 15 early stage researchers across Europe which included multiple training schools and secondments. The international and cross-sectorial nature of the network allowed for collaborations between academic and non-academic sectors such as industry- and policy partners. Additional information can be found at: https://dementiainduct.eu/.

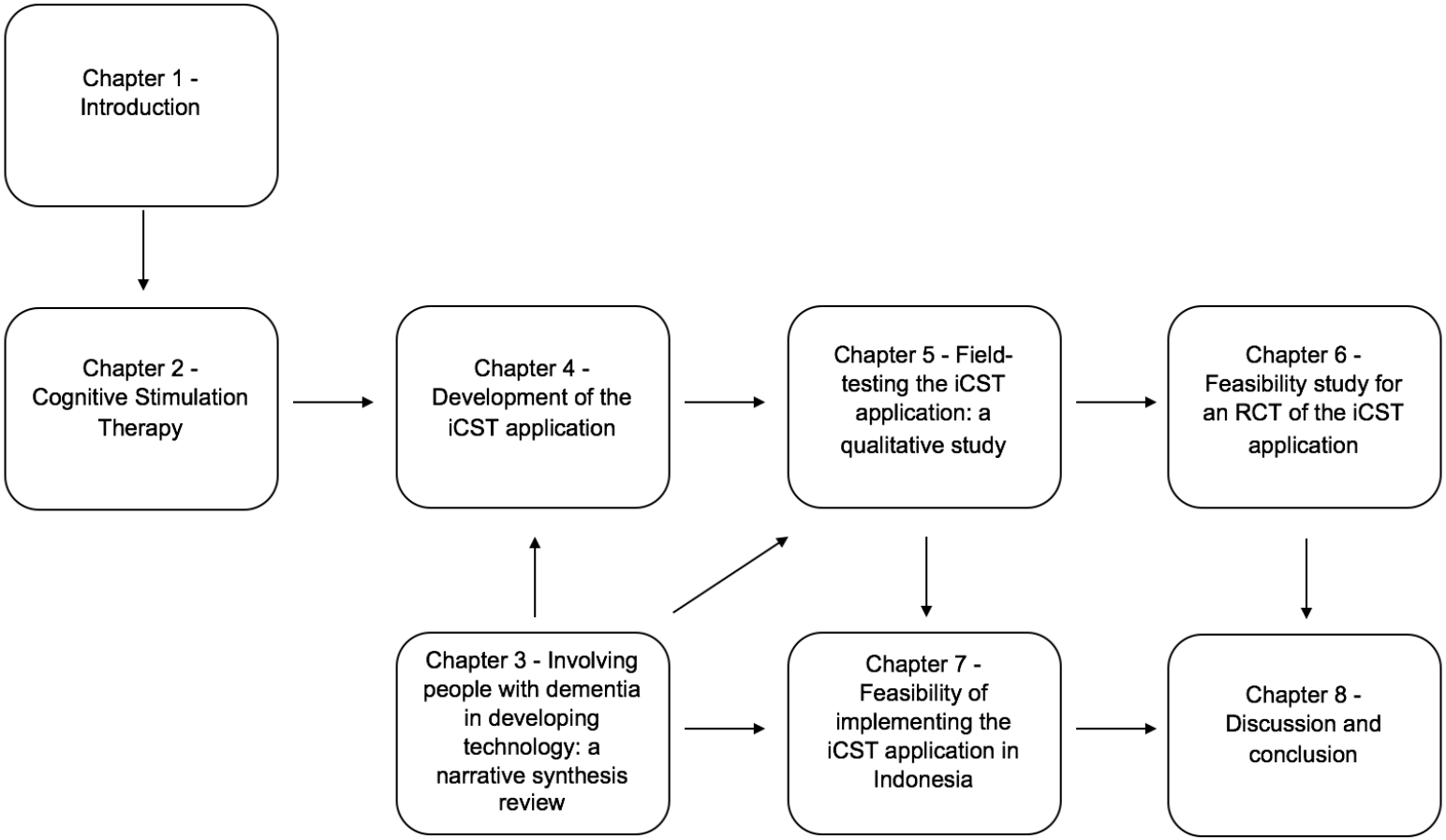


Figure 1.4. Overview of the thesis.

Chapter 2 - Cognitive Stimulation Therapy (CST)

This chapter was based on a journal article: Rai, H., Yates, L. A., & Orrell, M. (2018). Cognitive Stimulation Therapy for Dementia. *Clinics in Geriatric Medicine, 34*(4), 653-665. https://doi.org/10.1016/j.cger.2018.06.010.

2.1. Background

Cognitive Stimulation Therapy (CST) is a brief psychological treatment for people with mild to moderate dementia. It offers a person-based approach to help people with dementia stay mentally stimulated and engaged while providing an optimal learning environment. CST was developed 20 years ago at a time when there were few psychological therapies available for people with dementia, and the potential for engagement in mentally stimulating, enjoyable activities in everyday life to preserve cognitive health and protect against decline had not been realised. From the perspective of the population, there was a clear need to have something available which would provide people with dementia with a meaningful way to spend their time. Clinicians and policy-makers anticipated the development of new anti-dementia medication as the benefits of Tacrine, the only pharmacological therapy available, were modest and the risks of adverse events (AEs) made the drug unsuitable for some people with dementia. Therefore, the field of psychological treatments remained unexplored and trials for psychological interventions were often small in scale and methodologically unsound. From a research perspective, the need for more rigorous investigation of new and/or existing psychological therapies for people with dementia was evident. Considering both the gaps in research and the needs of people with dementia, a research team in the United Kingdom (UK) set out to develop a novel, psychological therapy whose evaluation would be built on a strong methodological

foundation comparable to that of pharmacological treatments (Orrell & Woods, 1996). The first steps towards developing CST included the review of evidence from existing psychological therapies which could serve as a strong foundation. This review included two systematic literature reviews on reality orientation and reminiscence therapy. Reality orientation finds it origins in the late 1950s and aims to improve the quality of life (QoL) of people with dementia through the repeated presentation of orientation and memory information (Taulbee & Folsom, 1966). Despite evidence of benefits on cognition and behaviour (Spector, Davies, Woods, & Orrell, 2000), reality orientation has received criticism due to its 'rigid and confrontational' approach which can lead to AEs such as frustration, anxiety, depression, and lowered self-esteem (Dietch, Hewett, & Jones, 1989). This critique appears to have made the intervention less common and modifications were made to reality orientation which helped develop CST (Spector, Orrell, Davies, & Woods, 2001). In addition, the work on CST was influenced by Breuil's approach to cognitive stimulation (Breuil et al., 1994). The approach differed from traditional reality orientation by setting out to engage people in enjoyable cognitive tasks provided in a group format. Breuil et al. (1994) conducted a randomised controlled trial (RCT) among 56 people with dementia and found their cognitive stimulation approach had positive effects on cognitive functioning. The UK workgroup went on to combine the effective techniques from the key therapies and multi-sensory stimulation to form the CST programme (Spector et al., 2001).

CST shows measurable benefits on cognition and QoL which are similar to the effects of some anti-dementia medication (Spector et al., 2003). In addition, it is cost-effective (Knapp et al., 2006) and very much enjoyed by people with dementia. Therefore, CST has grown to be widely used over the course of 20 years with three CST manuals published to date. CST is the only non-pharmacological

therapy recommended by the National Institute for Health and Care Excellence (2018) guidelines for treating cognitive symptoms of dementia in the UK. These advise that CST should be available to people with dementia regardless of medication received. In addition, nearly all memory services in the UK offer CST in regular groups with people with dementia (Clary, Colwill, Copland, & Hodge, 2016). On a global level, CST is recommended to be offered routinely to people with dementia around the world in World Alzheimer's reports produced by Alzheimer's Disease International (Patterson, 2018; Prince, Comas-Herrera, Knapp, Guerchet, & Karagiannidou, 2016). The International CST Centre at University College London has supported the adaptation and/or implementation of CST in over 25 countries. The successful uptake of CST in different countries led to the development of specific guidelines for future adaptations of CST (Aguirre, Spector, & Orrell, 2014).

2.1.1. CST programme

CST consists of 14 twice-weekly group sessions (Table 2.1) which take place over the course of seven weeks (Spector, Thorgrimsen, Woods, & Orrell, 2006).

Table 2.1. CST sessions (Spector, 2017).

Session 1:	Physical games	*Session 8:*	Being creative
Session 2:	Sound	*Session 9:*	Categorising objects
Session 3:	Childhood	*Session 10:*	Orientation
Session 4:	Food	*Session 11:*	Using money
Session 5:	Current affairs	*Session 12:*	Number games
Session 6:	Faces/scenes	*Session 13:*	Word games
Session 7:	Associated words	*Session 14:*	Team games

All sessions are diverse in nature and the programme offers a wide array of topics to ensure it meets the group's interests and cognitive abilities. Every CST group has personalised elements to it such as choice of a group name and song. These are displayed on a reality orientation board during the session. Sessions last 45 minutes including a 10-minute, non-cognitive warm-up, and a 10-minute closing activity (summary and/or the group song). CST is typically delivered by a trained healthcare professional or care assistant to groups of five to eight people. The facilitators are encouraged to adhere to the key principles of CST which help create the most optimal environment for mental stimulation and enjoyment. Examples of the 18 key principles are: mental stimulation, using reminiscence as an aid to the here and now, implicit learning, fun, choice, building/strengthening relationships, and focusing on opinions, rather than facts. These features are unique to CST.

2.1.2. Evidence

The development of CST followed the guidance of the Medical Research Council (MRC) Framework for the Evaluation of Complex Interventions (Craig et al., 2008). This framework includes a development-evaluation-implementation process in which all the phases interact with each other (see Chapters 3 & 4).

The first draft version of CST was taken forward in a pilot study (Spector et al., 2001). A total of 27 people with dementia, recruited from a day centre and three residential homes were included. Seventeen were randomised to the treatment group receiving CST and 10 were allocated to a treatment as usual (TAU) control group. The results were promising and indicated that for the CST treatment group, there were positive signs regarding cognition, and depression and anxiety seemed to be reduced compared to the control group. No negative effects were observed

as a result of the treatment. The positive findings from this pilot study formed a strong argument for investigating the effects of CST in a large RCT.

Following a few adjustments to the CST programme according to the findings from the pilot study, a single-blind, multi-centre RCT was conducted which included 201 people with dementia (Spector et al., 2003). The participants were distributed over 23 CST groups and were recruited from five day centres and 18 care homes. The following inclusion criteria applied to all participants:

- Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for dementia (American Psychiatric Assocation, 1994).
- Score of between 10 and 24 on the Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975).
- Some ability to communicate and understand (e.g. ability to give informed consent).
- Able to see and hear well enough to participate in the group and make use of most of the material in the programme.
- No major physical illness, learning disability, or other disability that could affect participation.

These inclusion criteria have been commonly applied in CST studies since, and are referred to as the Spector et al. (2003) standardised criteria.

Participants were randomised to either a CST group (n = 115) or a TAU control group (n = 86). Researchers aimed to assess benefits across several outcomes measures with primary outcomes of cognitive functioning and QoL. The trial results were positive: participants in the CST group showed significant improvements in cognitive functioning as measured by the MMSE (Folstein et al., 1975) and the

Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) (Rosen, Mohs, & Davis, 1984) compared with the TAU control group. Self-rated QoL was higher in the CST group as measured by the Quality of Life-AD (QoL-AD) (Logsdon, Gibbons, McCurry, & Teri, 1999). Lastly, there was a positive trend for communication on the Holden Communication Scale (Holden & Woods, 1995). No significant differences were found for the secondary outcomes such as functional ability, anxiety, and depression. The significant improvements on the primary outcome measures and the fact that people with dementia really enjoyed CST, encouraged the research team to publish the CST training manual and to make it more widely available.

A few years later, the CST findings from the trial were supported with qualitative data when researchers investigated the experiences of people with dementia, carers, and group facilitators who attended CST groups (Spector, Gardner, & Orrell, 2011). This study included 38 participants recruited from three existing CST groups. Two main themes (along with seven sub-themes) emerged from the focus groups and interviews: 'positive experiences of being in the group' and 'changes experienced in everyday life'. Participants shared many reflections, some of which are highlighted below. Regarding changes in everyday life, participants reported noticing some benefits in their memory.

Yes remembering the recent events has been a lot more simple and a lot more logical than it was certainly. – Person with dementia.

Cognitive benefits in other areas such as communication were also observed by carers:

She's clearer on the telephone. Clearer I suppose in the way she holds the conversation it's not that she speaks differently. It's just that the flow of the conversation is a little easier. – Carer.

In conclusion, personal experiences reported by participants support the notion of CST being a positive and mentally stimulating experience, which is in line with previous quantitative findings (Spector et al., 2011).

2.1.3. Maintenance Cognitive Stimulation Therapy (MCST)

The first CST trial showed positive results. However, the need for more research regarding potential longer-term outcomes and more CST content for people with dementia in general, led to the development of an extended version of CST called MCST (Aguirre et al., 2011). The MCST programme includes the regular seven-week CST programme with an extension of an additional 24 weekly maintenance sessions. Table 2.2 gives an overview of all the MCST themes in the published MCST manual.

Table 2.2. MCST session themes (Orrell & Forrester, 2017).

My life	Useful tips (new)
Current affairs	Thinking cards (new)
Food	Visual clips (new)
Being creative	Art discussion (new)
Number game	Faces/scenes
Team games, quiz	Word game
Sound	Associated words, discussion
Physical games	Orientation
Categorising objects	Using money
Household treasures (new)	

The researchers considered the theory behind the original CST programme and the findings from a previous exploratory pilot study while finalising the MCST programme (Orrell, Spector, Thorgrimsen, & Woods, 2005). In line with CST, MCST was developed according to the MRC Framework and used a mixed methods approach (Aguirre et al., 2011). Evidence from the following sources were combined: (1) a Cochrane review of cognitive stimulation for people with dementia (Woods et al., 2012), (2) a Delphi consensus process (involving key stakeholders), (3) focus groups with key stakeholders, and (4) a Delphi survey. This led to the development of the MCST manual which includes themed sessions and resembles the consistent structure of CST (e.g. group name/song, non-cognitive warm-up) (Aguirre et al., 2006). The finalised MCST programme was evaluated in a large-scale RCT. Trial results indicated that at the six-month follow-up, the MCST treatment group showed significant improvements on the self-rated QoL-AD compared to the TAU control group but no significant effects were found on the ADAS-Cog or other secondary outcomes at both follow-ups (Orrell et al., 2014). At the three-month follow-up, results showed positive effects for people with dementia on the proxy-rated QoL (DEMQOL) by carers and care staff, and daily activities (ADCS-ADL) (Galasko et al., 1997; Smith et al., 2005).

The MCST trial did not find additional benefits to cognition beyond the initial phase of CST followed by MCST (Orrell et al., 2014). As dementia is associated with progressive decline in cognition, participants in both the MCST and the control group were likely to have shown cognitive deterioration at the six month follow up. This decline might have limited further cognitive improvement with MCST following the standard CST programme. However, less cognitive decline occurred in the MCST group taking acetylcholinesterase inhibitors (AChEIs) compared to the MCST group without medication and CST only group. This indicates that better

results might be obtained if drug treatments are combined with CST. The research team concluded that more research is needed regarding continued CST as this was the first rigorous trial of MCST and the results did not seem to be conclusive. However, the significant improvements on QoL due to MCST were an encouraging finding.

2.2. Individual Cognitive Stimulation Therapy (iCST)

2.2.1. Development

With the increasing evidence for the benefits of CST and its uptake in routine services, the need to offer CST through different avenues became apparent. It was acknowledged that CST is not always accessible for those who are either unwilling or unable to attend groups. Taking their needs and wishes in consideration, the individual version of CST (iCST) was developed. Unlike CST and MCST, iCST is home-based and is facilitated by an informal carer (e.g. a family member, friend, or anyone who is close to the person with dementia) or a paid carer (e.g. home support worker).

The development of iCST followed the MRC Framework and included several research activities (Yates, Leung, Orgeta, Spector, & Orrell, 2015). In the first stages of development, people with dementia, carers, and care staff were asked to share their feedback and thoughts on the idea of iCST in an informal survey. The research team then reviewed existing literature of CST, MCST, one-to-one programmes of cognitive stimulation, and reality orientation. The evidence collated from the literature was then reviewed by a small group of key stakeholders such as carers and healthcare professionals who provided their advice on important considerations for the adaptation of CST to iCST. These activities led to the first draft of sessions 1-12 of the iCST manual which were appraised in focus groups

and interviews with people with dementia and carers. Participants were generally positive about the iCST materials and also shared their views on mentally stimulating activities and the feasibility of iCST. The research team proceeded with a field-testing phase of the full programme, which included both informal carers and paid carers. Both quantitative (e.g. questionnaires, rating of enjoyment, interest, communication, and level of interest) and qualitative data (e.g. through telephone support) were collected. Lastly, a two-stage modified Delphi consensus process (online survey and conference) was employed to reach consensus on themes that participants of focus groups, interviews, and field-testing could not agree upon. The sample consisted of academics, healthcare professionals, researchers, and carers (Yates, Leung, et al., 2015; Yates et al., 2014).

2.2.2. iCST programme

The iCST intervention follows the same principles of group CST however, a few adjustments had to be made in order to make it suitable for use at home. Instead of the introduction and closing element of group CST, iCST sessions begin with a discussion of orientation information and current affairs followed by a themed activity. Following patient and public involvement (PPI) feedback about potential use at home, each iCST session lasted around 20 to 30 minutes and sessions can be done thrice-weekly. Each CST or MCST session was split to create two iCST sessions, which resulted in a 75-session programme over 25 weeks. Table 2.3 gives an overview of the iCST session themes; some themes occur more than once. iCST omits the key principles geared towards the group process rather, it stimulates discussion between the person with dementia and the carer and also encourages them to enjoy the time they spend together.

2.2.3. Evidence

iCST was tested in a multi-centre, single-blind large-scale RCT (Orrell et al., 2017). A total of 356 participants were recruited from a variety of community settings and allocated to either the iCST intervention group (n = 180) or the TAU control group

Table 2.3. iCST session themes (Yates, 2017).

My life	Thinking cards
Current affairs	Visual clips discussion
Food	Art discussion
Being creative	Faces/scenes
Number games	Word games
Quiz games	Slogans (new)
Sounds	Associated words discussion
Physical games	Orientation
Categorising objects	Using money
Household treasures	Childhood (new)
Useful tips	

(n = 176). All participants met the Spector et al. (2003) standardised criteria with the addition of the following two criteria: living in the community and the availability of an informal carer. The main outcome measures were cognition (ADAS-Cog) (Rosen et al., 1984) and QoL for the person with dementia (QoL-AD) (Logsdon et al., 1999), and QoL of the carer (SF-12) (Ware, Kosinski, & Keller, 1996). The primary and secondary outcomes measures were completed at three time points: baseline, first follow-up at 13 weeks and second follow-up at 26 weeks. Throughout the trial, participants received support from the research team in the form of regular telephone support and monitoring visits. The trial results demonstrated no significant differences between the iCST and TAU control group on any of the primary outcome measures at both follow-up time points. However, for one of the

secondary outcome measures, significant improvements in the quality of the caregiving relationship from the person with dementia's perspective were found. For the carers, QoL (EuroQoL Group, 1990), was significantly better in the iCST group at the second follow-up (Orrell et al., 2017).

The results of this trial are not consistent with group CST findings and the following reflections may help to better understand the iCST evidence. Since iCST is a longer intervention, the findings might indicate that a short-term, more intense dose of CST could be more beneficial or effective. The social setting provided during group CST might also be crucial to enhancing cognition and QoL, thus lacking this, iCST may not elicit benefits. It is suggested, in previous research, that improvements in cognition from cognitive stimulation mediate improvements in QoL for people with dementia (Woods et al., 2012). Hence, the lack of change in cognition experienced by iCST participants could explain the lack of results on QoL. The biggest challenge of the trial proved to be adherence to iCST. The research team observed that, on average, dyads completed just less than half of the recommended 75 sessions over 25 weeks. While prior to the trial, during the development phase, carers determined the iCST format to be feasible, in reality carers identified several barriers to delivering the intervention post-trial such as time constraints, physical health problems, and motivation. Lastly, when the data was analysed, adherence was shown to be lower than expected considering the regular contact by phone calls.

This trial was innovative for several reasons. The iCST trial is the largest known piece of CST research to date and it is the first trial investigating a home-based, carer-led format of CST. This trial demonstrated that, in general, carers are able to deliver an intervention which is a key finding supporting carer-led interventions. The observed improvements in the quality of the caregiving relationship are

encouraging and could enhance the QoL of people with dementia. The results from this trial are not conclusive due to the poor adherence, and there is a need for continued research on iCST in order to clarify its effectiveness.

2.3. Summary

The CST journey has spanned for over 20 years so far and innovations continue to be made in this field. When CST was developed, it helped fill the existing gap in evidence-based psychological treatments for people with dementia. In this regard, it can be seen as a fundamental step towards shifting some of the focus from pharmacological treatments to psychological ones. The positive effects of CST further amplified the importance of looking beyond anti-dementia medication and it fuelled the realisation that the two might actually provide the most optimal benefits to people with dementia when combined. Findings regarding experiences of people with dementia were just as encouraging as people have reported enjoyment and even increased confidence following CST. Therefore, CST has managed to provide both a meaningful and stimulating way for people with dementia to spend their time. The success of the original group CST made it possible to go even further and develop extensions of group CST ensuring that the intervention can be offered to people with different needs. In addition, the adaptation guidelines made it possible for CST to successfully be adapted and offered in a variety of countries around the world.

Still, there is more to be explored in the field of CST as some questions remain unanswered. The optimal dose for long-term CST is unknown and future research could help give an indication of what the most beneficial duration and frequency of CST could be. Other work could focus on iCST e.g. enhancing methods of support and training could help improve adherence. In terms of exploring different

platforms for CST, incorporating technology seems to be an attractive option as the use of technology can benefit the cognitive functioning of older people (see Chapter 1), and may be better able to support adherence.

For the future, it is hoped this growth of CST can be maintained and different avenues for offering CST can be explored on both a national and international level. The CST research team aims to continue connecting stakeholders from around the world at CST conferences and generate ideas and discussions on what works and what can be done even better. This would help create an improved understanding of CST and encourage other researchers and clinicians to explore the field of CST so that CST will continue to be available to people with dementia who want and need it.

Chapter 3 - Improving the involvement of people with dementia in developing technology-based interventions: A narrative synthesis review and best practice guidelines

This chapter was based on a journal article: Rai, H. K., Cavalcanti Barroso, A., Yates, L., Schneider, J., & Orrell, M. (2020). Involvement of people with dementia in the development of technology-based interventions: A narrative synthesis review and best practice guidelines. *JMIR, 22*(12). https://doi.org/10.2196/17531.

3.1. Introduction

Technology may be used to address some of the challenges of dementia care and enable people with dementia to maintain their independence for as long as possible (Prince et al., 2015). Despite the wide variety of available technology (e.g. reminder devices, touch-screen devices and applications (apps), and computerised cognitive/physical interventions) (Gibson et al., 2016), there is a lack of evidence on efficacy and many interventions are either in the development or in a prototype phase (Meiland et al., 2017). Moreover, there has been little involvement of people with dementia in the development of technology-based interventions (Meiland et al., 2017; Span, Hettinga, Vernooij-Dassen, Eefsting, & Smits, 2013). Possible reasons for this lack of involvement include stigma, concerns about the frailty of older people, and the anticipated distress among participants caused by trying out less developed information technology applications (Orpwood et al., 2007). Underdeveloped technology-based interventions with inadequate involvement could have residual faults, and could

potentially make early prototypes harder for people with dementia to operate and lead to a reluctance to use them (Orpwood et al., 2007). Consequently, technologies are being developed which are not user-friendly, nor fit for purpose for people with dementia (Meiland et al., 2017; Span et al., 2013). Technology that is faulty or poorly designed may not be helpful in supporting people with dementia.

A previous systematic review showed that people with dementia are able to provide useful feedback such as comments on screen size, language difficulties and the importance of personalisation on private spaces of websites, which help to improve the quality of the intervention (Span et al., 2013). This approach improves the usability and acceptability of the technology-based intervention (Span et al., 2013), and can generate enjoyment and enthusiasm in the participants with dementia (Hanson et al., 2007; Robinson, Brittain, Lindsay, Jackson, & Olivier, 2009). However, Span et al. (2013) reviewed papers up to 2010, and many innovations in technology have taken place subsequently. Furthermore, Astell et al. (2008); Span et al. (2013) assert that in order to optimise technology by ensuring the needs and preferences of people with dementia are addressed, it is crucial to implement a participatory process in which people with dementia are involved throughout the development process (Astell et al., 2008; Span et al., 2013).

Information on how to optimise the involvement of people with dementia is dispersed and there is a clear need to bring the evidence together in a systematic manner through an appraisal of the involvement of people with dementia in the development of technology-based interventions, and guidelines on how to best facilitate and optimise this involvement.

3.2. Aims

This narrative synthesis systematic review sets out to appraise the methods used by applying existing frameworks such as the Medical Research Council (MRC) Framework for the Evaluation of Complex Interventions and Centre for eHealth Research (CeHRes) roadmap (Craig et al., 2008; van Gemert-Pijnen et al., 2011), and to create best practice guidelines on how to better involve people with dementia in developing technology-based interventions accompanied by a logic model.

3.3. Methods

3.3.1. Narrative synthesis

Narrative synthesis is “an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings” (Popay et al., 2006). Narrative synthesis can be used to address a multitude of questions regarding the effectiveness of interventions including what works but also why and how. Narrative synthesis is preferred for this review as it can be used to convert the evidence into clear, structured best practice guidelines on how to facilitate the participation of people with dementia in the development of technology-based interventions. The approach consists of four elements.

3.3.1.1. Element 1: Theory development

Theory development underpins the systematic review, informing the review question and the types of studies to include. Our starting point is the desirability of end user involvement in technology development. Several studies suggest that feedback from people with dementia can lead to improvements in the overall quality of the technology (Astell et al., 2008; Span et al., 2013). This would result

in more useful and suitable pieces of technology, and would also increase the willingness to use the technology. Furthermore, the involvement of end users in developing technology could also support implementation of a technology in the future leading to a better range of technology to improve the quality of life (QoL) of people with dementia. We therefore only include studies which clearly illustrate how feedback was gathered from people with dementia during development. This would exclude studies with a sole focus of including participants as objects of studies where no meaningful involvement has taken place. The narrative synthesis undertaken here will contribute to a refinement of our theoretical starting point and support the application of the review's findings (Popay et al., 2006).

3.3.1.2. Element 2: Developing a preliminary synthesis

The preliminary synthesis develops an initial description of the results of the included studies organised in such a way that a pattern can be described in terms of effects or impact (Popay et al., 2006). This can be done through the use of textual descriptions, grouping and clusters, and tabulation. This preliminary synthesis is necessary in order to inform the next steps of the narrative synthesis.

3.3.1.3. Element 3: Exploring relationships within and between studies

The patterns that emerge from the preliminary synthesis are subjected to a more detailed analysis in which the reviewers move towards exploring the relationships within and across the included studies (Popay et al., 2006). Relationships between the characteristics and reported findings of different studies are reviewed. This element of narrative synthesis will help identify the factors which may have influenced the results, and will seek to provide an explanation of how and why a particular intervention works (Popay et al., 2006). Methods used here include qualitative case descriptions and the development of a conceptual model based

on the grouping of study findings. This will help to structure the inferences drawn from our results.

3.3.1.4. Element 4: Assessing the robustness of the synthesis

The final element of narrative synthesis sets out to review the trustworthiness of the results (Popay et al., 2006). Trustworthiness of the synthesis is affected by the quality and quantity of the evidence base on which the synthesis is built and by the methods used. Therefore, an appraisal is undertaken to judge the strength of the evidence for the findings, and for generalising them to different populations and contexts (Popay et al., 2006).

3.3.2. Electronic searches and screening

This review was registered in the international Prospective Register of Systematic Reviews (PROSPERO) under protocol number: CRD42017068933. After conducting two pilot searches with support from an information specialist, we systematically searched the following databases: EMBASE, PsycINFO, MEDLINE, CINAHL and Web of Science in January 2019. Studies published between 2000 and 2019 were considered. The search strategy consisted of combinations and variations of search terms in the following three key categories: “dementia”, “technology”, and “involvement in development”. Involvement terms also included “co-design’, “participatory research”, and “user participatory development” (see Appendix 3).

After removal of the duplicates, a three-stage screening process was independently conducted by two review team members (HR and ACB): (1) titles were screened for relevance to the review question, irrelevant studies were archived, (2) abstracts were assessed (referring to the full text whenever necessary to clarify relevance of the study), and (3) quality assessment of the

remaining studies (see section 3.3.5. Data extraction and study quality assessment). Reasons for exclusion were recorded by archiving the excluded studies in relevant folders in Endnote. In case of a disagreement between the two reviewers, a third review team member was consulted (LY). The additional studies from the review by Span et al. (2013) were distributed separately among four review team members (ACB, JS, HR, and LY) for data extraction and quality assessment. The reference lists of studies that passed the quality assessment were reviewed in order to ensure the inclusion of other relevant papers.

3.3.3. Criteria for inclusion and exclusion of studies

Types of participants: People with a diagnosis of dementia, irrespective of age, type of dementia or stage of the disease.

Types of intervention: Involvement of people with dementia in the development process of a technology-based intervention.

Types of studies: Quantitative, qualitative, and mixed methods studies published from the year 2000 onwards as English language journal paper with sufficient study quality (a minimum of five criteria met as assessed with CASP guidelines or 50% of the criteria met as assessed with the Downs and Black checklist).

3.3.4. Description of development phases

The development process of a technology-based intervention consists of several stages. In order to identify the key stages of technology development for this review, we have employed the MRC Framework, together with the CeHRes roadmap (Craig et al., 2008; van Gemert-Pijnen et al., 2011). Both frameworks have a focus on developing interventions however, where the MRC Framework is

more widely used for developing complex interventions, the CeHRes roadmap has a focus on digital health interventions (Table 3.1).

Table 3.1. Description of the MRC Framework (Craig et al., 2008), and CeHRes roadmap (van Gemert-Pijnen et al., 2011).

	MRC Framework	CeHRes roadmap
Development	• Single phase • Identifying evidence base (e.g. systematic review) • Identifying/developing theory (e.g. scope existing theories and interviewing stakeholders) • Modelling process and outcomes (e.g. undertaking a pre-trial economic evaluation, focus groups, surveys, case-studies)	• Multiple phases such as contextual inquiry, value specification and design • Identifying problems and needs of intended users (e.g. literature review, field observations, interviews, workshops) • Determining most favourable solutions based on stakeholders' values • Building prototypes to fit values and user requirements (e.g. focus groups and field-testing)
Feasibility/piloting	• Specific phase for feasibility/piloting • Activities consist of: testing procedures for acceptability, determining appropriate sample size, estimating rates of recruitment	• N/A (can be part of design phase)

Table 3.1 continued

Evaluation	• Assessing clinical and cost effectiveness (e.g. RCT) • Understanding processes (process evaluation)	• Summative evaluation • Assessment of the impact of eHealth technologies in clinical, organisational, and behavioural terms
Implementation	• Getting evidence into practice • Surveillance, monitoring, and long term outcomes	• Operationalisation • Activities to introduce, adopt, and employ the technology in practice (e.g. creating a business model)

3.3.5. Data extraction and study quality assessment

A standardised data extraction form was developed by the primary researcher (HR) in which the review team members recorded the extracted data from the final studies including the study quality rating.

Quality was assessed using the Critical Appraisal Skills Programme (CASP) guidelines. These guidelines consist of eight checklists for various types of studies and include items which assess multiple aspects of research (e.g. recruitment, risk of bias, confounders, data collection, data analysis, results, and implications) (Critical Appraisal Skills Programme, 2017). The studies were rated as high quality if eight or more criteria were met, medium quality if five to seven criteria were met and low quality if they met four criteria or less (Bayliss et al., 2016). Studies not meeting the criteria for assessment with the CASP guidelines were assessed with the Downs and Black checklist (Downs & Black, 1998). This checklist is

appropriate for both randomised and non-randomised studies and consists of 27 items over five domains (reporting, external validity, internal validity: bias and confounding, and power). The maximum score was dependant on the study design but each study was rated as high quality if it met over 81% of the criteria, medium quality for 66% to 80% of the criteria, fair quality for 51% to 65% of the criteria and low quality if it met 50% of the criteria or less (McDermott, Crellin, Ridder, & Orrell, 2013). Studies considered to have low quality were excluded. The review team members independently assessed the studies for sufficient study quality. Any differences in judgement between two reviewers were resolved by a third review team member.

3.3.6. Consultations with the patient and public involvement (PPI) group

One reviewer (HR) presented the findings at a PPI consultation meeting on two different occasions. This PPI group is run on a monthly basis at the Institute of Mental Health (IMH) in Nottingham. The aim of both meetings was to gain insights in people's own views on optimal involvement in developing technology-based interventions, their feedback and comments on the findings, and more specifically their feedback on the guidelines drafted by the authors. This feedback would then be integrated within the findings from this review and used to strengthen the best practice guidelines.

The first meeting was attended by two people with dementia, one carer, one volunteer, and one researcher and lasted for 45 minutes. The second meeting was attended by two people with dementia, two carers, one volunteer, and four researchers and lasted for 25 minutes. After a brief introduction on the review and its findings, the best practice guidelines were presented one at a time on a projector. In the first meeting, printed hand-outs were distributed to each

participant. A short discussion in terms of relevance and accuracy encompassed each guideline and notes were taken throughout the meeting.

3.4. Results (Narrative synthesis element 2: Developing a preliminary synthesis)

3.4.1. Search results

A total of 2156 potentially relevant titles were identified across the five databases (Figure 3.1). Removal of duplicates, screening of titles, abstracts, and full texts resulted in 20 studies that met the inclusion criteria. Most frequent reasons for exclusion were the lack of a technology-based intervention and absence of a development process. Additional hand searching led to the inclusion of one other study making up a total of 21 studies. This study came from the review by Span et al. (2013) which was not captured by the current search strategy. Other studies from the same review not captured by the search strategy (n = 7) were excluded due to not meeting the inclusion criteria (e.g. not a journal paper, low study quality).

3.4.2. Description of included studies

The main study characteristics of all 21 studies include study sample and design, description of the technology-based intervention, and rating of study quality (Table 3.2 and Table 3.3). Using the CASP Qualitative checklist, 11 studies were assessed as high quality and eight studies were of medium quality. Only one study was assessed with the CASP Randomised Controlled Trial (RCT) checklist and this met seven out of 11 criteria (Hattink et al., 2016). One other study was assessed with the Downs and Black checklist. It was rated as fair quality, meeting 65% of the criteria for a before and after follow up study (Khosla, Nguyen, & Chu, 2017).

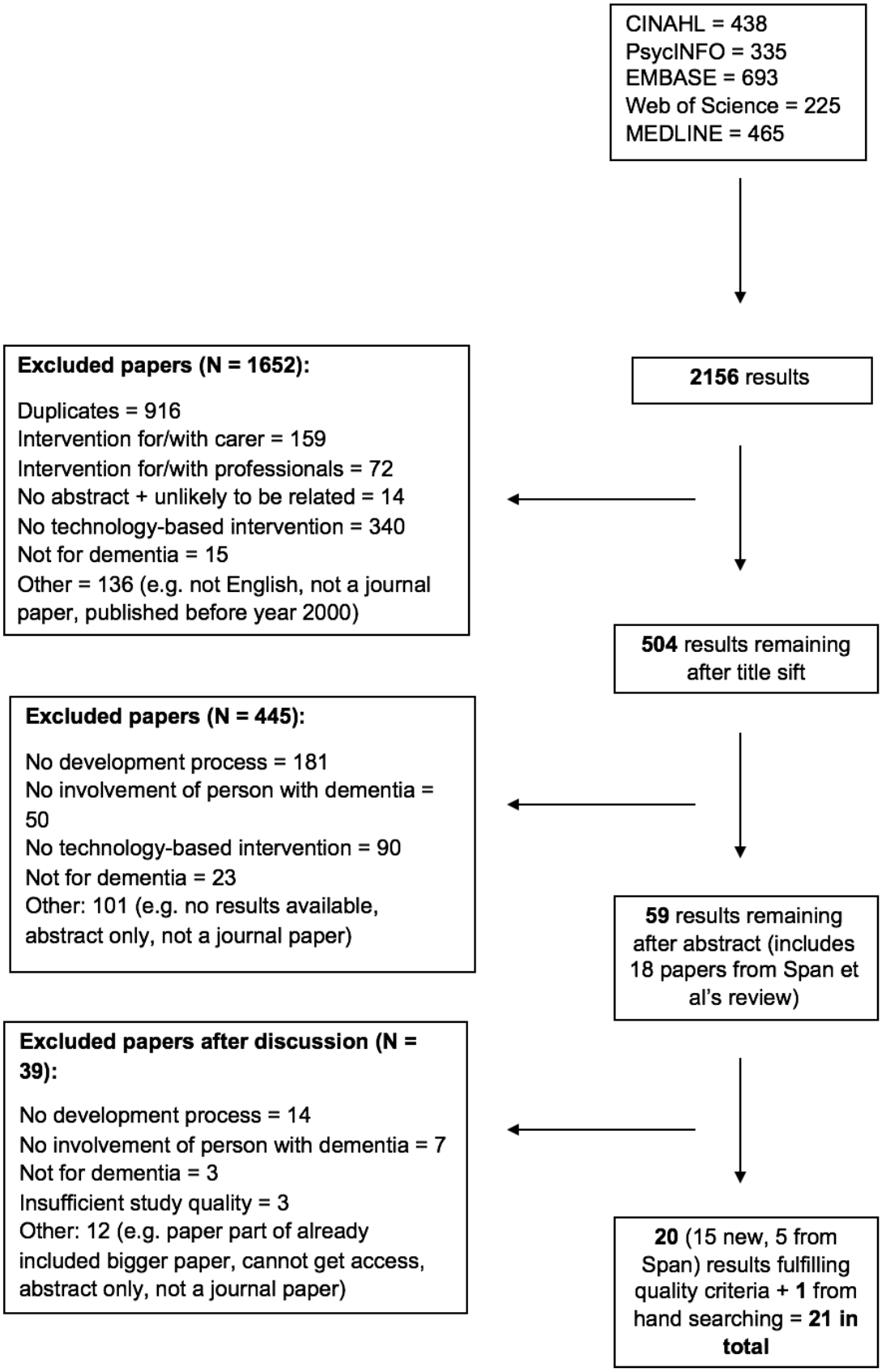


Figure 3.1. Flowchart of study selection.

Most studies were conducted in Europe (n = 17), three studies took place in Australia (Khosla et al., 2017; Moyle, Jones, Dwan, Ownsworth, & Sung, 2018; Moyle, Jones, Dwan, & Petrovich, 2017), and one other in Canada (Begum, Wang, Huq, & Mihailidis, 2013).

A majority of the studies adopted purely a qualitative methodology (n = 14). A total of six studies employed a mixed methods approach, of which one combined qualitative methods with a controlled trial (Hattink et al., 2016). Only one study adopted a purely quantitative methodology (Khosla et al., 2017). The studies described a variety of technology-based interventions including communication aids, music tools, devices to support activities of daily living, reminder systems, and tracking devices. In the majority of the studies people with dementia were involved along with carers or other professionals who either supported the person with dementia in their involvement or provided separate input themselves (n = 17). Only four studies solely included people with dementia (Freeman et al., 2005; Khosla et al., 2017; Orpwood et al., 2009; Span et al., 2017).

Table 3.2. Main characteristics of included studies.

Author & year	Country	Study sample	Study design	Description technology-based intervention	MRC phase of development (CeHRes phase)	Number/percentage of quality criteria fulfilled
1. Begum et al., 2013	Canada	PwD (n = 5), carers (n = 5).	Mixed methods	Assistive mobile robot Aim: to help PwD with activities of daily living such as hand washing and tea making.	Feasibility/piloting (design)	7
2. Boman et al., 2014	Sweden	PwD (n = 6), carers (n = 10), occupational therapists (n = 8).	Qualitative	Easy to use videophone for PwD Aim: to support PwD to make videophone calls without assistance.	Development (value specification)	9

Table 3.2 continued

3. Davies et al., 2009	Sweden, Netherlands, United Kingdom	PwD (n = 17), carers (n = 17).	Qualitative	Touch screen devices Aim: to support independent living in four domains: 1. Remembering 2. Maintaining social contact 3. Performing daily life activities 4. Enhanced feelings of safety.	Development and feasibility/piloting (contextual inquiry, value specification, design)	7
4. Freeman et al., 2005	United Kingdom	PwD (n = 5).	Mixed methods	Two prototype informational websites for PwD Aim: to produce recommendations for the next stage of the design process.	Development (value specification, design)	9
5. Hanson et al., 2007	Sweden	Development group: PwD (n = 7), carer (n = 1). Test group: PwD (n = 19), relatives (n = 12).	Qualitative	The ACTION “Living with Dementia” multimedia education and support program consisting of the Life Story Book, the Diary, and the Family Tree	Development (contextual inquiry, value specification, design)	9

Table 3.2 continued

				Aim: to provide PwD and family carers living at home with early information, education, and support.		
6. Hattink et al., 2016	Belgium, Germany, the Netherlands	PwD/MCI (n = 42), informal carers (n = 32), professional home-care workers (n = 6).	Mixed methods	A fully integrated, multifunctional system consisting of three subsystems (Rosetta) Aim: to help people with MCI and dementia in performing the daily activities they indicated to be of importance (e.g. reminders for activities, support in recreational activities and social contact, autonomous surveillance).	Evaluation (summative evaluation)	7
7. Jamin et al., 2018	The Netherlands	PwD (n = 10), informal carers (n = 2), activity supervisors	Qualitative	An interactive artwork for nursing home residents (VENSTER)	Feasibility/piloting (design)	7

Table 3.2 continued

		(n = 2), manager (n = 1), client representatives (n = 5).		Aim: to help nursing home residents to connect with the outside world through an interactive physical window and therefore to help decrease feelings of isolation.		
8. Kerkhof et al., 2015	The Netherlands	PwD (n = 6), informal carers (n = 5), staff members (n = 6).	Qualitative	Memory aid consisting of digital planning boards Aim: to structure and support the daily activities for PwD.	Development (contextual inquiry, value specification, design)	9
9. Khosla et al., 2017	Australia	PwD (n = 115).	Quantitative	Social robot (Matilda) Aim: to support emotional well-being through the delivery of diversion therapy services to older PwD.	Feasibility/piloting (design)	65% (Downs & Black)

Table 3.2 continued

10. Klein et al., 2018	Germany	Contextual inquiry: PwD (n = 50), carers (n = 18), relatives (n = 17). Test 1: PwD (n = 24), test 2: PwD (n = 25), test 3: PwD (n = 4), cognitive impairment (n = 2).	Qualitative	Multimedia approaches such as haptic and virtual reality artefacts (the Jukebox, Pyramid, and the Binoculars). Aim: to improve well-being through providing reminiscence therapy.	Development (contextual inquiry, value specification, design)	7
11. Lopes et al., 2016	France	PwD/MCI (n = 46), informal carers (n = 35), formal carers (n = 29) across five studies.	Qualitative	Item locator device (TROUVE system) Aim: to help older adults with MCI and AD to find misplaced or “lost” personal items at home.	Development (contextual inquiry, value specification, design)	9

Table 3.2 continued

12. Martin et al., 2013	United Kingdom	PwD (n = 8), healthy older people (n = 12).	Qualitative	NOCTURNAL system Aim: to address disturbed sleep patterns and night time wandering of PwD in an assisted living home.	Development and feasibility/piloting (contextual inquiry, value specification, design)	7
13. McCabe et al., 2013	United Kingdom	PwD (n = 12), carers (n = 3), healthy older people (n = 5).	Qualitative	A GPS/safe walking device Aim: to give more confidence to go out independently and to help carers locate the person with dementia if needed.	Development (contextual inquiry, value specification)	9
14. Meiland et al., 2012	The Netherlands, Sweden, United Kingdom	Field test 1: PwD (n = 16), carers (n =16). Field test 2: PwD (n = 14), carers (n = 13). Field test 3: PwD (n = 12), carers (n =12).	Mixed methods	COGKNOW Day Navigator Aim: to give support for PwD in reminding, social contact, daily activities and feelings of safety.	Feasibility/piloting (design)	8

Table 3.2 continued

15. Meiland et al., 2014	Germany, the Netherlands	PwD/MCI (n = 14), informal carers (n = 13), formal carers (n = 6), dementia experts (n = 9), care partners (n = 7), volunteer (n = 1).	Qualitative	New version of the "Rosetta" system Aim: to combine three systems - COGKNOW Day Navigator (CDN), the EMERGE system and the Unattended Autonomous Surveillance system (UAS) – for PwD and carers, providing support in daily functioning, monitoring patterns in daily behaviour and to automatically detect emergency situations.	Development (contextual inquiry, value specification, design)	9
16. Moyle et al., 2018	Australia	PwD (n = 5), carers (n = 5), health professionals (n = 12).	Mixed methods	Telepresence robot (Giraff) Aim: to support the connection and engagement of PwD and family members though video calls.	Feasibility/piloting (design)	9

Table 3.2 continued

17. Moyle et al., 2017	Australia	PwD (n = 10), family members (n = 10), care staff (n = 9).	Mixed methods	Virtual Reality Forest (VRF) on large interactive screen Aim: to improve quality of life through improving engagement, apathy, and mood states.	Feasibility/piloting (design)	8
18. Orpwood et al., 2009	United Kingdom	PwD (n = 26, 16 living at home and 10 living in care homes).	Qualitative	Four items developed from a "wish list": 1. Music player 2. Window on the world: to reduce social isolation 3. A conversation prompter 4. Sequence support for several tasks e.g. sending a letter, finding a TV programme. Aim: to support quality of life of PwD.	Development (contextual inquiry, value specification, design)	7
19. Robinson et al., 2009	United Kingdom	Scoping stage: PwD (n = 10), carers (n = 11). Participatory	Qualitative	Two prototype tracking devices: armband and electronic notepad	Development (contextual inquiry, value specification, design)	7

Table 3.2 continued

		design stage: PwD and carers (n = 22). Prototype development stage: PwD (n = 2), carer (n = 1).		Aim: to facilitate independence for PwD and to facilitate mutual communication between PwD and their families.		
20. Span et al., 2017	The Netherlands	Interviews: PwD (n = 23). Focus groups: PwD (n = 18) Usability tests: PwD (n = 3). Field study: PwD (n = 4).	Qualitative	The DecideGuide (a web tool) Aim: to help PwD, informal caregivers, and case managers make shared decisions.	Development and feasibility/piloting (contextual inquiry, value specification, design)	9
21. Topo et al., 2004	Finland, Norway, Ireland, UK	PwD (n = 23), staff members (n = 17).	Mixed methods	The Picture Gramophone (PG) multimedia programme Aim: to be used by PwD, to stimulate them and to give them pleasure.	Feasibility/piloting (design)	7

PwD = people with dementia, MCI = mild cognitive impairment, AD = Alzheimer's disease

Table 3.3. Methodological quality of included qualitative studies (n = 19).

CASP Qualitative Checklist (https://casp-uk.net/casp-tools-checklists/)	Begum et al., 2013	Boman et al., 2014	Davies et al., 2009	Freeman et al., 2005	Hanson et al., 2007	Jamin et al., 2018	Kerkhof et al., 2015	Klein et al., 2018	Lopes et al., 2016	Martin et al., 2013	McCabe et al., 2013	Meiland et al., 2012	Meiland et al., 2014	Moyle et al., 2018	Moyle et al., 2017	Orpwood et al., 2009	Robinson et al., 2009	Span et al., 2017	Topo et al., 2004
1. Clear statement of aims?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2. Qualitative methodology appropriate?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3. Research design appropriate?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4. Recruitment strategy appropriate?	+	+	+	+	+	+	+	-	+	-	+	+	+	+	-	+	+	+	-
5. Data collected in a way that addressed the research issue?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6. Has the relationship between researcher and participants been adequately considered?	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7. Ethical issues taken into consideration?	-	+	-	+	+	-	+	+	+	+	+	+	+	+	+	-	-	+	-

Table 3.3 continued

8. Data analysis sufficiently rigorous?	-	+	-	+	-	-	+	-	+	-	+	-	+	+	+	-	-	+	+
9. Clear statement of findings?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10. How valuable is the research?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Total	7	9	7	9	9	7	9	7	9	7	9	8	9	9	8	7	7	9	7

+ = criterion met; - = criterion not met

3.4.3. Methods of involvement and key findings

The methods used to involve people with dementia along with the phases of the MRC Framework and CeHRes roadmap are summarised in Table 3.4 allowing for an initial synthesis of the findings.

Table 3.4. Methods used to involve people with dementia in the studies (N = 21) according to the MRC Framework phases.

MRC Framework phase	Methods of involvement
Development (contextual inquiry, value specification, design)	Behavioural observations (4, 10), Focus groups (2, 5, 11, 13, 15, 19, 20), Interviews (3, 5, 8, 11, 12, 15, 18, 20), Workshops (3, 19), Questionnaires (4), User tests (5, 10, 11, 18, 19, 20)
Feasibility/piloting	Behavioural observations (1, 7, 9, 14, 16, 17), Interviews (1, 3, 12, 14, 16, 17, 21), Questionnaires (1, 9, 14, 21), Field-testing (3, 14, 20), Technical system usage (12)
Evaluation (summative evaluation)	RCT (6), focus groups (6), interviews (6), questionnaires (6)
Implementation (operationalisation)	N/A

3.4.3.1. Development phase (n = 10)

A total of 10 studies involved people with dementia solely in the development phase which coincides with the contextual inquiry, value specification, and design phase of the CeHRes roadmap. The majority of these studies primarily employed qualitative methods such as focus groups and semi-structured interviews. These

were at times accompanied by user tests, observations, and questionnaires. Table 3.4 gives an overview of all methods used in the development phase. The aims of the studies ranged from identifying people's needs, wishes, and thoughts regarding certain areas for development (e.g. independence or cognitive reinforcement) to gaining feedback on the design of future or existing technologies (Figure 3.2).

Needs assessment and design of future technology

Two studies included needs assessments followed by discussions about the design of future technology using qualitative methods. Boman, Nygard, and Rosenberg (2014) used focus groups to capture experiences, expectations, and thoughts concerning a videophone and its design concepts. The design should be flexible in order to meet the needs of people with dementia, be easy to use and not look like assistive technology (AT). Another example is the study by Robinson et al. (2009) who also used focus groups to elicit views and concerns about independence from people with dementia and carers. A list of priorities was derived from the findings. Areas for functional improvement included two-way communication, flexibility of functionality, and something to "guide" them home when outside. Workshops were then used to identify the preferred design and functionality aspects of future technologies. Finally, user tests were performed with paper prototypes until two fully functional devices were developed.

Needs assessment and user tests

In three other studies, needs assessments were followed by user tests with functional technologies. Orpwood et al. (2009) used interviews with users (user surveys) to compile a wish list of issues that were of importance in maintaining QoL of people with dementia. A large list of potential technologies that could

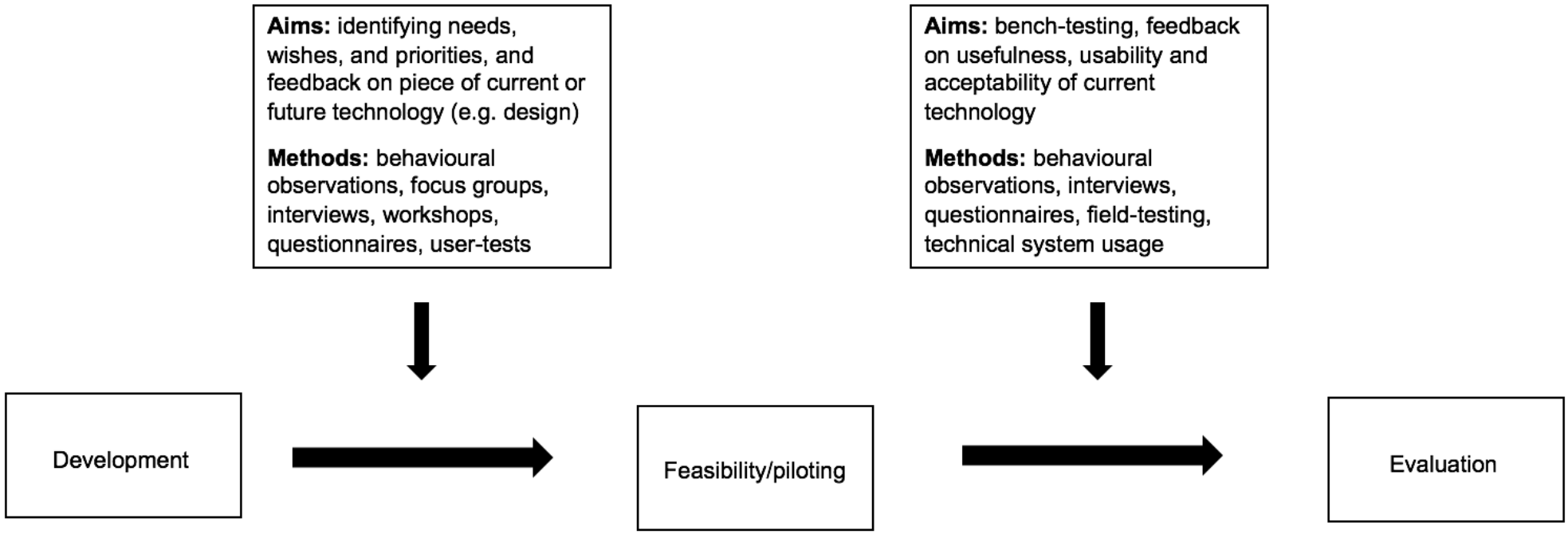


Figure 3.2. Aims and methods of involvement along the development stages of technology.

address these issues was generated. Four of these were selected for initial development: a music player, a device to reduce social isolation, a conversation prompter, and a device to support sequences of tasks. Useful design guidelines were derived from the user tests particularly for intuitive control interfaces (e.g. controls need to stand out, be big, and simple).

Touch screens appear to be very intuitive and prompts seems to be more effective than verbal or visual instructions. Hanson et al. (2007) used focus groups to identify user needs and preferences, and to structure the material within a multimedia programme. A prototype was taken forward in user tests followed by in-depth interviews. These led to the identification of problems such as logging into and out of the programme, and accessing the exercises. Participants enjoyed the computer training sessions and gained considerable satisfaction from learning a new skill that they previously thought was not feasible. Lopes et al. (2016) used interviews to analyse user needs and identify commonly misplaced items such as keys, glasses, cell phones and identity papers. Focus groups and user tests were then used to try out existing item locators and define the following system requirements of a new item locator prototype: ease of use, capacity for customization, low price, non-stigmatizing design, and being “fun” to use. The next step included user tests with the first prototype in which participants commented they would prefer to be guided by a customised sound of a voice system to find an item.

Design of existing or future technology

In two studies, feedback was solely gathered on the design of future technologies using qualitative methods only. In Meiland et al. (2014), non-functional mock ups were reviewed after discussing potential functionalities of an integrated, assistive

system in focus groups and interviews. Participants valued help in case of emergencies, navigation support, and the calendar function the most. The least preferred functionalities were activity support and picture phone dialling. McCabe and Innes (2013) found that people with dementia and carers gave specific feedback on the form and features of a potential Global Positioning System (GPS) design during focus groups (e.g. waterproof watch style design with a range of colours) however, participants would have preferred to comment on an actual and active device rather than talking hypothetically as it did not provide them with enough context.

In three studies, participants gave feedback on the design of an existing and functional technology. Freeman et al. (2005) analysed observational data of people with dementia using two websites. This data helped to uncover three major problems: scrolling, non-recognition of more information on a page, and becoming stuck. There was a high degree of overall satisfaction with both sites measured through questionnaires. Kerkhof, Rabiee, and Willems (2015) interviewed residents after bench-testing a memory aid (planning board). The majority appreciated the use and function of the aid but successful implementation was difficult due to installation errors, limited user friendliness and lack of knowledge regarding the function and use of the aid. Areas of focus for improvement include: software programme adaptation, additional technological applications, internet connectivity, accessibility, and addition of media. Lastly, Klein, Uhlig, and Will (2018) also observed participants while testing two prototype devices. Based on the findings from these tests, a third prototype device was developed. Special attention was given to more personally relevant and engaging content, contextual factors, higher levels of immersions, and more control for the user.

3.4.3.2. Feasibility and piloting phase (n = 7)

Seven studies included only the feasibility and piloting phase which can be part of the design phase of the CeHRes roadmap (Begum et al., 2013; Jamin, Luyten, Delsing, & Braun, 2018; Khosla et al., 2017; Meiland et al., 2012; Moyle et al., 2018; Moyle et al., 2017; Topo et al., 2004). In this phase, people with dementia were given the opportunity to try out a piece of technology in a pilot study or through field-testing. Often the aim was to gain insights in the usefulness of a device along with its acceptability and usability (Figure 3.2). In the majority of the studies (n = 5), a mixed methods approach was adopted where participants were observed while using the device and feedback was obtained through semi-structured interviews and questionnaires. Table 3.4 gives an overview of all the methods used in the feasibility and piloting phase.

Begum et al. (2013) used observations to investigate adherence to prompts from a robot, engagement with the robot, and how often a task was completed. Interviews and questionnaires gave information on the acceptance, ease of use, usefulness, and physical attributes of the assistive robot. Meiland et al. (2012) field-tested an integrated digital prosthetic with multiple functionalities. Data on usability was collected through behavioural observations, interviews, and questionnaires and it was deemed to be user-friendly and useful but there was a wish for more personalisation and configuration of reminders.

Moyle et al. (2018) explored the acceptability of a telepresence robot using observations through video recordings and follow up interviews. Participants indicated a positive social presence, which was also observed through the display of positive emotions. A similar methodology was adopted in another study by Moyle et al. (2017). Observations through video recordings were used to describe

the effectiveness of a Virtual Reality Forest (VRF) on engagement, apathy, and mood states. Overall, the VRF was perceived to have a positive effect but there were higher levels of fear/anxiety. Follow up interviews were used to explore the experiences of using the VRF. Most participants reported positive perceptions and suggested to make the experience more active.

Topo et al. (2004) used questionnaires to collect information on functional ability of people with dementia. Through interviews, data was collected on the usage and usefulness of an existing music tool two weeks after installation in a care home. Most participants benefitted from its use and had positive experiences. Some problems were reported with the sensitivity of the touch screen and the font size being limited due to the screen size.

Jamin et al. (2018) used a qualitative approach where participants were involved in usability testing and were observed while interacting with “VENSTER”. The content of VENSTER, which needs to provide enough context in order to be meaningful, was interesting and suitable for the participants. Khosla et al. (2017) was the only study using a quantitative methodology where participants were observed while interacting with a social robot to gain insights in emotional, visual and behavioural engagement. In addition, user surveys were used to assess the acceptability. The participants generally had a positive attitude towards social robots. Most of the participants gave high ratings in terms of the perceived usefulness and enjoyment of their experience with the robot.

3.4.3.3. Development + feasibility and piloting phase (n = 3)

Three studies elaborated on both the development, and feasibility and piloting phase (Davies et al., 2009; Martin et al., 2013; Span et al., 2017). These studies systematically described the involvement of people with dementia over the course

of each phase: the identification of user needs and wishes, determination of the design, and testing a prototype version through a pilot or field test. For each of these activities, a wide array of methods was applied such as focus groups and interviews but also workshops and usability tests.

In the study by Span et al. (2017), the development phase consisted of interviews to identify needs and preferences for an interactive web tool and focus groups to discuss the results of the interviews and to make any additions to the problems and experiences shared. Several user requirements were identified such as social contacts, daily activities, care, and autonomy, involvement, communication specifically for the decision making process. Paper mock ups were discussed in focus groups in order to design the interactive prototype. Hereafter, individual user tests were organised to gather feedback on an interactive prototype regarding design, content, and user friendliness. Some participants found it difficult to comment on paper mock ups but overall mentioned that information per screen and the amount of screens should be decreased, and the accuracy of language was of importance. For the feasibility and piloting phase, an interactive prototype was field-tested to gain feedback on the user friendliness of the tool, participants' contentment, and how they valued the tool for decision making.

Martin et al. (2013) used interviews in the development phase to establish the main issues and risks, and care needs arising during night time. Main themes included: promoting independence, maintaining dignity, maximising social inclusion, managing risk, and providing stimulation. In the feasibility and piloting phase, participants were involved in any of the three phases of iterative validation and evaluation of a prototype through technical system usage and interviews. The phases included testing for stability, usability and integration within a full telecare

system, and implementation of music and light. Participants liked the mobile component of the night time system and the easy navigation.

Davies et al. (2009) used both interviews and workshops to identify user needs in specific areas of cognitive reinforcement in the development phase. The following areas were identified by the participants: remembering, maintaining social contact, performing daily life activities, and enhanced feelings of safety. Interviews accompanied field-testing in the feasibility and piloting phase. After trying out four prototypes, participants highlighted the need for personalisation, less complex functionality, and an extended use within the home environment.

3.4.3.4. Evaluation phase (n = 1)

One study involved people through evaluation in a controlled trial (Hattink et al., 2016). Participants used an assistive system and filled in post-test questionnaires to assess impact. Despite no significant effects on impact, post-trial interviews and focus groups were used to assess qualitative impact and participants found the system to be very useful but not user-friendly due to the technical difficulties including unresponsiveness of touch screens and issues with gaining access. For people who had not used touch screen before, the system was deemed unintuitive.

3.4.4. Involving people with dementia

3.4.4.1. Impact on the developed technology

In all but five studies (Davies et al., 2009; Khosla et al., 2017; Klein et al., 2018; Moyle et al., 2018; Orpwood et al., 2009), researchers directly reflected on the involvement of people with dementia in the development of the technology-based intervention. Researchers concluded that it was both necessary and feasible to involve people with dementia throughout the development process. In addition,

Kerkhof et al. (2015) argued that it is not sufficient to respond to the needs of people with dementia by solely involving carers or staff members. This is further supported by Meiland et al. (2014) and Lopes et al. (2016) who found that exploring the user perspectives from various stakeholders including people with dementia is necessary in order to understand the problem and come up with possible solutions. Jamin et al. (2018) also emphasized that co-design with all stakeholders can make the overall experience more pleasurable but also more meaningful as it allows for the users to be kept at the centre of the decision-making process and adaptations can be made to new insights as they emerge. In several studies it was recognised that people with dementia continue to be one of the most excluded groups from research and the design of new services (Boman et al., 2014; Hanson et al., 2007). Possible reasons for this could be difficulties in recruitment or the cognitive impairment of people with dementia (Begum et al., 2013; Meiland et al., 2012). However, despite these challenges, all studies recommended to involve people with dementia in future studies as this could lead to obtaining views on new concepts or ideas for technology, and to more concrete feedback on the usability and user friendliness of a device. For instance, one study determined how to maximise website suitability for people with dementia after receiving feedback (Freeman et al., 2005). Another study adapted the appearance of a robot and made it more socially interactive (Begum et al., 2013). Lastly, people with dementia suggested the interaction between end users and a virtual reality system could be improved by incorporating reminiscence within the tool (Moyle et al., 2017).

3.4.4.2. Impact on the person with dementia

Positive effects of involvement for people with dementia themselves included the empowering effects of involvement which were evident in increased feelings of well-being, being able to voice opinions, learning a new skill through the use of

technology, and an enhanced sense of control experienced by the majority of the participants (Hanson et al., 2007). Participants were also motivated to make a contribution to research and a better QoL for future people with dementia (Kerkhof et al., 2015; Span et al., 2017). No distress or adverse events from involving people with dementia were reported in any of the studies.

3.4.4.3. Outcomes of the PPI consultation meetings

PPI group members reflected both on how to optimise involvement in research and in developing technology-based interventions, and endorsed the guidelines (Table 3.5). Additions were made to some guidelines. For example, there was consensus among members that researchers need to focus on individual research participants, which includes awareness of their type of dementia, any other relevant conditions, and any specialised knowledge of participants which could further support the development of technology. Awareness among participants in terms of the relevance and positive effects of involvement for themselves was also important.

A friendly research environment was helpful to make people feel comfortable to ask questions in case they did not understand something. This is especially helpful when developing new technology, which can include some unknown aspects and so, researchers should also aim to avoid abbreviations and acronyms on top of avoiding technology-related jargon. In addition, PPI group members suggested that researchers should present their materials at a PPI meeting before an actual research activity takes place to ensure the use of jargon is limited.

Involving people with dementia as early as possible in the development process and in multiple phases of development, should lead to increased familiarity and a better understanding of the technology. Members were also positive about

encouraging technology developers to interact directly with people with dementia, but did highlight that a mediator (e.g. a researcher) would be necessary to ensure a good level of understanding among both people with dementia and the developers. A person with dementia also mentioned taking a technology into the community (e.g. a memory café) to gather feedback as this would allow for the technology to be used in a real life setting.

Lastly, a “Wizard of Oz” method was suggested by a researcher where participants interact with a working prototype, but under guidance from an unseen researcher. The two PPI group members with dementia mentioned they would not have an issue with this in terms of ethics and it was regarded as a good idea. This method could serve as a way to limit the amount of errors.

3.5. Discussion (Narrative synthesis element 3: Exploring relationships within and between studies)

People with dementia can contribute effectively to the development of technology but are often excluded from research in this area. With the rise of innovative technology, there is a need for an overview of the current evidence regarding the involvement of people with dementia and recommendations on how to optimise this involvement in the development process. This is to ensure the developed technologies are suitable and tailored towards the needs of the end users. This is the first narrative synthesis systematic review to synthesize the findings from high quality studies of involvement of people with dementia in developing technology-based interventions, and has created best practice guidelines based on the evidence summarised below.

A strength of this review is the strict inclusion criteria leading to the synthesis of high quality papers. This has further supported the robustness of the findings and

the developed guidelines. Furthermore, the application of narrative synthesis in this systematic review allowed for a highly systematic approach to searching for and making sense of the evidence. The underpinning theory as part of the first element of narrative synthesis helped define the research questions and the studies to be included in the review. In addition, the preliminary synthesis supported the tabulation of the findings, which is highlighted in the text, tables and figures. This approach also proved helpful in converting the evidence into best practice guidelines by looking for relationships within and between the studies (see section 3.5.2. Best practice guidelines). Good examples of involvement were extracted and incorporated into the guidelines, which were modified by the input of the PPI group. This enabled the invaluable perspectives of people with lived experience on the findings, and helped strengthen the robustness of the synthesis and relevance of the guidelines.

3.5.1. Summary and interpretation of findings

The findings suggest that the involvement of people with dementia varies depending on the development stage and methods used which is in line with previous research (Span et al., 2013). A big part of involving people with dementia revolves around identifying user needs and preferences. The majority of the studies included this aspect in their research and primarily used qualitative methods such as focus groups and interviews. The identification of needs often helped to prioritise the most pressing issues for people with dementia.

Another component is gathering feedback on either the prospective or existing design of a device. These activities mostly include qualitative methods while using observations and questionnaires. People with dementia take on an active role in voicing their opinions and trying out the available prototypes. Once a piece of

technology has been developed into a more refined version, the involvement of people with dementia shifts more towards the participants becoming the objects of study. In several studies, people with dementia were asked to use a piece of technology more rigorously during a field-testing phase accompanied by observations, and to give feedback after the test phase. Interestingly, no studies involved participation of people with dementia in the implementation phase.

These findings are congruent with findings from Span et al. (2013). However, in this review we found studies, which described more elaborately the involvement of people with dementia and demonstrated that it is feasible to include them throughout the entire development process rather than in a single phase. The involvement of people with dementia started with exploring their needs and gaining understanding of a current problem, which led to the development, and testing of various prototypes together with people with dementia in order to tailor it to their needs. These studies set a good example for future studies by also applying various methods and obtaining in-depth data from people with dementia. The impact of the involvement is also evident as studies gave examples of concrete pieces of feedback from people with dementia, which improved the developed technology. However, there is also impact of involvement on the person him/herself as some studies showed that involvement of people with dementia can be empowering and lead to increased feelings of well-being (Hanson et al., 2007). Participants expressed the importance of being able to make a contribution to the research through voicing their own opinions (Hanson et al., 2007; Kerkhof et al., 2015; Span et al., 2013). None of the studies noted any distress caused through the involvement of people with dementia. This is helpful for future studies as anticipated distress from trying out underdeveloped technology was seen as reason not to include people with dementia in development (Orpwood et al., 2009).

Some challenges were described in the involvement of people with dementia such as the risk of obtaining socially desirable answers (Boman et al., 2014; Meiland et al., 2012). However, this risk is not specific to this population and in general, is not uncommon in research. Another challenge was obtaining in-depth feedback from participants as the use of unfamiliar terms related to technology made it difficult for participants to comprehend the questions (Topo et al., 2004). Jamin et al. (2018) emphasized the need for the involvement of multiple stakeholders but acknowledged that this adds a level of complexity to the design process as researchers or developers would have to navigate various differing opinions. Despite these challenges, all studies recommended that people with dementia should be involved in developing technology and also to keep including relevant stakeholders such as (in)formal carers and technology developers where possible.

3.5.2. Best practice guidelines (Narrative synthesis element 4: Assessing the robustness of the synthesis)

Based on the findings from the studies included in this review and the contributions from the PPI consultation meetings, best practice guidelines for the involvement of people with dementia in developing technology-based interventions were developed (Table 3.5). A previous best practice model included in a systematic review by Di Lorito et al. (2017), served as an example to better organise the findings according to goals of involvement, preparations and, the contributions from the PPI consultation meetings. A score can be allocated to each guideline depending on whether it has been fully met (2), partly met (1), or not met (0). The availability of 12 guidelines means that a total score of 24 can be achieved, indicating that each guideline has been met in full when developing a technology-based intervention for people with dementia.

Having the right prerequisites in place prior to involvement can help overcome the challenges and to optimise the involvement of people with dementia. When it comes to the participants, prioritising their well-being and ensuring they are aware of the purpose and relevance of their involvement can help contribute to an enjoyable research experience (Boman et al., 2014; Hanson et al., 2007). Both findings from this review and suggestions from the PPI group members emphasized the need for skilled researchers, and the need for a comfortable research environment. Researchers need to take time to get to know participants and PPI group members added that researchers should be aware of any specialised knowledge of people with dementia prior to their involvement. This could strengthen their contributions and it would easily enable them to become co-researchers. Furthermore, determining the goal of involvement and where it is best suited in the development process will help avoid wasting time of people with dementia (Martin et al., 2013).

Keeping in line with this, multiple methods for involvement need to be considered to obtain the most optimal feedback and where possible multiple phases of development should be included. This was confirmed by the PPI group members and in addition to this, early involvement of people with dementia was considered to be helpful as it would also help to identify their own needs and ideas for technology. The latter is crucial in some of the studies included in this review in which people with dementia are involved in needs assessments and prioritising areas for functional improvement before moving on to prototype development. It is also recommended to involve all relevant stakeholders and allow interaction between them to obtain a well-rounded view from several user perspectives but also to enable people with dementia to become part of the research and development team (Jamin et al., 2018; Kerkhof et al., 2015).

Table 3.5. Best practice guidelines for the involvement of people with dementia in developing technology-based interventions.

Guideline	Goals to be achieved	Preparation	PPI additions
		Prior to involvement	
1. The well-being of people with dementia should be prioritised (Hanson et al., 2007).	• Ensure a positive research experience for participants.	• Involve skilled researchers/practitioners. • When working in groups, ensure these are small in size (max. eight people with dementia). • Allow for time to get to know the participants.	• Researchers need to be aware of the type of dementia and any other relevant conditions that might influence participation. • The positive aspects of participating need to be highlighted. • A friendly, light hearted environment is needed so participants feel comfortable to ask questions about things they do not understand.

Table 3.5 continued

2. People with dementia should be made aware of the purpose of their involvement (Boman et al., 2014).	• Decrease the risk of socially desirable answers.	• Explore participants' expectations regarding their involvement. • Encourage participants to be honest and critical. • Give participants the opportunity to be co-researchers.	• Researchers need to highlight the relevance of participation.
3. Researchers need to set the goal of involvement and take stock of when and where in the development process its best suited (Martin et al., 2013).	• Ensure the involvement is optimal and meaningful.	• Determine which stage of development the technology is currently at. • Assess what kind of information is needed from participants.	• Participants should be involved as early as possible. • Hone in on specialised knowledge of participants (e.g. prior experience with technology development).
4. Involve people with dementia in several phases such as the development, validation and evaluation of technology (Martin et al., 2013; Span et al., 2017).	• Wider uptake of the technology, and continued use by target population.	• Get familiar with the phases of technology development by applying existing frameworks.	• Involve the same participants in multiple phases.

Table 3.5 continued

5. Identify the best methods for providing feedback. A combination of several methods should be considered.	• Obtain diverse and in-depth data which is representative of the participants' feedback.	• Determine the type of data which needs to be obtained. • Qualitative methods such as focus groups and interviews are appropriate to identify needs and user requirements or to gain feedback after bench-testing a technology. • Quantitative methods such as surveys, user tests are appropriate when field-testing a technology.	• Gather feedback in community settings such as memory cafes.
6. Involve all relevant stakeholders including people with dementia, informal carers, staff members, technology developers and where possible allow interaction between stakeholders	• Obtain a well-rounded view through the feedback from several user perspectives. • Accentuate or confirm value of findings across the groups.	• Organise various research activities for each stakeholder group and explore where appropriate activities may be combined. • Create an opportunity for people with dementia to	• A mediator can help to promote the same level of understanding between technology developers and end users.

Table 3.5 continued

(Jamin et al., 2018; Kerkhof et al., 2015).	• Enable people with dementia to be part of a bigger team.	• meet technology developers or other stakeholders.	
7. Ensure all the practicalities for involving people with dementia are in place such as sufficient time and a suitable location (Hanson et al., 2007; Span et al., 2017).	• Build a trusting relationship between participants and research team. • Create a familiar and supportive environment. • Increase accessibility to the research activity.	• Factor in time dedicated to socialising and getting to know each other. • Funders can facilitate researchers' responsibility by counting in extra time for participation of people with dementia. • Location should include disabled access, car parking, public transport, and amenities such as a kitchen or pantry, and hot drinks.	• A long session can lead to fatigue. Sprints of 45 minutes could be appropriate depending on people's preferences.

Table 3.5 continued

During involvement			
8. Use appropriate terminology and words when asking questions (Topo et al., 2004).	• Obtain more meaningful answers. • Avoid confusion.	• Adopt multiple methods for data collection for example observations paired with interviews. • Develop clear and easy to answers questions. • Avoid the use of uncommon or unfamiliar technology jargon. • Check whether terms/questions are understood by all participants.	• Present any materials to be used at a PPI meeting prior to the actual research activity. • Avoid the use of acronyms and abbreviations.
9. When assessing the design or usability of a technology, gather feedback from people with dementia on working prototypes which can be operated by the users rather than paper prototypes	• Ease of providing feedback for people with dementia. • Create a better understanding of the technology to be developed.	• Create digital mock ups. • Have the device present and switched on at the time of asking questions so participants can test it.	• Wizard of Oz method which includes an unseen researcher operating the device from a distance, could be an alternative.

Table 3.5 continued

(McCabe & Innes, 2013).			
10. When evaluating the impact of a technology on daily life, ensure the system meets an acceptable standard of stability and reliability (Hattink et al., 2016).	• Avoid frustration among participants due to faulty technology. • Avoid missing out on essential feedback.	• Have multiple rounds of development (sprints) to iron out some faults. • Bench-test the technology before it is used over a longer period of time.	• If possible and applicable, offer the technology on different platforms (e.g. computers, touch-screen devices).
11. Offer people with dementia the opportunity to learn a new skill through their involvement (Hanson et al., 2007; Span et al., 2017).	• Contribute to the overall experience of involvement. • Empower and enhance well-being of people with dementia by enabling them to learn a skill which previously they may have thought was not feasible.	• Allow time for people with dementia to get familiar with the technology. • Where possible, include a training session on how to use a technology (e.g. a tablet). • Encourage people with dementia to learn about the technology either by themselves or together with others.	

Table 3.5 continued

After involvement		
12. Allow for people with dementia to receive updates on the development and implementation of the technology.	• Inform participants how their involvement and feedback supported development.	• Send out newsletters including updates and share contact details of the research team. • Where possible, give access to the developed technology. • If necessary, make sure technology is kept up to date and involvement of people with dementia takes places accordingly.

During the involvement of people with dementia, the research experience can be further enhanced if participants are able to learn a new skill involving technology (Hanson et al., 2007; Span et al., 2017). This can lead to increased motivation and feelings of empowerment. In addition, the use of appropriate terminology can be helpful in obtaining meaningful and more in-depth answers (Topo et al., 2004). Technology must meet an acceptable standard of stability and reliability when evaluating its impact (Hattink et al., 2016). This can help to avoid frustration among participants and to avoid missing out on essential feedback. PPI group members agreed it would be more useful to use functional devices during testing, and added that the technology should be compatible with different platforms if applicable (e.g. a computer or a mobile phone). However, members also reflected on the “Wizard of Oz” method and the idea of an unseen researcher operating the device from a distance while people with dementia would interact with it. This method could potentially function as a good alternative where paper-based prototypes are not suitable but fully functional prototypes are not available either. After involvement has taken place, it is advisable to keep participants up to date regarding further development or implementation of the new technology.

Figure 3.3 includes a logic model based on the findings from this review and the best practice guidelines. It describes the current problem of a lack of involvement of people with dementia in developing technology and how this can be remedied through key intervention change techniques such as setting goals of involvement and using appropriate methods. This will lead to key and long term outcomes including more useful pieces of technology and decreased costs of dementia care.

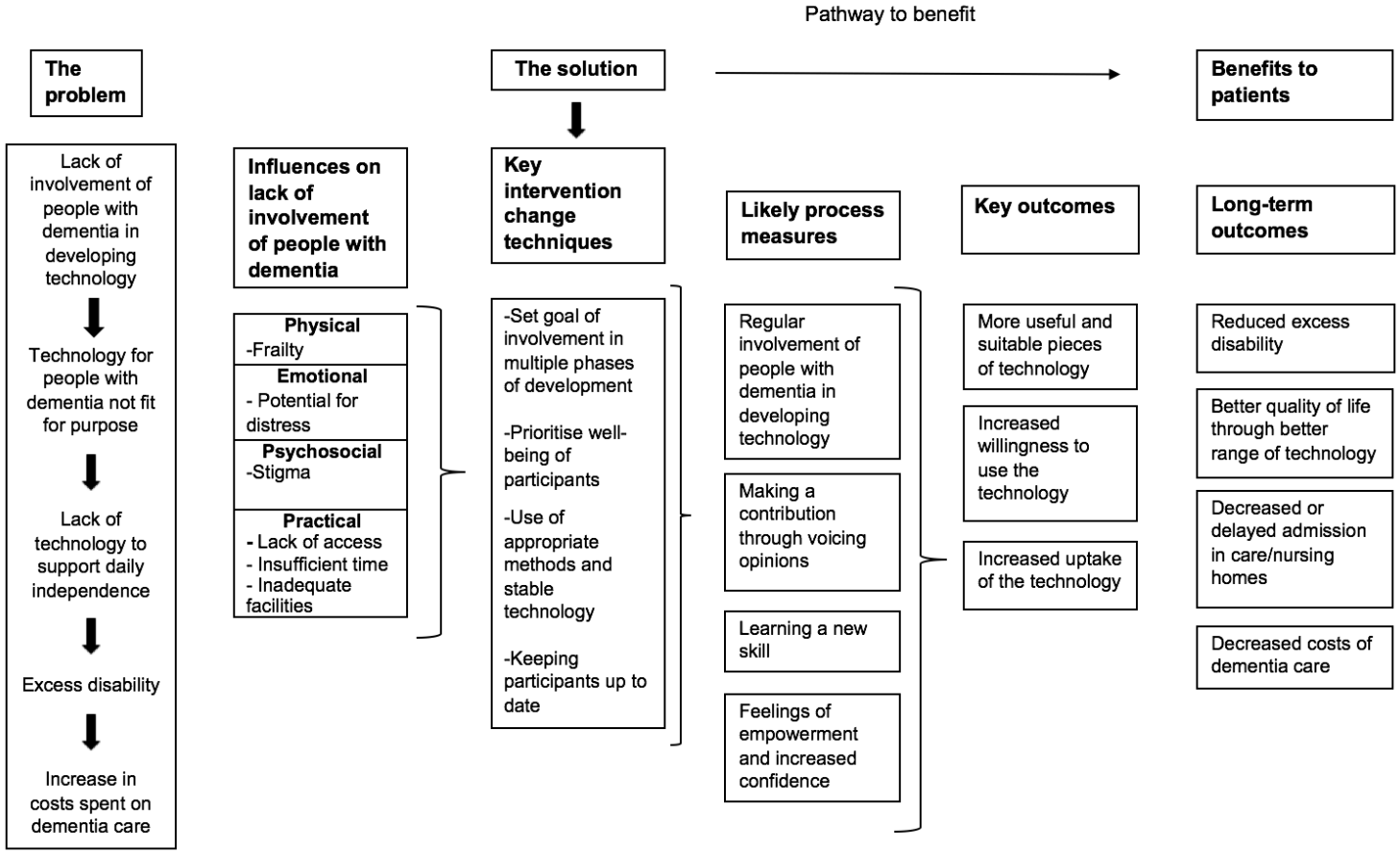


Figure 3.3. Optimising the involvement of people with dementia in developing technology-based interventions: Logic model.

3.5.3. Limitations (Narrative synthesis element 4: Assessing the robustness of the synthesis)

This review included very few studies, which involved people with dementia in multiple stages of technology development. Furthermore, although this review did not focus on the passive involvement of people with dementia (e.g. in large-scale RCTs), few studies allowed for impact evaluation and subsequent sharing of feedback such as in the study by Hattink et al. (2016). Lastly, no studies were found which included the involvement of people with dementia in the implementation phase of development.

The definition of involvement in a development process was partly based on previous research and therefore only included studies in which people with dementia played an active part in development or were able to give feedback. This might have caused the exclusion of other potentially relevant studies, which involved people with dementia through other methods, which is a limitation of this review. Another limitation is the focus on English language peer reviewed journal papers only which may have led to the exclusion of other, potentially relevant content.

3.5.4. Future research

In order to develop more tailored technology and explore the possible roles for people with dementia in other phases, future studies should expand on the level of involvement of people with dementia. Suitably informed and able people with dementia should be co-researchers or advisors, and be made an integral part of the research team and the study. This would enable the same group of people with dementia to consistently provide feedback from the early stages of development (e.g. formulating the problem) towards the mid- and end stages (e.g. design and

implementation). Especially considering the lack of studies focussing on the implementation phase, future research should explore the role of people with dementia in both implementation and dissemination of a new technology. For instance, people with dementia can be involved in conference presentations, as co-authors on academic papers, or in dissemination through media outlets e.g. radio. Furthermore, people with dementia should be involved in the ongoing monitoring and updating of a new technology as part of the research and development team. In some current studies the researcher often acts as a mediator between the person with dementia and the technology developer. However, future studies could aim to facilitate direct knowledge transfer between the two in order for the technology developers to receive raw feedback.

3.6. Conclusion

Over time, studies have involved people with dementia more rigorously in developing technology. However, technologies still need to be tailored to the needs and preferences of people with dementia. In order to do this, people with dementia need to be given an active role in the development of technology so they can have the opportunity to voice their thoughts and opinions. This narrative synthesis systematic review has shown that it is feasible for people with dementia to assume a more active role throughout the development process from discussing and commenting, to try outs and testing. Involvement of people with dementia is associated with several benefits namely the development of better and more useful technology, an improved uptake of the technology and an increased willingness to use the technology. In addition, the evidence-based, best practice guidelines were deemed to be relevant by PPI group members and will help support future researchers, technology developers, and people with dementia to optimise

involvement when developing technology. This will not only ensure that future technology-based interventions are suitable but will also allow people with dementia to feel empowered by making an effective contribution to technology development and research in general.

Textbox 3.1. Summary guidance for involving people with dementia in developing technology.

Prepare for involvement:

- Make this a positive experience for participants by creating a friendly environment, where people can ask questions and feel supported.
- Involve a variety of stakeholders and users in order to collect a range of feedback and perspectives.
- Ensure all practicalities for involvement are in place to meet the needs of participants.
- Participants should be made aware of the purpose and relevance of their involvement to meet their expectations and encourage honest feedback.
- Explore the available methods for collecting feedback and select the ones best suited for the goal of involvement.

Practice involvement:

- Use appropriate terminology/words when asking questions to promote understanding and generate more in-depth feedback.
- Offer participants the opportunity to learn a new skill through their involvement in order to enhance well-being and empowerment.
- Involve participants throughout the development process to create a more suitable piece of technology for wider uptake.
- Keep participants informed after their involvement so they can stay up to date on further development and implementation of the technology.

Chapter 4 – Development of the individual Cognitive Stimulation Therapy application (iCST app) for people with dementia

This chapter was based on a journal article: Rai, H. K., Schneider, J., & Orrell, M. (2020). An individual Cognitive Stimulation Therapy app for people with dementia: Development and usability study of Thinkability. *JMIR Aging, 3*(2). http://doi.org/10.2196/17105.

4.1. Introduction

In order to successfully implement effective interventions that are fit for purpose, there is a need for a rigorous approach towards development with the help of appropriate frameworks. In line with previous Cognitive Stimulation Therapy (CST) and individual CST (iCST) work (Spector et al., 2003; Yates, Leung, et al., 2015), the Medical Research Council (MRC) Framework was applied in the development of the iCST application (iCST app). The MRC Framework offers a rigorous approach for evaluating complex interventions and describes the entire process from development to implementation (Craig et al., 2008). For the development of novel technology, in particular, van Gemert-Pijnen et al. (2011) have developed the Centre for eHealth Research (CeHRes) roadmap which includes distinct development phases from contextual inquiry to summative evaluation. Together with the MRC Framework, this enables a highly systematic approach towards the development of the iCST app as described in this study, to ensure the intervention is both usable and useful for people with dementia.

4.2. Aims, hypothesis, and objectives

The aim of this study was to develop an iCST app which can be used by people with dementia and carers on touch-screen tablets.

It was hypothesized that a development approach supported by evidence-based frameworks and stakeholder involvement would result in a well-designed and suitable iCST app because an effective design process can contribute to the usefulness and usability of an intervention.

Objective 1

To develop a first prototype based on an understanding of the theoretical mechanisms behind CST, iCST and use of technology, the attitudes of people with dementia towards paper-based iCST and the iCST app, and a selection of iCST activities suitable for a touch-screen app.

Objective 2

To evaluate the first prototype in terms of clarity, suitability and ease of use, and to expand on the selection of activities for the second prototype.

Objective 3

To bench-test the second prototype with people with dementia and carers in order to refine and modify the prototype and improve on its usability, and to develop the full list of 21 activities for the third prototype based on the findings (see Chapter 5).

4.3. Methods

In the development of the iCST app, the research team at the University of Nottingham worked collaboratively with a software development company (Eumedianet) in Maastricht, the Netherlands. The teams adopted an agile

approach during which development takes place in an iterative and dynamic manner while collaborating with all relevant stakeholders (Larman & Basili, 2003). This approach is especially helpful as it encourages meaningful involvement of end users throughout development.

There are different types of agile development approaches (e.g. Scrum, Extreme Programming, and Crystal methodologies), but they share common key principles and characteristics (Larman & Basili, 2003). These include individuals and interactions over processes and tools, working software over comprehensive documentation, customer collaboration over contract negotiation, and responding to change over following a plan (Dybå & Dingsøyr, 2008). Scrum was chosen as the agile development method for the iCST app. This method was best suited due to its focus on efficient project management, iterative development, and feedback loops (Dybå & Dingsøyr, 2008). This allowed the research and software development teams, in collaboration with end users, to monitor the development of iCST app on a regular basis and ensure it met the necessary requirements. In Scrum, each iterative stage of development is labelled as a sprint. For the iCST app this led to the development of three prototypes over three sprints within the development phase of the MRC Framework, and the contextual inquiry, value specification, and design phases of the CeHRes roadmap (Figure 4.1).

The development of the iCST app also adopted elements from an action research oriented approach. Action research seeks to use action or intervention in a cyclical research process including the development, implementation, and evaluation of plans for practice improvement (Kemmis, McTaggart, & Nixon, 2014). Where agile development focusses on building software, action research allows for a better understanding of the problem to be solved together with active participation from relevant stakeholders including the population group. For this study, these action

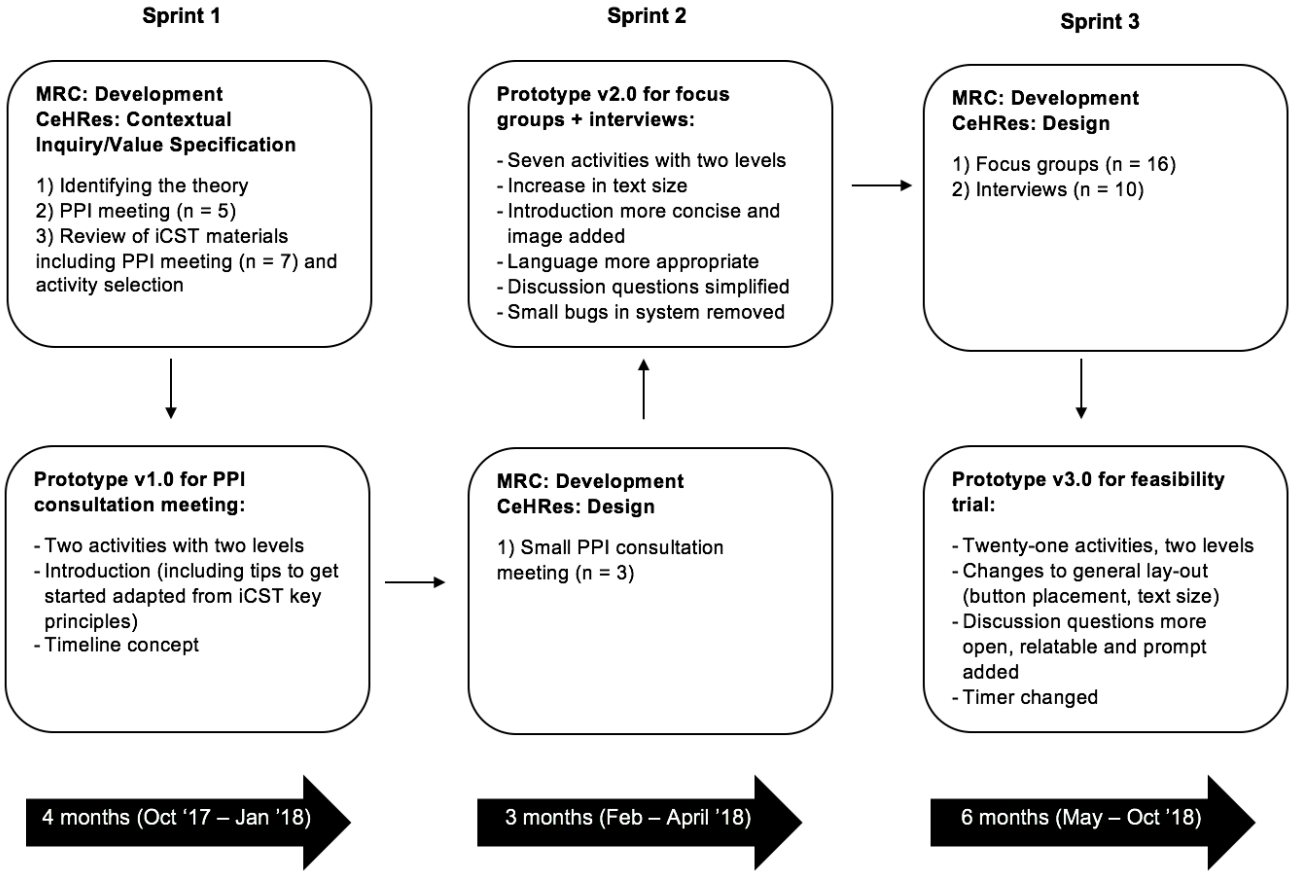


Figure 4.1. Agile development of the iCST app according to the MRC Framework and CeHRes Roadmap.

research elements were incorporated in the sprints to explore barriers and facilitators towards the usability and feasibility of the iCST app and identify possible solutions.

4.3.1. Sprint 1: Development of prototype v1.0

The first sprint consisted of three research activities in order to develop the first prototype of the iCST app: identification of the evidence base and theory behind CST and technology, a patient and public involvement (PPI) consultation meeting, and a review of existing iCST materials (including a PPI consultation meeting and activity selection). These activities reflect the recommendations of both the MRC Framework and CeHRes roadmap. Within the developmental phase, the MRC Framework recommends exploring the evidence base and identifying the theoretical mechanisms to better understand how an intervention can bring about change before any developmental work takes place (Craig et al., 2008). Therefore, the research team reviewed the current literature on the effectiveness of CST, iCST, and use of technology for people with dementia to better understand the mechanisms behind each component of the iCST app (Garcia-Casal et al., 2017; Quinn, 2018; Woods et al., 2012).

4.3.1.1. First PPI consultation meeting

In order to better understand the context, following the CeHRes roadmap, a PPI consultation meeting was organised with people with dementia and carers (N = 5). We wanted to explore their attitudes towards a potential iCST app, and to identify facilitators and barriers towards using (touch-screen) technology in general. A brief presentation was given about CST and the aims of the research project, followed by a short discussion. Topics included willingness to use an iCST app, potential

benefits and limitations, and practicalities such as time investment. Notes from the meeting were communicated with Eumedianet.

4.3.1.2. Review of paper-based iCST materials

The CeHRes roadmap indicates that contextual enquiry be followed by value specification, which helps to determine the most favourable solutions and features based on the values of the intended users and other stakeholders (van Gemert-Pijnen et al., 2011). The iCST manual consists of 75 activities spread over 21 themes, leading to roughly three or four activities per theme. In order to better understand which features and activities should be included in the iCST app, a second PPI consultation meeting with people with dementia and carers (N = 7) was organised at the Institute of Mental Health (IMH). A researcher (HR) presented a short video clip from the iCST DVD of different caregiving dyads using paper-based iCST materials. Participants were given iCST manuals and, in pairs, were asked to review the materials and discuss which qualities they liked or disliked. Participants were also asked to discuss how the iCST manual could best be adapted into a touch-screen version. A group discussion followed and key topics included the design, content, and feasibility of a potential iCST app. The notes and contributions from the PPI meeting were fed back to Eumedianet.

Value specification should involve all stakeholders and therefore, both the research and software development teams also evaluated the iCST materials. Each activity was evaluated for its potential to be adapted onto a touch-screen platform. Considerations included the added level of interactivity and novelty, promoting mental stimulation or the sharing of ideas and opinions, and overall enjoyment. Based on these considerations, all activities were first categorised per iCST theme and type of activity (e.g. a quiz, picture game, audio etc.) and then

ranked according to priority for development by the research and software development teams separately (see Appendix 4). After reaching a consensus in terms of priority, a first small selection of activities was developed for the iCST app prototype v1.0.

4.3.2. Prototype v1.0

Following the principles of an agile approach towards development, there was a need to develop a working prototype rather than paper wireframes which provide a static and more basic representation of the product in terms of design and lay-out. In contrast, a working prototype allows end users to operate a device which resembles the final product, and hence to obtain more accurate feedback. In terms of design, Castilla et al. (2016) recommend a linear navigation over a hyper-textual structure. In a linear structure, the user makes his/her way through the intervention in the order that is intended by the developer. He/she does not make decisions that reorganise the content. In a hyper-textual structure, the content is rearranged based on the user's choices leading to nonlinear pathways (Castilla et al., 2016). The researchers assert that a linear navigation resembles an analog format of books and magazines for instance which are more familiar to older adults. Familiarity then further supports the learning process with the technological intervention.

The first prototype consisted of several key features: a home screen, welcome/introduction, two activities with two levels of difficulty, and a timeline. When opening the app, users were first presented with the home screen (Figure 4.2). It included a welcome icon, which took the user to an introduction section. This section explained the purpose of the app, and provided a few tips and aims derived from the CST and iCST principles. Furthermore, users could select a new

activity on the home screen. Prototype v1.0 included a Sounds and Past Events activity (Figure 4.2). A short summary preceded the actual activity in order to provide some instructions. Within the activity itself, there was a timer, which counted down from 20 minutes to keep track of the amount of time spent, and some buttons to move through the activity or finish it. Lastly, each completed activity was added to the timeline on the home screen. This enabled users to keep track of their journey through the app.

4.3.3. Sprint 2: Evaluation of prototype v1.0

Design is the third stage of the CeHRes roadmap and is used to build prototypes that fit with the user requirements. End users are invited to give feedback and test prototypes to assess whether it matches their expectations in terms of system, content, and service quality (van Gemert-Pijnen et al., 2011).

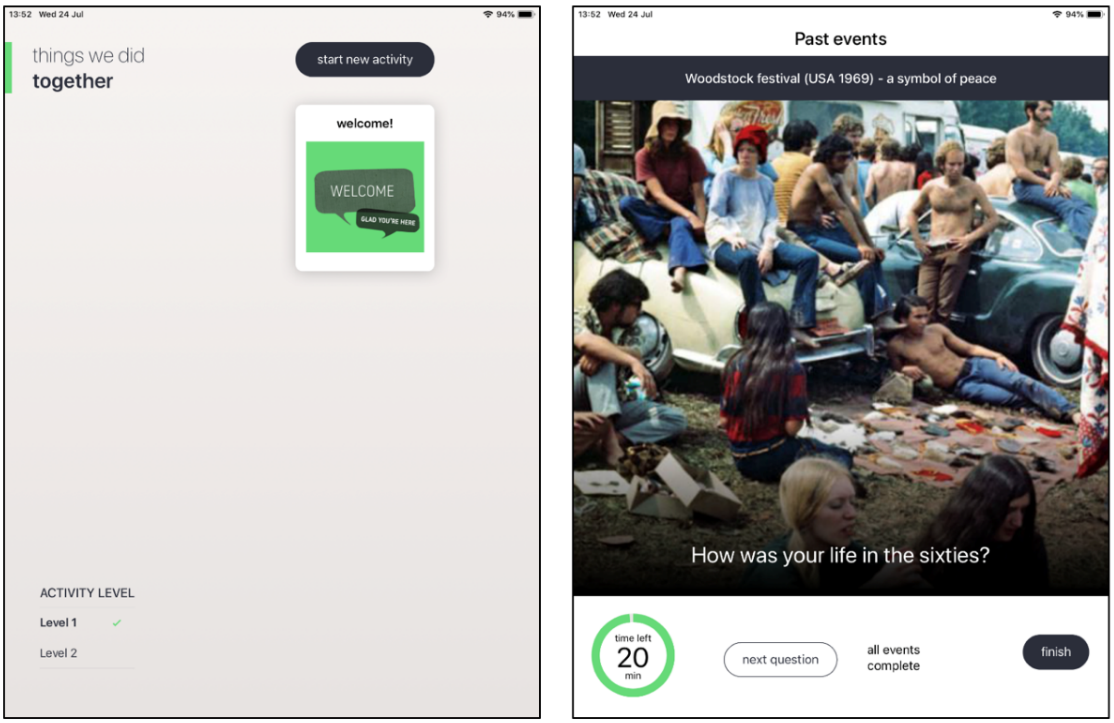


Figure 4.2. Screenshots of prototype v1.0: home screen (left) and Past Events (right).

The iCST app prototype v1.0 was taken forward in a small PPI consultation meeting with two people with dementia and one carer at the IMH. Eumedianet supplied the research team with a list of questions relating to clarity and overall ease of use. Main topics included the design, navigation, and content of the prototype. After an introduction and general explanation about the prototype, each participant was given a touch-screen tablet in order to use the prototype for 15 to 20 minutes. HR provided support and guidance in case of any difficulties and answered questions throughout the trialling period. This was followed by a group discussion of approximately one hour. JS made observations and took detailed notes during the meeting which were communicated with Eumedianet through video conferencing. Feedback from the consultation meeting was used to further expand the prototype and build version 2.0 for bench-testing.

4.3.4. Prototype v2.0

Following the feedback from the PPI consultation meeting, the second prototype was expanded with an additional five activities making it a total of seven (Table 4.1). These five activities (Garland, Hangman, Odd One Out, The Price is Right, Useful Tips) were chosen based on the initial selection of activities during sprint 1. The aim was to have a diverse selection and therefore included several types of activities such as a number game, categorisation activity, and a video. The introduction section was simplified and an image displaying two people interacting with a tablet was added (Figure 4.3). Lastly, some bugs in the system were removed such as incomplete captions within activities.

4.3.5. Sprint 3: Evaluation of prototype v2.0

Chapter 5 provides a more detailed description of the methods used to evaluate iCST prototype v2.0. A brief summary is given below.

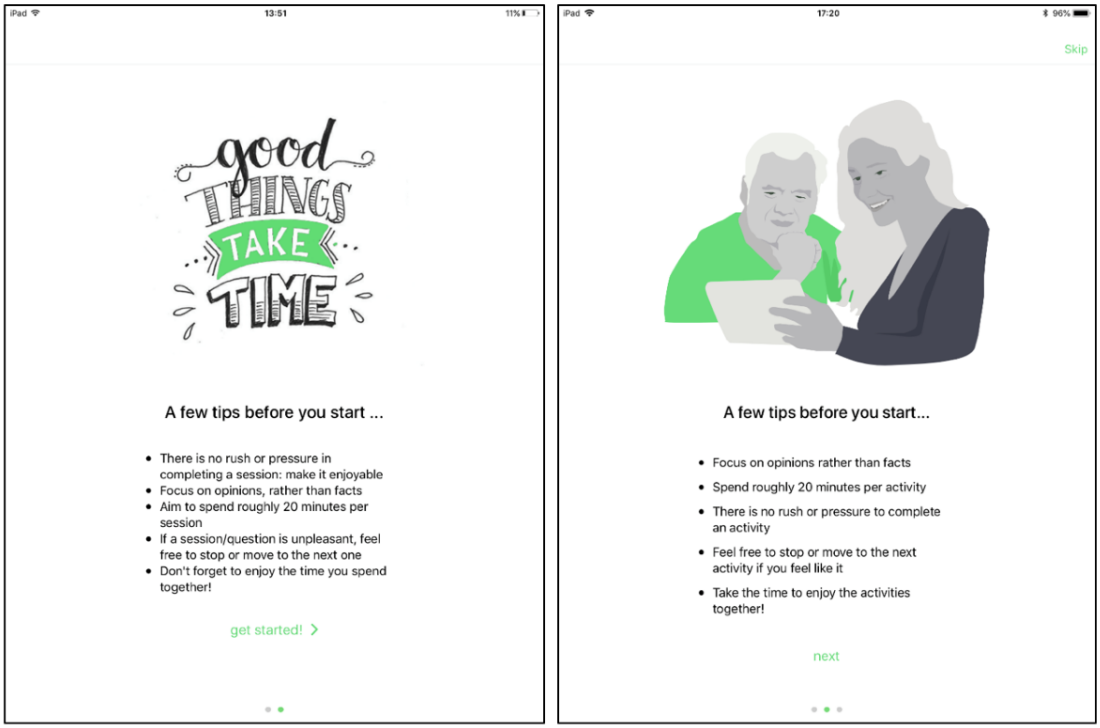


Figure 4.3. Screenshots of the introduction section of prototype v1.0 (left) and prototype v2.0 (right).

4.3.5.1. Design

The evaluation of the second prototype also comprised the design phase of the CeHRes roadmap. However, focus groups and semi-structured interviews were included in this sprint as per the recommendations of the MRC Framework which enabled the gathering of more in-depth and rich qualitative data. The second prototype was presented to people with dementia and family carers in order for them to bench-test it and modify, refine, and improve its usability. Ethical approval for the involvement of vulnerable adults with dementia and their carers was obtained through the National Health Service (NHS) Health Research Authority – Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (REC number 17/YH/0405).

4.3.5.2. Sample

A total of 13 people with dementia and 13 family carers participated in the focus groups and interviews (N = 26). Eligibility criteria were adapted from previous iCST research (Orrell et al., 2017). Recruitment took place in primary and secondary care settings including memory clinics, voluntary sector organisations, and support groups through the Nottinghamshire Healthcare NHS Foundation Trust (NHFT).

4.3.5.3. Methods

Four focus groups were organised: one with people with dementia (n = 4), one with family carers (n = 4), and two mixed groups with both (n = 8). In addition, 10 individual interviews took place with people with dementia (n = 5) and family carers (n = 5) in the homes of participants. All interview participants completed an additional usability and acceptability questionnaire (Castilla et al., 2016). This is a seven-item measure used to identify user opinions on perceived ease-of-use, confidence and control whilst using an app. Responses range from totally disagree (0) to totally agree (4) on all items except for item five which ranges from extremely negative (0) to extremely positive (4). Due to time restrictions, the questionnaire was only administered to interview participants, who were able to complete these individually. The aim of combining these methods was to gather more diverse data. Participants were asked to trial the app in pairs for 10 to 15 minutes prior to the discussion while two researchers gathered observational data as per the recommendations of Eumedianet. The feedback and contributions from this qualitative study supported the development of the iCST prototype v3.0.

4.3.5.4. Analysis

The data from the focus groups and interviews was audio-recorded and transcribed by the research team. Two researchers then coded the data using

inductive thematic analysis in order to identify the key themes within the data (Thomas, 2006). The findings were further supported by observational data.

4.3.6. Prototype v3.0

Based on these findings, the third prototype was expanded with the full range of 21 activities to be taken forward in a feasibility trial (Table 4.1).

Table 4.1. Overview of activities for each prototype version.

Prototype v1.0	**Prototype v2.0**	**Prototype v3.0**
Sounds	Sounds	Sounds
Past Events	Past Events	Past Events
	Garland	Being Creative
	Hangman	Spaceman
	Odd One Out	Odd One Out
	The Price is Right	The Price is Right
	Useful Tips	Useful Tips
		iSpy
		Trivia Quiz
		Word Search
		Sudoku
		Globe Trotter
		Sayings
		My Life
		Being Active
		Food
		Brainstorm
		Arts
		Old Wives' Tales
		Toys Are Us
		In Pairs

Since participants were happy with the diversity of the activities in prototype v2.0, the teams decided to continue with building the remainder of the activities which

were selected in sprint 1. Some suggestions for new activities given by the participants were incorporated in the prototype v3.0 such as a word search and a quiz. The majority of the improvements were related to the design of the app and activities (Figure 4.4).

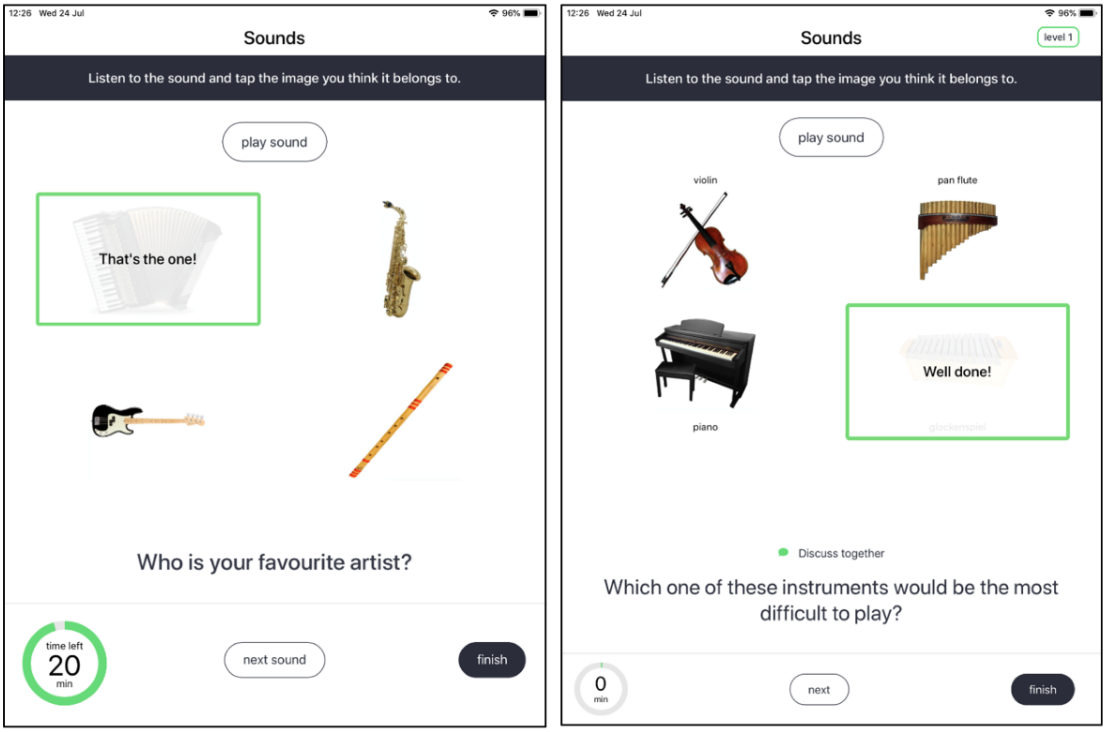


Figure 4.4. Screenshots of the Sounds activity in prototype v2.0 (left) and prototype v3.0 (right).

For instance, some participants felt rushed while doing an activity due to the timer counting down the amount of minutes. Therefore, the timer was changed to count up to 20 minutes with participants being able to spend more time on it if they wanted to (Figure 4.4). In addition, the level of the activity was added in the top right corner. The activity Hangman was changed to Spaceman as the initial icon image included a noose which was too negative. The language was deemed appropriate and free of jargon, however more changes to the discussion questions

were necessary. As a result, the questions were written to be more open and relatable. Furthermore, some participants suggested to add a little prompt above the question saying 'discuss' in order to clarify the purpose of the questions. Lastly, some more context was provided to the Garland activity to clarify it is an activity which can be done without the tablet.

4.4. Results

4.4.1. Sprint 1: Development of prototype v1.0

4.4.1.1. Identifying the evidence base and theory behind CST and technology

Chapters 1 and 2 have provided a more detailed overview of the current literature surrounding dementia and technology, and CST-based approaches. A summary of the key pieces of evidence for the development of the iCST app are included below.

A recent book published by CST research members served as a main resource for key evidence relating to CST and iCST. Both group CST and iCST were developed following the MRC Framework which helped to create a strong foundation for both interventions (Yates, Yates, Orrell, Spector, & Woods, 2018). For group CST, a large-scale randomised controlled trial (RCT) demonstrated positive effects on the cognitive functioning and quality of life (QoL) of people with dementia, which were further supported by qualitative findings (Spector et al., 2011; Spector et al., 2003). CST is multifaceted and its key principles reinforcing mental stimulation, use of reminiscence, enjoyment and more, contribute to its effectiveness. Evidence suggests that stimulating activities targeting certain neuropsychological domains, like in CST, can improve cognition (Hall, Orrell, Stott, & Spector, 2013). Furthermore, CST provides a social context for its participants and previous

research suggests that social interaction between two or more individuals can improve cognition (Yeh & Liu, 2003). The effects of CST on QoL may be explained through the mediating role of improvements on cognitive functioning (Woods et al., 2012).

The large-scale RCT with iCST did not find positive effects on the cognition and QoL for people with dementia which could perhaps be due to a low completion rate of the planned activities. Instead, researchers found improvements in the quality of the caregiving relationship between the person with dementia and the carer (Orrell et al., 2017). Although iCST is as multifaceted as group CST, the trial results may be the result of a lack of adherence to the intervention. Alternatively, the lack of a social setting in iCST may have contributed to the results. Researchers emphasize the need for more research, particularly with experimenting with computerised platforms for providing iCST. Novel cognitive stimulating activities which promote the learning of a new skill can have benefits on the cognitive functioning of older people (Quinn, 2018). For example, Chan et al. (2016) found that training healthy older adults to use iPads could lead to benefits in episodic memory and processing speeds. Increased processing speeds are especially beneficial as they are associated with improved execution of various technological tasks (Slegers et al., 2009).

Computerised cognitive interventions for people with dementia are slowly becoming more widespread. Garcia-Casal et al. (2017) concluded that computerised cognitive interventions led to significant improvements in cognition, depression and anxiety among people with dementia. Potentially, therefore, computerised cognitive interventions may have even more of an impact on cognition than non-computerised cognitive interventions like group CST (Garcia-Casal et al., 2017). However, these interventions can vary greatly and therefore,

there is a need for more research, with computerised cognitive stimulation in particular, to better understand the effects. The platform on which an intervention is offered is also of importance for instance a touch-screen device or a computer. There is considerable evidence suggesting that touch-screen tablets are highly intuitive for older people with dementia (Joddrell & Astell, 2016; Lim et al., 2013; Orpwood et al., 2009). Moreover, Tyack and Camic (2017) found that touch-screen interventions which are simple, intuitive, aesthetically pleasant and error free, can lead to several benefits for people with dementia including mood, mental health, and social relationships. The intervention should include slightly challenging content so the user is invited to apply more complex cognitive skills rather than simpler ones (Tyack & Camic, 2017).

Despite the current evidence and available technological resources, there is still a need for more technologies that provide people with dementia with independent activities for mental stimulation, enjoyment, and a meaningful way to spend time (Joddrell & Astell, 2016). An iCST app with appropriate content and design is well placed to fill this gap.

4.4.1.2. First PPI consultation meeting

Participants were particularly enthusiastic about CST and said they would welcome it in any format whether this was computerised or paper-based. They said researchers would have to keep a few things in mind when developing a computerised version of CST. Namely that there would be a need for personalisation according to the person's background, and a diverse selection of activities. Some participants mentioned the need for a facilitator to provide support with the activities. This could be an informal or a paid carer. Being able to keep

track of which activities were done and when, was also considered to be a useful feature.

Attitudes towards technology were diverse with some more willing to use technology than others. A person with dementia mentioned she would not want to be pushed to use technology, which might happen through the involvement of a carer. However, there was consensus among the group that people with dementia need to be empowered and to be made aware of how to handle technology. An example was given on how some people with dementia with a lack of experience with technology, may think it could break easily by pressing the wrong button. People would need an explanation on how to use the actual technology before using any kind of apps on it. Lastly, in order for technology to be useful for people with dementia, it should be free of jargon and difficult terminology as much as possible.

4.4.1.3. Review of paper-based iCST materials (PPI consultation and activity selection)

All participants liked the iCST manual in terms of content and usefulness, and the comments for improvements were mostly related to practicalities and some lay-out issues for a potential iCST app. For instance, participants agreed there was too much text on one page and that this would have to be minimised significantly for an app. Keeping with this, although the content was perceived to be useful, participants felt that there were too many activities and that researchers would need to consider which activities could be better for adaptation than others.

In terms of feasibility, flexibility was considered to be one of the most important needs for an iCST app. The amount of time needed to complete an activity and the whole app would differ between people with dementia. Therefore, people

should be able to use it according to their own pace and decide per day how much time they would like to spend on the app. One person with dementia was keen on using the app for any amount of recommended time as long as it could benefit her. Participants also emphasized some challenges: it might be difficult for some users to maintain concentration for a certain period of time. In addition, their physical condition might prevent them from using the app (e.g. pains).

After the PPI consultation meeting, the research and software development teams reviewed each iCST activity in each detail. All 75 activities were ranked according to type of activity and its potential for adaptation to a touch-screen platform. Following the advice from the PPI group members, the researchers decided to reduce the amount of iCST activities from 75 to 21 for the initial iCST app. This encompasses one activity per theme.

4.4.2. Sprint 2: Evaluation of prototype v1.0

The design was evaluated positively with a minor suggestion to increase the size of the text. Use of colours was deemed appropriate as well. One example came from a person with dementia who did not seem to have any problems with the colour scheme despite being colour blind. The navigation was intuitive as participants were able to move through different parts of the prototype with little difficulty. However, the purpose of the timeline was not clear and needed additional explanation from the researcher.

In terms of the content, the participants were positive about the type of activities and found them relevant and enjoyable. In order to encourage discussion based on the questions, it was suggested to simplify the questions by directing them to the person with dementia rather than a general question. Participants also had a look at the introduction section and suggested adding an image of a person with

dementia and a carer using the app together in order to clarify how it is meant to be used (Figure 4.3). Some changes were suggested to the language in order to make it more suitable. Suggestions included shortening the sentences and improving on the overall sentence structure. Some words were discussed in more detail for example using 'finish activity' rather than 'stop activity'. Lastly, participants were keen on seeing more levels included in the future.

All but few suggestions were included in the next iteration of the prototype. For instance, there was a need to add buttons on the screen to adjust for the sounds and brightness however, there was a potential that this would have made the interface more crowded and therefore less intuitive. It was decided to further investigate this in the next sprint.

4.4.3. Sprint 3: Evaluation of prototype v2.0

Chapter 5 provides a more detailed description of the qualitative results following the evaluation of iCST app prototype v2.0. This section includes a brief summary and findings from the usability questionnaire.

Thirteen people with dementia and 13 carers participated in the qualitative study. Four main themes emerged from the analysis including 'approaches to technology', 'quality of the iCST app', 'perceived benefits of the iCST app', and 'involvement of a relative or friend'.

The majority of the participants were enthusiastic about the app and found it to be useful. Some participants also appreciated the novelty of the intervention:

I think it's nice to have something different every so often. Yeah it's something different because it's not something that crept up before shall I say. – Person with dementia, Interview 5.

Observations indicated that the app was intuitive for most participants which was confirmed through the discussions and usability questionnaires. There were some cases where researchers needed to provide some assistance and although the navigation was generally considered to be appropriate, there was a need for better signposting and clearer button placement:

For navigation purposes I found it difficult if I wanted to go back and start another one. (…) I thought that one (button) could be bigger… or more obvious. – Carer, Interview 2.

Participants noted that the images and text could both be slightly bigger but overall they were rated well in terms of clarity:

I understand what each one is showing and that's all that's necessary for it to do. So long as the image is clear I don't see a problem, and generally speaking they are clear. – Person with dementia, Interview 7.

Lastly, there was no general consensus on the colour scheme with some participants opting for the inclusion of more colours and others preferring the current scheme with fewer colours in order to avoid distractions.

Table 4.2 describes the usability and acceptability of the iCST app prototype v2.0 according to people with dementia (n = 5) and carers (n = 5) who participated in the individual interviews. For clarity, responses including 'totally agree' and 'agree' were collated under 'positive', and 'neither agree or disagree', 'disagree' and 'totally disagree' were included under 'don't know/negative'. Item 5 includes one missing response from a person with dementia. Overall, the iCST app was rated well in multiple areas namely: its ease of use, usefulness, and suitability of the letter/button size for both people with dementia and carers suggesting that the overall design was appropriate.

Table 4.2. Results from the usability questionnaire with the iCST app prototype v2.0.

Questionnaire item	Person with dementia (n = 5)		Carer (n = 5)	
Response	Positive	Don't know/Negative	Positive	Don't know/Negative
1. Ease of use	5	0	5	0
2. Usefulness	5	0	5	0
3. Knew what to do at any time	4	1	5	0
4. Felt confident while using the application	3	2	5	0
5. Feeling while using the application	3	1	5	0
6. Suitability letter/button size	5	0	4	1
7. Willingness to use application often	3	2	5	0

Even though most participants indicated they knew what to do at any given time, carers felt more confident while using the app than people with dementia and were also more willing to use it frequently. This suggests that the navigation of the iCST app might not be as intuitive for people with dementia as it is for carers. The majority of the suggestions for improvements and additions to the app were made and these were taken forward in the next iteration for the feasibility trial (see Chapter 6) which has been registered on clinicaltrials.gov (registration number NCT0328277).

4.5. Discussion

This is the first study which set out to create an interactive, touch-screen iCST app for people with dementia and carers, based on the principles of CST and iCST.

The systematic approach to development included an agile methodology, principles from action research, and guidance from the MRC Framework and CeHRes roadmap (Craig et al., 2008; van Gemert-Pijnen et al., 2011). To the best of our knowledge, this is also the first study to combine these elements in the development of a technology-based intervention for people with dementia and carers. Within this approach lie the strengths of this study. For instance, the agile methodology helped to create and regularly review prototypes of the app in an iterative manner. This was necessary to monitor the overall progress and direction of development, but also to find and resolve any faults on a continuous basis. Both the MRC Framework and the CeHRes roadmap helped to better define the development process and determine which research activities were necessary at each stage. In lieu of this, there were various, diverse research activities ranging from PPI consultations to a qualitative study and questionnaires, leading to the collection of in-depth and rich data. Lastly, the involvement of end users at each stage, as per the principles of action research, was beneficial as their consistent and useful feedback helped to refine the iCST app prototypes.

4.5.1. Principal results

The MRC Framework recommends using the best available evidence and appropriate theory in the development of a new intervention (Craig et al., 2008). Sprint 1 supported this and pinpointed several mechanisms behind the use of CST and technology such as mental stimulation of neuropsychological domains, providing a social context, and learning a new skill (Hall et al., 2013; Quinn, 2018; Yeh & Liu, 2003). The combination of these elements might be able to demonstrate how an iCST app can benefit the cognition compared to paper-based iCST which did not find such benefits for the person with dementia. An iCST app would also allow for improved monitoring of adherence to the intervention through analytics,

which was a challenge in previous iCST research (Orrell et al., 2017). This would provide further insights in the potential benefits of an iCST-based approach. Furthermore, as part of contextual inquiry, researchers explored the attitudes of people with dementia and carers towards technology. Attitudes were varied but most participants were willing to use technology as part of their daily lives. The most important conclusion was that people with dementia would need individually tailored support on how to use the technology. This is in accordance with previous research showing that technology can be helpful for people with dementia but some might require continuous support and education to maximise the benefits (Hanson et al., 2007). This support could be provided through the involvement of skilled practitioners or informal carers. In 2018, it was estimated that 42% of the people aged 65 and over in Great Britain (GB) use a tablet computer to access the internet making it the most popular choice of device among the age group (Office for National Statistics, 2018). However, there is a need to increase education and awareness of using technology such as touch-screen tablets to support the empowerment of people with dementia which was another prerequisite mentioned in the first PPI consultation meeting. Still some people may be unable to access technology and thus the iCST app, and the availability of other CST resources such as group CST and paper-based iCST will help them to access a form of CST.

Through value specification, people with dementia and carers were asked to identify their most important needs for an iCST app. The identification of needs is a common process in the development of technology as it helps to define and prioritise user requirements. In PPI consultation meetings, people with dementia and carers stressed the need for minimising the current paper-based iCST content, flexibility in using the iCST app, and a diverse range of activities to appeal to personal interests. These requirements are supported by Tyack and Camic (2017)

who found that touch-screen interventions should be tailored where possible in terms of content but should also include a simple and intuitive interface. This can facilitate the uptake of the intervention. Minimising the iCST content would make the interface less crowded and more easy to use. Value specification was continued by the both the research and the software development teams to assess which paper-based iCST activities should be taken forward in the iCST app. Based on the priority ranking of each team, a small first prototype was developed.

In sprint 2, the development moved towards the design aspect of the CeHRes roadmap during which a first version of the digital health intervention is communicated with end users to collect feedback. It is recommended to initially present a prototype which does not fully resemble the final product but does include the essential features, and then build on the successive prototypes (van Gemert-Pijnen et al., 2011). Therefore, the iCST app prototype v1.0 only included two activities in addition to the main features (e.g. the timeline). Participants in a PPI consultation meeting rated the format of the iCST app prototype v1.0 positively, particularly the design was deemed appropriate. However, there was a need to simplify the content. For instance, the introduction contained some jargon and the discussion questions needed to be clearer. This feedback informed the expansion of the next prototype which better resembled the final product.

Sprint 3 was an extension of the design stage of the CeHRes roadmap and included more formal usability testing through focus groups, interviews, and questionnaires. These activities are also recommended by the MRC Framework to assess the acceptability of the intervention (Craig et al., 2008). The iCST app prototype v2.0 was evaluated positively and participants gave some suggestions for improving the design including increase in the size of the text and images (see Chapter 5).

By adhering to the MRC framework and CeHRes roadmap, we enabled a systematic approach to the development of the iCST app and obtained feedback from people with dementia and carers across multiple development sprints. This feedback highlighted that the iCST app can be useful in terms of potential benefits and has an attractive design, which further supports the earlier hypothesis that an effective design process supported by evidence-based frameworks and stakeholder involvement can contribute to the usefulness and usability of an intervention.

4.5.2. Limitations

Working agile requires a quick turn-around for prototypes in terms of development and evaluation. The latter proved more challenging as research activities with end users require a sufficient amount of time for recruitment and organisation. For instance, the lack of time caused the evaluation of prototype v1.0 in sprint 2 to be less in-depth. An additional challenge in recruitment meant that the PPI consultation meetings contained a small sample size potentially leading to insufficient data and feedback. To better cope with these challenges and add more value to development, it is recommended to involve one or two people with dementia as co-researchers throughout the development process in order to receive consistent feedback.

4.5.3. Future research

Future studies involving new technology-based interventions for people with dementia, will need to establish a strong collaboration with researchers, software developers, and end users from the beginning stages of development. Furthermore, new interventions and their development will need to be supported by the appropriate frameworks and methodologies. These recommendations will

help to create an intervention which is fit for purpose and has better potential to be successfully implemented into practice.

This study did not include the last development phases of piloting, evaluation, and implementation. Therefore, the next iCST app prototype (v3.0) will be taken forward in a feasibility trial to better understand its acceptability, usefulness, and any potential signs of effectiveness of the iCST app in daily life (see Chapter 6).

4.6. Conclusion

This study demonstrates that an agile approach towards technology development where all relevant stakeholders are involved, can be effective in creating suitable technology for people with dementia. This process can be further supported by using appropriate frameworks to better understand the development process and determine the necessary research activities. Furthermore, this study demonstrated that there is an interest and willingness to use an iCST app among people with dementia and carers. Therefore, these results have added to our previous knowledge of paper-based CST and a commercial release of the iCST app will strengthen CST's current international impact by making it more accessible to users around the world.

Chapter 5 – Field-testing the individual Cognitive Stimulation Therapy application (iCST app) with people with dementia and carers: A qualitative study

This chapter was based on a journal article: Rai, H. K., Griffiths, R., Yates, L., Schneider, J., & Orrell, M. (2020). Field-testing an iCST touch-screen application with people with dementia and carers: A mixed method study. *Aging & Mental Health,* 1-11. https://doi.org/10.1080/13607863.2020.1783515.

5.1. Introduction

The Medical Research Council (MRC) Framework and the Centre for eHealth (CeHRes) Research roadmap both recommend the involvement of service users throughout the development and testing cycle in order to ensure the intervention is tailored to the needs and interests of people with dementia (Craig et al., 2008; van Gemert-Pijnen et al., 2011). Previous research suggests that, especially for technology-based interventions, people with dementia are able to give useful feedback ranging from the content to the design (Span et al., 2013). It is worthwhile to involve various stakeholders such as carers in the development process in order to obtain a well-rounded view as different stakeholders may point out different issues with a technology (Lopes et al., 2016; Meiland et al., 2014). This study provides a more detailed description of sprint 3 as described in Chapter 4. The aim was to try out the individual Cognitive Stimulation Therapy application (iCST app) prototype v2.0 with people with dementia and carers in order to modify and refine the app and improve its usability.

5.2. Methods

5.2.1. Sample

People with dementia and family carers were recruited for this study. The inclusion criteria were modified from Spector et al. (2003).

Person with dementia:

- Meet Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for dementia (American Psychiatric Assocation, 1994).
- Score of 10 or above on the Mini Mental State Examination (MMSE) (Folstein et al., 1975) or a score of 16 or above on the Montreal Cognitive Assessment (MoCA) (Trzepacz et al., 2015).
- Sufficient ability to communicate and demonstrate understanding, including to give informed consent.
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.
- Age range: over 50 years – no maximum age limit.
- Availability of a carer (or friend/befriender) to participate in the interviews and focus groups.

Carer:

- Minimum age: 21.
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.

A Research Delivery Officer (RDO) from the Nottinghamshire Healthcare NHS Foundation Trust (NHFT) made initial contact and completed eligibility checks for

participants recruited through primary care settings. Participants were also recruited through leaflet advertisements in secondary care settings including memory clinics providing specialist services for people experiencing memory difficulties, and voluntary sector organisations. Researchers (HR, RG) presented at several support groups for people with dementia and carers in Nottinghamshire to support recruitment. A participant information sheet (PIS) was sent after initial contact was made and if still interested, participants were recruited.

5.2.2. Study design

Semi-structured individual interviews and focus groups were used to gather qualitative data on the feasibility and experience of using a prototype version of a computerised iCST programme. These methods are appropriate in order to gather rich and in-depth data. While focus groups allow participants to share thoughts with each other and explore varying opinions (Alshenqeeti, 2014), individual interviews may be more suitable for participants who do not feel comfortable to voice their opinions in groups. Discussion guides, developed by the researchers, consisted of semi-structured questions which explored key areas about the usability, lay-out and content of the app, using the app together, and general points (see Appendix 9 and 14).

5.2.3. Intervention – iCST app

The intervention was a second version of an iCST app prototype as described in Chapter 4. This research tested a sample of the app content as part of its early development. This included a welcome section which described the aims of the app, information on how to use the app, and several key principles of CST and iCST. In addition, seven activities were included compromising word games, number games, discussion activities and a creative activity namely: *Being*

Creative, Hangman, Odd One Out, Past Events, the Price is Right, Sounds, Useful Tips. Screenshots of the app can be found in Figure 5.1. Participants could choose between two levels of difficulty, where activities on level two were more challenging than level one and the discussion questions went into greater depth.

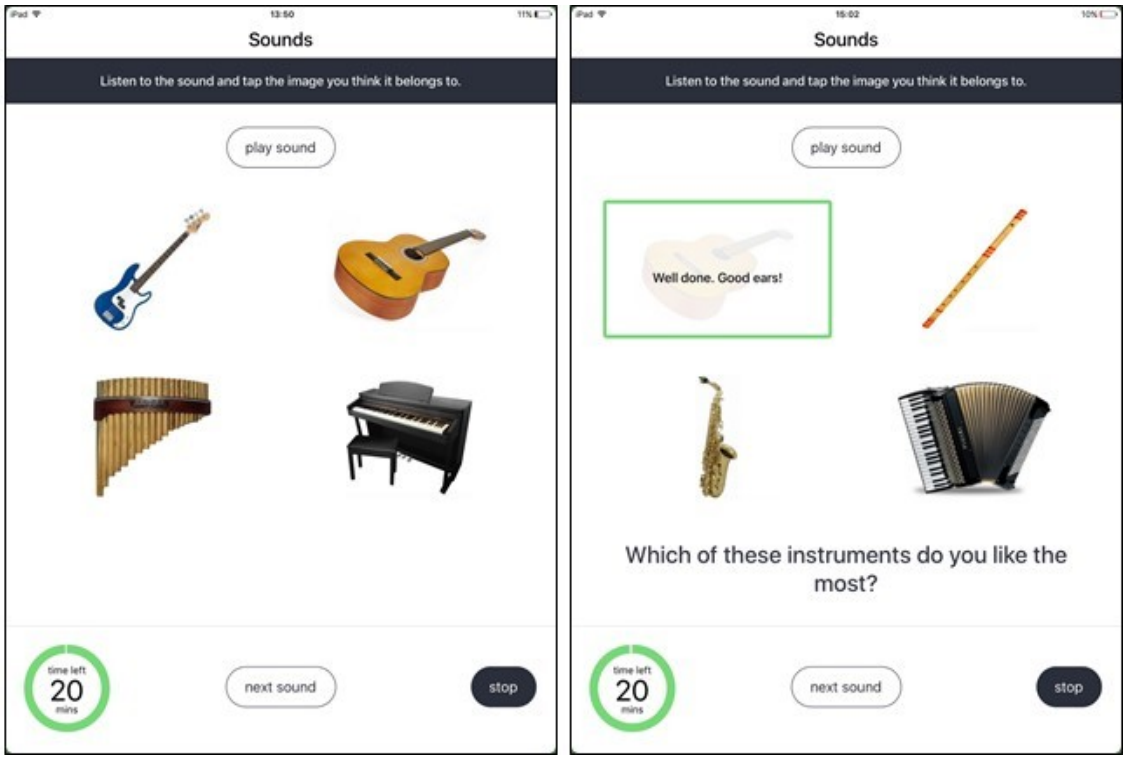


Figure 5.1. Screenshots from the iCST app. From left to right: a question from the *Sounds* activity, and after the correct answer has been selected with the discussion question below**.**

5.2.4. Procedure

5.2.4.1. Focus groups

Four focus groups were held in various locations across Nottingham; one carers only group (n = 4), one with people with dementia only (n = 4) and two mixed groups (n = 8). In keeping with previous iCST research, different types of groups were used to gather a holistic view of the impact of the iCST app on each member

of the caregiving dyad (Yates, Orrell, Spector, & Orgeta, 2015). Two researchers (HR, RG) were present in each focus group, with one to facilitate discussion and the other to take notes and assist with the interactive aspect of the group where participants tested the app. Participants were given 20 minutes to try the app together in pairs whilst written observational data was recorded by researchers. Researchers provided support regarding any technical difficulties or questions from the participants. However, guidance was kept at a minimum in order to assess whether the app was intuitive. The focus groups lasted approximately one hour and were audio-recorded and transcribed by the researchers (HR, RG). All audio recordings and transcripts were anonymized and stored on a password-protected University of Nottingham computer drive.

5.2.4.2. Individual interviews

Individual interviews were conducted with five people with dementia and carer dyads. All interviews took place in participants' homes. Prior to each interview the dyad were given 20 minutes to try the iCST app whilst written observational data was being recorded by the researchers. Interviews were conducted individually with the person with dementia and the carer to allow each participant to share their opinions and to gather a well-rounded view of the app. Each interview lasted between 20-50 minutes. All interviews were audio-recorded and anonymized in transcription and stored securely as already described. Interview participants completed a usability and acceptability questionnaire for older people (translated from Spanish) of which the results have been described in Chapter 4.

5.2.5. Ethical approval

Ethical approval was obtained through the National Health Service (NHS) Health Research Authority – Yorkshire & The Humber – Bradford Leeds Research Ethics

Committee (REC number 17/YH/0405). Participants with dementia were in the mild to moderate stages of the disease, and were able to provide informed consent for participation (Yates, Orrell, et al., 2015). Written informed consent was gathered from the carer and person with dementia separately on the day of the research activity. However, participants were given a choice to sit together during the consenting process if they wished to. Consent forms were checked by researchers once signed to ensure they had been fully completed. Each participant was given a copy of the signed consent form to keep.

5.2.6. Analysis

The data was coded and analysed thematically using an inductive approach to ensure the themes were strongly linked to the data itself (Thomas, 2006). This approach is guided by detailed readings and interpretations of the raw data. The researcher's evaluation objectives help to provide a framework for domains and topics to be investigated while coding and analysing the data. During the analysis process, the researcher makes decisions about what is of importance within the data which helps to make the findings more applicable (Thomas, 2006). Consequently, the findings are based on analysis of the raw data rather than presumptive ideas and expectations of the researcher. This data-driven approach best suited the aims of the research, which was to gather exploratory data regarding opinions of the iCST app. Two researchers (HR, RG) analysed the data independently using NVivo software for entering the coding categories and supporting data excerpts from the transcripts. Some examples of codes include 'text', 'navigation', and 'potential challenges'. Where needed, observational notes were examined to provide additional clarifications. Hereafter, a proportion of the data which was coded by a second coder was exchanged and any discrepancies were clarified to reach consensus and ensure reliability of analysis. In order for the

themes to be relevant to the evaluation objectives, the emerging categories were reviewed and revised on a continuous basis.

5.3. Results

The sample included 13 people with dementia and 13 family carers (Table 5.1). Most participants had some experience with using related technology prior to participation (77% of the people with dementia, 100% of the carers). Usage ranged from desktop computers to touch-screen tablets and smartphones. Three people with dementia indicated they had no previous experience with using such technology.

Table 5.1. Demographics of people with dementia and carers in focus groups and interviews.

Demographics		Focus groups (%)	Interviews (%)
Person with dementia		n = 8	n = 5
Gender	Female	3 (37.5)	2 (40)
Ethnicity	White	7 (87.5)	4 (80)
	South Asian	1 (12.5)	
	Prefer not to say		1 (20)
Age	Mean age (years)	75.50 (range 69 - 86, *SD* = 5.76)	72.20 (range 67 - 83, *SD* = 6.61)
Experience with technology	Yes	6 (75)	4 (80)
Carer		n = 8	n = 5
Gender	Female	5 (62.5)	4 (80)
Ethnicity	White	8 (100)	5 (100)
Age	Mean age (years)	70.37 (range 54 - 82, *SD* = 7.89)	67.20 (range 49 - 82, *SD* = 11.99)
Relationship	Spouse	7 (87.5)	4 (80)
	Child	1 (12.5)	1 (20)

Table 5.1 continued

Living status	Spouse lives with person	7 (87.5)	4 (80)
	Person lives alone at home	1 (12.5)	1 (20)
Experience with technology	Yes	8 (100)	5 (100)

Thematic analysis of the qualitative data led to the following main themes: 'approaches to technology', 'quality of the iCST app', 'perceived benefits of the iCST app', and 'involvement of a relative or friend'. Most main themes included several subthemes (Table 5.2).

5.3.1. Theme 1 – Approaches to technology

Some participants noted that it would be helpful for older people to have some prior experience with technology before using a new intervention such as the iCST app and they might need more guidance on how to use it:

It's helpful if the person has got the experience of using a computer. Younger people are brought up with computers, it's always there. So there is no learning curve, it's just there. (…) but if you're older, you know we're talking about our situation you might have to ask how to explain it, explain what you mean. – Person with dementia, Focus group 4.

Familiarity was also related to the platform or operating system itself (Table 5.2). Some found touch-screen tablets easy and useful because of their size:

… something that's a bit more like this (…) would be more of an advantage, whereas if it's a little thing like a phone, it'd be too small on the screen. – Carer, Interview 8.

Participants were also optimistic about the potential uses such as a map app to navigate:

I can't think of any disadvantages… these sort of machines are not too expensive to buy, and you'd probably use it for other things if you had one anyway, so a lot of people would probably have access to them. – Carer, Interview 2.

Both people with dementia and carers recognised some limitations associated with the use of technology. Even though all carers used technology, one mentioned the attitudes of older people could hinder the acceptance of technology:

There is a lot of fear with older people with anything electronic. – Carer, Focus group 3.

A person with dementia said they need to be empowered:

I think that's a big thing for older people. You have got to get them realising that they are actually capable of doing this. – Person with dementia, Interview 1.

Lastly, participants identified some practical challenges regarding the use of technology such as faults or minor technical difficulties and mentioned having support would help to navigate these issues.

5.3.2. Theme 2 – Quality of the iCST app

The iCST app was well-received and participants were generally very satisfied with the quality of the materials, the content and the usability.

Content

Participants felt activities were relevant and spoke about enjoying the interactive features of the app including the discussion questions (Table 5.2).

Table 5.2. Main- and subthemes with comments from people with dementia and carers.

Main theme	Subtheme	Comment
Theme 1 – Approaches to technology		*For me it would be a tool that I'm using every day of the week. It's like suddenly if you was given a new laptop, how would you feel, because it's now a different system… You've gone over to Apple or something like that (…) you would feel lost I'd tell ya!* – Person with dementia, Interview 9.
Theme 2 – Quality of the iCST app		
	Content	*I liked the, sort of, you do one thing with the sounds and there's a second bit and that's a question and that's the conversation, I quite liked that idea.* – Carer, Focus group 3.
	Usability	*I thought it was a very usable programme.* – Person with dementia, Focus group 2.
	Feasibility	*You know it helps take the, well not the pain away but you don't concentrate on it if you know what I mean. It takes away the thought of it yeah.* – Person with dementia, Interview 7.
	Comparison to paper-based iCST	*If it was somewhere that you've got a piece of paper, fair enough. If you've got something like this, you've got both choices then. So you know you're not stuck either way are you.* – Person with dementia, Interview 5.
Theme 3 – Perceived effects of the iCST app		
	Mental stimulation	*I think anything that you do, you do together that stimulates the brain at any time, even if it's a short space of time, I'll have a go at it.* – Carer, Focus group 1.

Table 5.2 continued

	Quality time together	*Yes I think I would use it at the times where there has been a little bit of an altercation and then say right ok: so let's sit down and do this or do that. Because sometimes it's very difficult because the altercations that you would have as a normal couple, I shouldn't say normal like that, are different to the ones you have when there isn't an issue about the memory*. – Carer, Focus group 1.
	Sharing ideas and opinions	*Two people would look at something like that and start to read it slightly differently but if you look at it together and say discuss it, you come up with the solution.* – Person with dementia, Focus group 4.
	Enjoyment	*Yeah I found it erm … informative and that made it a bit more enjoyable.* – Person with dementia, Focus group 4.
Theme 4 – Involvement of a relative or friend		
	Choosing the right person	*I feel as though that's the question you're asking is that do you think that I could do this activity with anybody and I think the answer to that would be no.* – Person with dementia, Interview 9.
	Using it alone or together	*Um… if it did what it did today, I might not be able to get back to the right place, but it seems very simple doesn't it… and, but it would be handy to have somebody to ring if it failed for some reason.* – Carer, Interview 2.

The variety of the activities was thought to be appropriate, but a clear need for more diverse content was identified in order for the app to retain its appeal, and to cater towards the interests of as many people as possible. When discussing the possible scope of the app a person with dementia commented:

Yeah, well I'm hoping beyond triple (the amount of activities), I hope it goes way beyond that, with more facilities to do more things. I appreciate that it would have to have some sort of confinements for the app, but the more varieties there is available, the more people that are gonna get involved with it. – Person with dementia, Interview 9.

Lastly, participants discussed ideas for future iterations of the app including personalisation by uploading their own content.

Usability

The design of the app was judged by participants to be sophisticated. Although there was a consensus that the text and images were appropriate, most felt that both could be slightly larger to improve readability. Opinions were divided in terms of the use of colours. Whereas some people liked the calmness of the green and would find too many colours to be distracting, others expressed a preference for a more colourful design:

I kind of liked the green. That's a bit unusual. – Carer, Focus group 4. *It's relaxing.* – Person with dementia, Focus group 4.

Yes, I mean it's nice… it is a nice lay out it's just me I just like things a little bit more colourful. – Person with dementia, Interview 3.

Participants were usually able to find their way around the app with minimal support:

No it's fine. It's self-explanatory, it's easy so that's exactly what you need. – Carer, Interview 4.

Apart from suggestions to improve the button placement in terms of clarity and prominence, the navigation of the app was user-friendly.

Feasibility

In terms of feasibility, most participants were happy to use the iCST app for the recommended time of one and a half hours per week however, some did worry about finding the time to schedule it into their day:

Yes, but it's having the time though... That's the problem with it. – Person with dementia, Focus group 2.

Participants felt the iCST app would be useful during 'empty' times of the day and also during the winter months as they are then more likely to spend time at home.

Often carers described a few limitations related to symptoms of dementia or physical limitations such as backache and hearing problems which would make it more difficult for them to use the iCST app with the person they were caring for:

Sometimes, (…), they need longer for it to register in the brain and then come out. – Carer, Focus group 3.

Interestingly, a person with dementia mentioned that the iCST app could be used as a distraction for herself when experiencing pain (Table 5.2).

Comparison to paper-based iCST

Most people with dementia (n = 10) and carers (n = 12) expressed a preference for a computerised version as they felt it was the next logical step after using books, and was more fun due to the interactive features. Although three people

with dementia and one carer said it very much depends on an individual's preference. Finally, having the availability of both versions would also be beneficial as it would allow for a choice (Table 5.2).

It makes it seem like it's a more academic grown up activity. Some of these games, are games you would think are suitable for children, but if you're doing it on a computer it looks more grown up somehow. – Carer, Interview 2.

I honestly don't know. He's not really very orientated into technology, he doesn't like it. If it was the book he'd probably like it better. He does like his paper thing... – Carer, Focus group 3.

5.3.3. Theme 3 – Perceived benefits of the iCST app

Mental stimulation

Participants said mental stimulation provided by the iCST app was important. Several people with dementia mentioned things like 'keeping the brain active' or 'keeping the brain alert' after being asked why they would use the iCST app.

It's not just a reminiscence tool, it's something to get us thinking. – Person with dementia, Focus group 2.

Carers also valued mental stimulation. One was concerned about uncertainties in the future regarding the dementia (Table 5.2). Another carer also mentioned that the content of the app was quite novel and therefore encouraged the dyad to think about it more. This suggests that benefits in terms of cognitive stimulation for the person with dementia would be a leading reason for people to use the iCST app.

Quality time together

When asked how dyads currently spent their time together, some mentioned gardening, walking, and going out with family or friends. Others were less active and said they would like to spend more time together doing various activities. Often this was not possible due to the progression of the dementia or lack of time. One of the perceived benefits of using the iCST app was being able to spend more time together as a dyad:

Uhm … just that… to spend more time together really I suppose. Other than that we do different things when we're not together so at least you spend more time together yes. – Person with dementia, Interview 7.

Several participants made it clear that the iCST app would be an extension of the time already spent together and not a replacement of activities. On top of the time spent together, another carer pointed out that she found the physical proximity pleasant while doing an activity on the app. She felt this would not happen when doing more conventional activities such as playing cards. Another carer would consider this to be quality time spent together with the person with dementia. Lastly, participants said the iCST app could be particularly useful when there are difficult or tense moments (Table 5.2).

Sharing ideas and opinions

The iCST app led to discussions between the person with dementia and the carer with some activities allowing for more discussion than others. Carers valued this and pointed out that starting a conversation with the person they are caring for can be difficult at times. The iCST app provided useful prompts to get a conversation started. The content could be used to generate various topics ranging from new ideas to more reminiscence-based topics.

Gives you variety doesn't it, you're not just trolling through a list of things... Least you've got time to reminisce, give your own opinion... because reminiscence and opinions aren't the same are they... – Person with dementia, Focus group 2.

Some pointed out that the discussion should be pleasant and one should be cautious not to evoke frustrations or disagreement. The latter was elaborated on by a person with dementia:

I think you could have a nice discussion so long as people don't lose their temper... If you listen to each other, and listen to what they say, and then you decide... Am I going to change to what they think, or stay as it is... – Person with dementia, Focus group 2.

But there was agreement that this was not necessarily a problem as these issues could be resolved between themselves by respecting the other person's opinion. Having differing opinions or perspectives was also positive, allowing people to reflect in a different way (Table 5.2). A carer mentioned that if a particular activity leads to conflict, then you would not do it again and try something else as you would always have this choice within the app.

Enjoyment

The activities of the iCST app were enjoyable and fun. People with dementia expressed several reasons for this enjoyment including having to use logic and reasoning to do some of the activities and also that the app was informative (Table 5.2).

Carers enjoyed doing activities together and the communication aspect. One carer mentioned that enjoyment would come from seeing the person with dementia benefit from using the app.

5.3.4. Theme 4 – Involvement of a relative or friend

Choosing the right person

Some people with dementia said they would put some thought into who they would use the iCST app with (Table 5.2). Most participants said they would use it with their spouse. A daughter felt that the app was perhaps more suitable for couples, to help bring them closer together. Some participants said they would use the app with their grandchildren as they are generally more tech-savvy and the discussions could lead to different thoughts and perspectives:

I think it would be different and it could be... quite... a revelation... because two different generations, because our perceptions are different on things. – Person with dementia, Focus group 2.

Using it alone or together

Some participants with dementia expressed a preference for using the iCST app on their own or at least to have the choice, saying that a family member or friend might not always be available and therefore it would be good if they could then use the app alone. Others preferred to do the activities with another person and found it more enjoyable:

I was thinking if I'm gonna sit with... at a tablet I'm isolating myself again, on my own. To do it with somebody, carer, friend... Somebody I didn't even know (!)... Was much better and more enjoyable. – Person with dementia, Focus group 2.

Some participants mentioned that the app was quite straightforward and that they would be able to use it by themselves. Others said they would reach out to someone within their own network for support in order to resolve the issues that way or in case of any technological difficulties (Table 5.2). A person with dementia

mentioned it might be useful to have a way to reach out to other users of the app and be able to share experiences.

5.4. Discussion

People with dementia and carers were positive about the iCST app and liked the sophisticated design and the variety of the content. They also suggested how it can be improved by adding more activities or an option to personalise it. The app was perceived to be useful with several potential benefits identified by the participants. Limitations to using the app were identified such as finding the time, and participants also reflected on different approaches to technology such as familiarity which could contribute to the uptake of the iCST app.

5.4.1. Approaches to technology

Some degree of familiarity with technology, including the platform on which the intervention is offered, would make it easier for people with dementia to use the iCST app. Generally, participants were able to operate the iPad without much help from the researchers, they found that touch-screen tablets were useful due to their practicalities such as size, and that they can be used for other purposes as well. Lim et al. (2013) also found that touch-screen tablets were considered to be intuitive by people with dementia.

Wandke, Sengpiel, and Sonksen (2012) argue that the attitudes of older people towards technology depend on factors such as age, gender, education, and previous computing experience but there can be misconceptions about attitudes, even among older people themselves. The current study showed a need to empower people with dementia to use technology which could increase the uptake of technology-based interventions such as the iCST app.

Technical difficulties or faults could make the use of the iCST app more difficult but these can be overcome with access to the right support (in the family or external).

5.4.2. Quality of the iCST app

The content was well received, but more and diverse content was needed to appeal to a wider audience and could include an element of personalisation as well. Tyack and Camic (2017) note that the content of touch-screen interventions should be tailored where appropriate to the user and should include a slight challenge so the user is invited to apply more complex cognitive skills rather than just simpler ones. Our participants also stated that enjoyment would come from engaging in more challenging activities. The iCST app has two levels of difficulty with a potential to include more levels to cater to the individual's cognitive skills.

The design was appropriate even though there was no clear consensus on the use of colours. The navigation was clear as well as the text and images with some minor suggested changes. A simple and intuitive interface which is aesthetically pleasant, error-free, and provides some guidance to the user on what to do, could help contribute to the uptake of an intervention (Tyack & Camic, 2017). The iCST app adopted these usability factors and was purposefully developed to be kept simple and appealing. Moreover, every activity includes a short summary with instructions. These features were received positively by the majority of the participants who found the design to be sophisticated and intuitive. Two participants with dementia disagreed about wanting to use the iCST app often despite rating the usefulness and ease of use of the app positively and both also preferred to use a paper-based version. However, the majority of the participants

preferred a computerised version of iCST stating reasons such as the interactive features and technology being better suited for current times.

In terms of feasibility, participants were positive about spending one and a half hours a week on the iCST app but there were some concerns about fitting it into their daily routine. This is congruent with findings from Yates, Orrell, et al. (2015) where participants stated, even with competing priorities, it would be feasible to use paper-based iCST three times a week for roughly 20-30 minutes. Findings from the large-scale randomised controlled trial (RCT) with paper-based iCST found adherence to be relatively low suggesting participants experienced challenges with implementing iCST in their daily lives for the recommended amount of time (Orrell et al., 2017). Difficulties with monitoring usage and adherence in the iCST study could be addressed with the iCST app, which could track usage and progress. In the current study, participants additionally mentioned physical limitations such as hearing problems which could affect the feasibility of using the iCST app. Therefore, there is a need for flexibility so that people can tailor the usage according to their own needs. The iCST app further supports this by monitoring usage based on choice of activity and amount of time spent.

5.4.3. Perceived benefits of the iCST app

Participants identified various benefits including mental stimulation, improved communication, enhancement of the dyadic relationship, and enjoyment. Mental stimulation was an important aspect for both people with dementia and carers. Similarly, Yates, Orrell, et al. (2015) noted benefits including engaging in mentally stimulating activities and being able to stay alert.

Using the iCST app with another person could also contribute to the dyadic relationship as dyads valued spending this time together and may help to settle

difficult moments within the relationship. A systematic review by Moon and Adams (2013) also found that dyadic interventions could lead to an improvement in the relationship quality, and highlighted the significance of mutual understanding within these types of interventions. Our participants mentioned the importance of respecting each other's opinions during discussions.

5.4.4. Involvement of a relative or friend

The iCST app is designed to be used by both the person with dementia and carer jointly which is in line with previous iCST research. Most participants preferred to use it together but some wanted a range of activities that could also be done by the person with dementia alone. A combination of both would be a good option as it would allow for a choice. Most participants felt comfortable using the iCST app without the involvement of external support and some mentioned asking friends or family for help with any technical difficulties if needed. However, participants did suggest it would be nice to get in touch with other users of the app. In the future, this could be incorporated in the form of a forum or club directly on the app or the accompanied website.

5.4.5. Methodological strengths

This study permitted an in-depth examination of the usability, feasibility and perceived benefits of the iCST app as it gathered data from both people with dementia and carers, and included a mixture of spousal and adult child caring dyads (Quinn, Clare, & Woods, 2009). This approach allowed us to gather feedback from participants from a range of ages and experiences. In addition, three separate types of focus groups were used to gather a well-rounded view of the iCST app. Separate types of focus groups enabled us to collect data from different perspectives of the caregiving dyad in environments which were set up to

remove conformity due to the presence of their caregiving partner in the discussion. The use of semi-structured individual interviews allowed for the collection of more rich data and provided an environment in which other participants could not influence one another in their responses. Interviews gather a depth of data that could not be accessed through other methods such as the usability and acceptability questionnaires (Alshenqeeti, 2014). Using discussion and interview guides shaped the discussion and supported participants to go into greater depth when sharing their feedback. Moreover, the data from interviews and focus groups was analysed with complementary observational data from the research settings resulting in a greater amount of feedback on the iCST app, especially regarding usability of the app.

5.4.6. Limitations

During the trial of the app people were not able to comment on all aspects of all activities (seven features in this prototype), the longitudinal effects of using the app, or receipt of the full programme (total of 21 activities for the next prototype) with accompanying training and support. However, this may have been reflected in the feedback, as at times there was a lack of elaboration of answers to the questions, limiting the richness of the data. Allowing for more time to try the app and incorporating more focused questions in the discussion guide may help to remedy this in future research. The sample was not representative of the general population of caregiving dyads, as it was a self-selected, white British sample.

5.5. Conclusion

The study highlighted the acceptability and usefulness of prototype v2.0 of the iCST app confirmed through focus groups, interviews, observations and a usability questionnaire (see Chapter 4). The design was rated positively with only minor

changes to the lay-out in certain areas. Level of familiarity or attitudes among users could affect the use of the app. The content was welcomed but with a need for additional, diverse activities to appeal to individual preferences, and for flexibility in the usage of the iCST app. There is potentially quite a broad scope for future developments and updates. The focus groups and interviews also gave insights in the perceived benefits of using the app ranging from mental stimulation to communication, and effects on the dyadic relationship.

The iCST app can be a worthwhile addition to paper-based iCST and the feedback obtained from this study will be used to develop the next iteration of the iCST app which will be taken forward in a feasibility trial (see Chapter 6).

Chapter 6 – Feasibility study for a randomised controlled trial (RCT) of the individual Cognitive Stimulation Therapy application (iCST app)

This chapter was adapted into two journal articles:

Rai, H. K., Schneider, J., & Orrell, M. An individual Cognitive Stimulation Therapy app for people with dementia and carers: Protocol for a feasibility randomised controlled trial. *JMIR Research Protocols* (forthcoming). http://doi.org/10.2196/24628.

Rai, H. K., Schneider, J., & Orrell, M. A feasibility study of a randomised controlled trial to examine the individual Cognitive Stimulation Therapy application (iCST app) for people with dementia (in process of submission).

6.1. Introduction

This feasibility study for a randomised controlled trial (RCT) forms the final development sprint prior to the commercial release of the individual Cognitive Stimulation Therapy application (iCST app). Furthermore, it is part of the feasibility/piloting phase of the Medical Research Council (MRC) Framework, and combines elements from the design and summative evaluation phases of the Centre for eHealth Research (CeHRes) roadmap. The main purpose of feasibility trials is to ensure study implementation is viable by estimating important parameters that are needed to perform a full-scale RCT (Tickle-Degnen, 2013). Feasibility trials can provide useful information on study aspects including recruitment and retention rates, feasibility and acceptability of the intervention, and suitability of outcome measures, which can all contribute to the success of the

main study (Thabane et al., 2010; Tickle-Degnen, 2013). The Consolidated Standards of Reporting Trials (CONSORT) statement, which has been extended to include randomised pilot and feasibility trials, is a widely used guideline designed to improve transparency and the quality of reporting RCTs (Eldridge et al., 2016). The 26-item CONSORT checklist of information to include when reporting feasibility trials has been used for this chapter to ensure all the necessary and relevant information is reported (Eldridge et al., 2016).

6.2. Aims and hypothesis

The aims of this feasibility trial were:

(1) to evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a treatment as usual (TAU) control group and,
(2) to assist the development of a protocol for a full-scale trial including power analysis.

It was hypothesized that the iCST app would lead to better outcomes for people with dementia and carers compared to paper-based iCST because the benefits of computer use on cognitive functioning and QoL may add to the overall effectiveness of the intervention as a result of engaging with novel and stimulating activities, increased confidence, and feelings of empowerment. This study sets out to test this hypothesis through a feasibility RCT using both quantitative and qualitative methods to gain feedback on the potential effectiveness and experience of the iCST app.

6.3. Methods

6.3.1. Design

This was a multi-centre, pragmatic, single blind feasibility trial. Participants were randomised to the iCST app intervention or TAU control group for 11 weeks. People with dementia and carers were recruited as dyads and completed a baseline assessment prior to randomisation to either the experimental group (completing two to three, 30-minute iCST app sessions per week for 11 weeks) or control group (TAU for 11 weeks). Dyads completed the first follow-up (FU1) five weeks post-baseline, and the second follow-up (FU2) 11 weeks post-baseline. A sample of the experimental group was invited for a semi-structured post-trial interview to gain insights in the acceptability of the iCST app including the experience of using the app and any facilitators and barriers for implementation in daily life.

6.3.1.1. Aspects of feasibility

In order to determine the feasibility of conducting a full-scale RCT with the iCST app in the future, this trial investigated key feasibility aspects including the rates of screening, recruitment, randomisation, and retention through the use of enrolment logs (Craig et al., 2008). Acceptability of the outcome measures was evaluated by assessing the completion rates, and the acceptability and fidelity of the iCST app were evaluated through weekly telephone support calls, analytics, a usability and acceptability questionnaire, and post-trial interviews.

6.3.2. Sample

6.3.2.1. Participants

The sample included people with mild to moderate dementia and their informal carers (relatives or friends). Recruitment took place in a variety of settings including primary care settings (general practitioner (GP) practices) and secondary care settings (community mental health teams (CMHTs), memory clinics, care

homes, memory cafes, support groups, and voluntary sector organisations such as the Alzheimer's Society). In addition, each participating study site referred to their own database of people with dementia and carers who had previously expressed interest in taking part in research. The study was also registered on the website Join Dementia Research (JDR), and was publicized through Twitter and other websites including the Institute of Mental Health (IMH), Alzheimer Europe and the Interdisciplinary Network for Dementia Using Current Technology (INDUCT). Remote recruitment also included the distribution of information leaflets and posters to organisations and professionals involved in the identification of possible participants.

6.3.2.2. Study sites

The participating study sites were all based in the East Midlands and included: Derbyshire Healthcare NHS Foundation Trust (DHFT), Leicestershire Partnership NHS Trust (LPT), Lincolnshire Partnership NHS Foundation Trust (LPFT), and Nottinghamshire Healthcare NHS Foundation Trust (NHFT). A principal investigator (PI) was involved at each site. Prior to involvement in the study, relevant documents including the schedule of events and statement of activities were completed for each site and along with the study protocol, were sent to the respective Research and Development (R&D) departments. After receiving approval, and confirmation of capacity and capability from the R&D departments, involvement of the sites in the study could commence. Prior to recruitment, each site received a minimum of two set-up visits from HR to provide information and training on the study, demonstrate the iCST app, and answer any questions. If sites did not have facilities to print documents for the study such as the assessment packs, HR distributed these materials either by post or during a set-up visit.

6.3.2.3. Sample size

Feasibility trials are not expected to have large sample sizes that are needed for statistical null hypothesis testing (Tickle-Degnen, 2013). Therefore, a formal sample size calculation similar to previous CST and iCST research was not appropriate for this study. A previous audit of trials registered in the Clinical Research Network (CRN) database in the United Kingdom (UK) found that most feasibility and pilot trials had a median of 30 or 36 participants per arm and the researchers recommend an upper limit of 60 participants for a feasibility trial (Billingham, Whitehead, & Julious, 2013). However, other research is less conclusive and sample size recommendations range from 24 to 50 participants (Julious, 2005; Sim & Lewis, 2012). Considering these recommendations, a target of 60 dyads was set for this study leading to 30 dyads per treatment arm. A recruitment goal was set for each site depending on the available resources and staff to work on the study. The targets for each sites were the following: 20 dyads for NHFT, 10-15 dyads for the remainder of the sites.

6.3.2.4. Inclusion- and exclusion criteria

The inclusion- and exclusion criteria were adapted from previous CST and iCST research (Orrell et al., 2017; Spector et al., 2003). One study specific criterion relating to the availability of a touch-screen tablet was added for this study. The eligibility criteria included the following:

Person with dementia:

- Meet Diagnostic and Statistical Manual of Mental Disorders (DSM IV) criteria for dementia (American Psychiatric Assocation, 1994).

- Score 10 or above on the Mini Mental State Examination (MMSE) (Folstein et al., 1975) or a score of 16 or above on the Montreal Cognitive Assessment (MoCA) (Trzepacz et al., 2015) where available.
- Some ability to communicate and understand (e.g. ability to give informed consent).
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.
- Age range: 50 years – no maximum age limit.
- Availability of a touch-screen tablet for the person with dementia and carer.
- Availability of a carer (or relative/friend) to participate in the activities.

Carer:

- Minimum age: 21.
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.

Exclusion criteria person with dementia and carer:

- Concurrent participation in any other interventional study for people with dementia/carers.

6.3.3. Procedure

This study adhered to the Good Clinical Practice (GCP) guidelines for which HR completed an online course prior to the study. All study sites received a trial manual written by HR, which described each trial activity in detail from study

preparation to study process and shutdown. The manual was also discussed during one of the set-up visits. Figure 6.1 describes the feasibility trial design including outcome assessments and intervention visits.

6.3.3.1. Screening for eligibility

The CRN East Midlands provided study support for the feasibility trial and as such, CRN staff members at each site checked the eligibility of referrals received from clinicians and staff at the recruitment sources who were provided with the inclusion criteria for the trial beforehand. CRN staff members were often referred to as Research Delivery Officers (RDOs). They had various educational backgrounds ranging from nurses to occupational therapists and psychologists.

Prior to checking against the formal inclusion- and exclusion criteria, the RDOs contacted the referred dyad by telephone and asked several screening questions related to the device they would use for the study. For instance, in order for the iCST app to be installed and work correctly, there was a need for a touch-screen tablet running on either an Apple (iOS) or Android operating system. Furthermore, the minimum requirements for the software versions included version 10 for iOS and version 4.4.2. for Android. Dyads were not always able to confirm these requirements. In such a case, the dyad would go through the baseline assessment and there would be a risk of the tablet not being compatible with the iCST app and therefore limiting their participation in the trial. If dyads were still happy to proceed, RDOs then checked their eligibility against the inclusion criteria.

Type of dementia was not specified in the inclusion criteria but was noted wherever available to be included in the analysis. Participants fulfilling the inclusion criteria as listed above were sent a participant information sheet (PIS) containing full details about the study. RDOs then contacted the dyad and if still interesting in

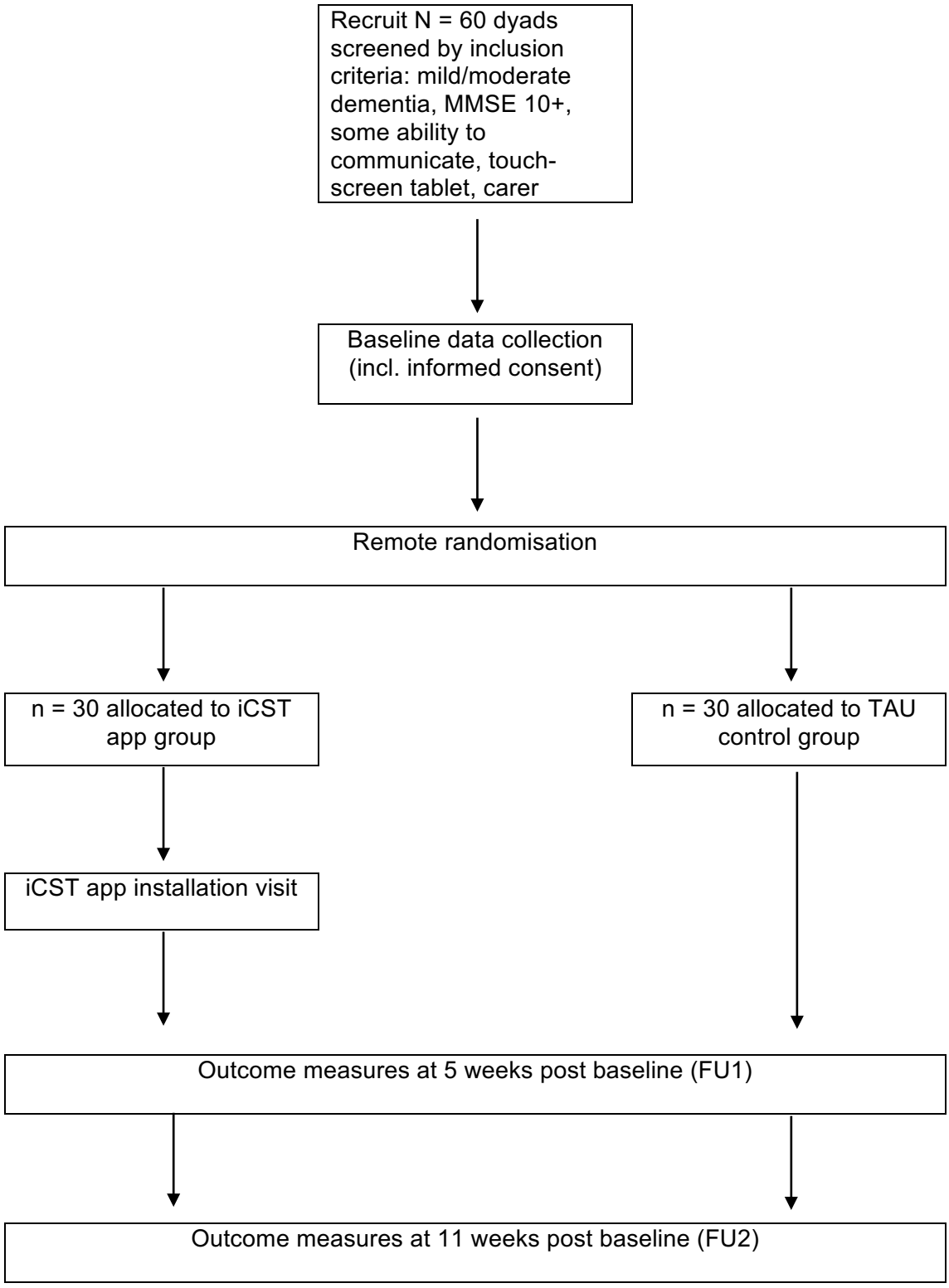


Figure 6.1. Flow diagram of the iCST app feasibility trial.

participating, the dyad was recruited into the trial. A date for the baseline assessment and consenting was set by the RDOs and on the day of the visit, the RDO spent some time in discussion with the dyad to further check suitability in terms of capacity (e.g. ability to communicate and understand the research) (see section 6.3.4.2. Consent).

6.3.3.2. Randomisation

Randomisation took place after consent and the baseline assessment using an online, central randomisation service called Sealed Envelope (https://www.sealedenvelope.com/). We employed block randomisation with block sizes of four to six (randomly varied and generated by Sealed Envelope). This technique is frequently used in clinical trials to minimise bias and to allocate an equal number of participants to each treatment arm by sequencing participant assignments by block. This method is especially useful for small sample sizes (Efird, 2011).

The researcher at the local site performed each randomisation using the participant identification code of the person with dementia only (see section 6.3.3.3. Blinding). The allocation to the experimental or TAU control group automatically applied to the carer as well. The allocation was fed back immediately on the website and in addition, both the (unblinded) researcher at the local site and HR received a confirmation email of the allocation arm. Dyads were informed of their allocation outcome over the telephone and, if necessary, a visit was arranged for dyads in the experimental group to install the iCST app. For the Nottingham site, HR was able to obtain contact details through a password protected Excel spreadsheet on a secure National Health Service (NHS) computer.

6.3.3.3. Blinding

The trial included both blinded and unblinded researchers at each local site. It was not possible to blind the participants to their treatment arm as the iCST app is a non-pharmacological intervention. However, each study site included at least one researcher who was blind to study allocations. The baseline assessment could be performed by either researcher. However, FU1 and FU2 were completed only by the researcher who was unaware of the randomisation outcome for each dyad (blinded). Participants could occasionally and inadvertently inform researchers of the treatment they were receiving. To reduce the likelihood of this happening, researchers gave explicit reminders to participants by telephone before the assessment visit that they should avoid disclosing their treatment arm. If disclosure did occur, this was recorded by the researcher on the assessment pack along with details on how it occurred and was communicated with HR as soon as possible. The unblinded researcher performed the randomisation, communicated the outcome with the participants, and for the experimental group, installed the iCST app, provided weekly telephone support calls, and completed the usability and acceptability questionnaire at the end of the study (see sections 6.3.3.5. Training and adherence, and 6.3.3.8. Outcome measures). Furthermore, the unblinded researcher was not informed about the results of the assessments. HR acted as an additional unblinded researcher for each study site in order to provide assistance with any difficulties with the iCST app.

6.3.3.4. Intervention – iCST app

Participants in the experimental group used the iCST app prototype v3.0 as described in Chapter 4 over 11 weeks post-baseline. The content of the app was

modified from the paper-based iCST manual including the principles, themes, and activities (see Chapter 2) (Orrell et al., 2017), and was also based on consultations and qualitative research with people with dementia, carers, and Eumedianet (see Chapters 4 & 5). Like iCST, the iCST app is a one-to-one, carer-led, home-based programme of structured cognitive stimulation for people with dementia but delivered on a touch-screen tablet. It includes 21 activities and a full list of activities is included in Table 6.1. Most activities included a combination of game-like, interactive features such as audio-visual stimuli, and discussion questions. This was to offer mental stimulation through the content on the app but also through conversation. A few were simply game- or discussion-based activities accompanied by some images. Based on recommendations of people with dementia and carers from the qualitative study as described in Chapter 5, a Word Search and Trivia Quiz were included as these types of activities would be more familiar to older people.

Table 6.1. List of the iCST app activities (prototype v3.0).

Game	Discussion	Game and discussion
Being Creative	Past Events	Sounds
Spaceman	Useful Tips	Odd one Out
Trivia Quiz	My Life	The Price is Right
Word Search	Arts	Globe Trotter
Sudoku	Old Wives' Tales	Food
Being Active	Toys Are Us	In Pairs
Brainstorm		Sayings
		iSpy

In addition, the app included several other features such as a short introduction section explaining the background and key tips for using the app, a home screen which features completed activities, and a choice from two levels. Level 2

contained either more challenging content or different questions from Level 1 and it was up to the participants to determine which level they felt more comfortable with for each activity.

Considering previous CST and iCST research and findings from the development work, it was recommended that participants use the app for two or three times a week for 30 minutes (Orrell et al., 2017). Participants were free to spend more time on the app if they wished, and this was recorded during the weekly telephone calls. The structure of an iCST app activity differed slightly from a paper-based iCST activity. A paper-based iCST activity includes a short orientation and current events discussion prior to the themed activity (e.g. day, weather, time, location, news). However, for the app, participants spend their time on the themed activity only. Findings from the qualitative work (see Chapter 5) suggested that participants found the interactive features of the app more appealing and would rather spend more time doing the actual activity. Therefore, it was decided to incorporate discussion and orientation elements within the themed activities. In terms of iCST principles, paper-based iCST includes 15 key principles (see Chapter 2). The app included a selection of these in the introduction/welcome section (Table 6.2).

Table 6.2. iCST app principles (Orrell et al., 2017).

iCST app principles
1. Mental stimulation
2. Focus on opinions rather than facts
3. Develop new ideas, thoughts, and associations
4. Provide triggers to support memory
5. Stimulate language and communication
6. Offer a choice of activities
7. Spend quality time together
8. Enjoyment and fun

Considering issues with usability, user-friendliness, and the need to limit the amount of text on the app as pointed out in previous consultation work with people with dementia and carers, the research and software development teams chose only to present a selection of the iCST principles on the app. The aim was to include a mix of the key principles which would offer some guidance on how to approach the iCST app (e.g. opinions rather than facts, enjoyment), and also on the cognitive functions which could be supported through the interactive features and the content of the app (e.g. memory, language and communication). This led to the omission of six original iCST principles (use a person-centred approach, using orientation in a sensitive manner, using reminiscence, stimulating planning abilities, maximise potential, and strengthen the care giving relationship). The iCST app principles were incorporated in a short summary text and bullet points.

6.3.3.5. Training and adherence

In order to ensure treatment integrity for all participants across the study sites, HR visited the individual sites to demonstrate the iCST app, and to provide training on how to install and use it prior to the start of recruitment. All information relating to the iCST app was also included in the trial manual.

Unblinded researchers were responsible for installing the iCST app on the devices of the dyads in the experimental group through an in-home visit. The researcher explained how the app worked using a short, supplementary document containing instructions with screenshots of the app. These instructions were given to the dyad to keep and also contained the contact details of both the unblinded researcher and HR. Furthermore, all dyads received weekly telephone support calls from the unblinded researcher in order to monitor adherence but also to track overall progress and any challenges and/or technical difficulties with using the iCST app.

Phone calls were completed with the carer and all questions were included on a standardised telephone sheet. The questions related to general experience, amount of sessions completed in a week (on average), amount of time spent per session (on average), enjoyment, and any likes/dislikes. Any reasons for not being able to use the iCST app over the week were also recorded on the telephone sheet.

Any technical difficulties with the iCST app were communicated directly to HR who notified Eumedianet. Eumedianet was responsible for identifying the cause of any bugs, rectifying these, and implementing an update for the dyads. Dyads received an automated notification when the update was available and could then install it. The unblinded researchers checked whether all dyads were able to successfully access the updates and if necessary provided support through telephone.

6.3.3.6. TAU control group

The control group consisted of a TAU control group and did not receive any additional interventions. TAU control groups are typically used to compare experimental interventions to care which participants already receive in practice (Freedland, Mohr, Davidson, & Schwartz, 2011). Therefore, the TAU control group enabled us to compare the effects of the iCST app with the natural progression of people with dementia under conditions of usual care.

The treatments and services which were already available to people with dementia and their carers randomised to the TAU control group, may have differed between and within recruitment sites. For instance, some people with dementia participating with the feasibility trial were taking acetylcholinesterase inhibitors (AchEIs). It was also possible that participants in the TAU control group could have been involved in some form of cognitive stimulation, since CST is a popular approach within day

centres and the manuals are widely available. However, it was unlikely that people had access to computerised versions of iCST since these do not exist to the best of our knowledge. The visiting researcher recorded any current participation with CST groups and/or use of AchEIs at the baseline assessment. Randomisation would ensure that both the experimental and TAU control group contained an equal number of participants who took medication and who were exposed to a form of CST.

Since the treatments and services offered to the TAU control group were also available to the experimental iCST app group, we examined the additional effects of the iCST app. Participants were not involved in any other interventional dementia study across the duration of the iCST app feasibility trial.

6.3.3.7. Assessment procedure

All assessments took place in the homes of the participants. Wherever possible, two RDOs visited the participants in order to interview the person with dementia and carer separately. On average, the assessments took 1.5 to 2 hours with the baseline taking slightly longer due to the consent process and addition of demographic information. It was possible to conduct the assessments over two days in case of fatigue or other practical issues such as lack of time. All RDOs received training on the questionnaires to ensure familiarity and all questionnaires included specific instructions for administration and scoring. Scoring on each assessment for all dyads was checked by HR to ensure reliability and minimise errors. As in the previous iCST trial, a mid-point FU1 was included to safeguard data against loss to follow up (Orrell et al., 2017). FU2 took place at 11 weeks post-baseline as this should be the point that participants in the experimental group would have completed each activity on the iCST app.

6.3.3.8. Outcome measures

Previous CST and iCST research informed the outcome measure selection for this study in order to draw comparisons where possible. Furthermore, outcome measure selection was also guided by the Interdem consensus statement on outcome measures for dementia (Moniz-Cook et al., 2008). Key outcome measures of interest for the person with dementia were cognition and quality of life (QoL) as previous CST research has shown improvements in these domains (Spector et al., 2003). For the carer, the key outcome measure was QoL as previous iCST research has shown to improve the QoL of carers (Orrell et al., 2017). This study additionally included technology-related scales to assess usability and acceptability of the iCST app and computer user self-efficacy.

Outcome measures for person with dementia:

a) Cognition was assessed using the Alzheimer's Disease Assessment Scale-Cognition (ADAS-Cog) (Rosen et al., 1984). It was designed to measure the severity of the most important cognitive symptoms of Alzheimer's disease (AD). This scale is commonly used as a cognitive testing instrument in clinical trials of drug treatments for dementia (Moniz-Cook et al., 2008). The ADAS-Cog consists of 17 items measuring different functions such as memory, language, praxis, attention and orientation. The subscale is scored between 0 (no impairment) to 70 (severe dementia). The ADAS-Cog is brief, widely-used and has good reliability and validity (Weyer, Erzigkeit, Kanowski, Ihl, & Hadler, 1997).

b) QoL was assessed with The Quality of Life – Alzheimer's Disease (QoL-AD) (Logsdon et al., 1999). It is a widely used brief, self-report questionnaire and consists of 13 items covering various domains such as physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self,

and life as a whole. It has been recommended in a European consensus statement on outcome measures for dementia (Moniz-Cook et al., 2008). The possible range of the QoL-AD is 13-52 with higher scores indicating a higher perceived QoL. The QoL-AD has good internal consistency, validity and reliability (Logsdon et al., 1999). In addition to the self-reported questionnaire completed by the person with dementia, carers completed the family version of the QoL-AD.

c) The Quality of the Carer Patient Relationship (QCPR) was used as a measure of relationship quality (Spruytte, van Audenhove, Lammertyn, & Storms, 2002). People with dementia and carers completed the measure separately. This scale comprises 14 items with five-point Likert-type scales, designed to assess the warmth of the relationship and the presence or absence of conflict and criticism. The possible total scores range from 14 to 70. The median of this range is used to differentiate between 'good' relationships (score > 42) and 'poor' relationships (score ≤ 42). The QCPR has good internal consistency for carers and people with dementia, and has concurrent validity (Spruytte et al., 2002).

d) Depressive symptoms were measured by the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988). The scale consists of 19 items in which depression is rated in five categories: mood-related signs, behavioural disturbances, physical signs, biological functions and ideational disturbances. Information was gathered separately from the person with dementia and the carer. Each item is scored for severity on a scale of 0-2. Scores below six are associated with absence of significant depressive symptoms. A score of above 10 indicates a probable major depression. Scores exceeding 18 indicate a definite major depression. The CSDD has good concurrent validity and interrater reliability (Alexopoulos et al., 1988).

e) The Neuropsychiatric Inventory (NPI) assesses the following 10 behavioural disturbances which can occur in people with dementia: delusions, hallucinations, dysphoria, anxiety, agitation/aggression, euphoria, disinhibition, irritability/lability, apathy, and aberrant motor activity and was rated by the carer (Cummings et al., 1994). The frequency (range 1-4) and severity (range 1-3) of a symptom during the last month was determined and a score of ≥ 9 is indicative of a significant problem. The NPI has good psychometric properties: both content and concurrent validity, and interrater, test-retest and internal consistency reliability are high (Cummings et al., 1994). In addition, the NPI is sensitive to behavioural changes and is recommended in the European consensus statement for outcome measures for dementia (Moniz-Cook et al., 2008).

f) Functional abilities of the person with dementia were measured with the Bristol Activities of Daily Living Scale (BADLS) (Bucks, Ashworth, Wilcock, & Siegfried, 1996). This covers 20 daily living activities rated by the carer. The minimum possible score is 0 which indicates total independence and the maximum possible score is 60 which indicates total dependence. The scale has acceptable face, construct, and concurrent validity. In addition, it has good test-retest reliability. The BADLS shows sensitivity to change in people with AD taking AchEIs and significantly correlates with changes in the ADAS-Cog (Byrne, Wilson, Bucks, Hughes, & Wilcock, 2000).

Outcome measures for carers:

a) The EuroQoL five dimensions questionnaire (EQ-5D) is a short, generic measure of health status and was completed by both the carer and the person with dementia (EuroQoL Group, 1990). The instrument is applicable to a wide range of health conditions and covers the following five dimensions: mobility, self-care,

usual activities, pain/discomfort, and anxiety/depression. The EQ-5D consists of two components: a description of the respondent's own health and a rating on a visual analogue thermometer scale. This provides a simple descriptive profile and a single index value for health status (EuroQoL Group, 1990).

b) The Hospital Anxiety and Depression Scale (HADS) consists of 14 questions across two subscales for anxiety and depression (Zigmond & Snaith, 1983). The two subscales each score 0–3, which generate scores for generalised anxiety and depression (0–21). The total score is out of 42 and higher scores indicate higher levels of anxiety and depression. The HADS is a widely used measure, validated for all age groups (including older people aged 65 to 80 years) and a range of populations (general population and somatic, psychiatric and primary care patients). It has good internal consistency and test-retest reliability. In addition, it has good concurrent validity (Bjelland, Dahl, Haug, & Neckelman, 2002).

Technology-related scales for people with dementia and carers:

a) The Computer User Self-Efficacy scale (CUSE) was used to assess self-efficacy beliefs in the context of computer/tablet use (Cassidy & Eachus, 2002). The measure was administered at baseline only to investigate whether previous experience with computers/tablets and confidence in one's abilities to use these tools, influenced the use of the iCST app. Even though the CUSE was designed to measure general computer self-efficacy in an adult student population, the CUSE has been successfully administered among an older population in another study (Lagana, 2008). The scale consists of two parts which have a total of 30 items. Participants are asked to rate their level of agreement or disagreement with a statement on a six-point Likert scale. A higher total score indicates more positive computer self-efficacy beliefs. The CUSE has good internal reliability and good

construct validity (Cassidy & Eachus, 2002). Data on the CUSE would be less meaningful if participants had no or limited previous experience with using technology. Therefore, if this was the case, administration of the CUSE was omitted for these participants.

b) The Questionnaire of Usability and Acceptability (CUA) is a questionnaire developed by colleagues at Jaume University I in Spain (Castilla et al., 2018). The CUA seems more appropriate than other commonly used usability questionnaires such as the System Usability Scale (SUS) as the CUA is developed specifically for older people, includes clear and easy to understand statements, and provides visual stimuli to help answer the questions. An updated version of the CUA from the qualitative study (see Chapter 5) was used for the trial. This updated version consists of 10 items on a Likert scale from strongly disagree to strongly agree. The CUA was administered over the phone by the unblinded researcher during the last weekly support call once the participants in the experimental group had used the full app. The researcher completed the questionnaire separately with both the person with dementia and carer. A copy of the CUA was taken along with the installation visit so participants were able to have it in front of them while answering the questions.

6.3.3.9. Post-trial interviews

A small proportion of dyads (N = 3) in the experimental group at the Nottingham site were invited to participate in joint, semi-structured interviews. Two dyads were interviewed one month after completing FU2, and one other dyad was interviewed three months after completing FU2 due to their prior unavailability. The purpose of the interviews was to gain additional information on the lay-out and content of the iCST app, the overall experience of using it as a dyad, and any practicalities

surrounding its use in daily life e.g. barriers. The interview served as a complementary data collection method to the weekly telephone support calls and the usability questionnaire as a semi-structured interview generates more in-depth data that otherwise cannot be accessed through quantitative methods only (Alshenqeeti, 2014). For this study, it gave participants more time to elaborate on their feedback and would also allow the person with dementia to voice his/her thoughts as the weekly telephone support calls were completed with the carer only. A discussion guide was developed including the key areas mentioned before that helped to guide the interview (see Appendix 30).

The post-trial interviews were undertaken with a convenience sample. Nottingham was selected as a site for practical reasons including proximity to HR for conducting the interviews. Furthermore, each dyad in the experimental group was offered to participate in the interview upon completion of the study. If interested, a PIS for the person with dementia and carer was sent by post. HR contacted the dyad by telephone to provide additional information and answer any questions about the interview. If a dyad agreed to participate, a date for the interview was set. All interviews took place in the home of the participants and HR explained the details of the interview once more before obtaining written informed consent from both participants prior to data collection. The person with dementia and carer were interviewed together in order for them to better reflect on the experience of using the app together. The interview lasted approximately 45 to 60 minutes. The data was audio-recorded and transcribed by HR, and was subsequently stored on a password protected computer at the University of Nottingham.

6.3.3.10. End of study activities

FU2 constituted the end of the study for participants. At this final visit by the blinded researcher, all participants were given a £10 Apple or Google Play store voucher in order for them to download the iCST app once it had been released on the app stores. This was accompanied by an instructional document on how to redeem the voucher and a newsletter containing information on what would happen next such as making improvements to the app, and analysing and disseminating the results.

Upon completion of the study, all the data was collected by HR from each study site. This included the assessments, weekly telephone support calls, and usability and acceptability questionnaires. Lastly, a second newsletter was sent out to all participants to inform them about the research outcomes. The newsletter included contact details of HR in case participants had any comments or questions.

6.3.4. Ethical considerations

The application for ethical approval was submitted to the Yorkshire and the Humber – Bradford Leeds Research Ethics Committee in November 2017 (REC number 17/YH/0405), and registered as a clinical trial on clinicaltrials.gov in September 2017 (registration number NCT0328277). The study was granted provisional approval in December 2017 and the committee requested further elaboration and modifications on the following issues:

- Some changes to the PIS were made in order to include more information about study withdrawal, the randomised nature of the study and the TAU control group, reimbursement of possible expenses, availability of the intervention to participants in both treatment arms after completion of the study, and the potential benefits of being allocated to the control group.

- Additional information was given to the committee explaining that an assessment could take place across two days due to the volume of questionnaires and potential burden on participants. Furthermore, one technology-related questionnaire was removed (SUS) and was replaced with a shorter questionnaire (CUA).
- A separate PIS and consent form was created for the subset of participants taking part in the post-trial interviews.
- The committee initially advised that participants who lost capacity during the study needed to be withdrawn. However, with support from MO, JS and the sponsor department of the University, HR argued for the inclusion of these participants as they would have capacity when consenting to take part prior to the study. In a letter to the REC, HR outlined regulations of the Mental Capacity Act and quoted findings from a report published by Alzheimer Europe in 2011 titled 'Ethics of dementia research'. Hereafter, the REC agreed to the inclusion of these participants and no modifications on this issue were necessary.

Full favourable opinion from the REC and the Health Research Authority (HRA) approval was obtained in March 2018 (see Appendix 1 and 2).

6.3.4.1. Risks and anticipated benefits

Previous work with CST, MCST, and iCST has not documented any harmful side effects nor any serious adverse events (SAEs) from participating in the intervention activities (Orrell et al., 2014; Orrell et al., 2017; Spector et al., 2003). Participants of CST groups have mentioned several benefits including enjoyment, feelings of validation, enhanced self-worth, and improved verbal fluency (Spector et al., 2011). Qualitative findings from iCST research suggest that iCST provided both

people with dementia and carers with opportunities to enjoy mentally stimulating activities and spend more time together in a meaningful way (Leung, Yates, Orgeta, Hamidi, & Orrell, 2017). Given that the iCST app is based on the principles of CST and follows a comparable structure to iCST, it was expected that similar benefits would occur in this study for both the person with dementia and the carer. Participants were fully informed of the potential risks and benefits of participation with the study in the PIS prior to giving consent.

In the case of any SAEs or adverse events (AEs), a standard procedure was put into place to ensure the chief investigator (CI) (MO) was notified. Typically, RDOs were made aware of any AEs during follow-up assessments or the weekly telephone support calls. The RDOs at the local sites first informed HR of the occurrence of an AE who then informed the CI. Together with the CI, HR assessed the severity of the AE and whether it was due to participation in the study. Hereafter, the RDO at the local site prepared a file note with detailed information about the AE and stored the file note in the trial master file at the site. SAEs included events such as death, illness related to a previous health condition, or hospitalisation.

6.3.4.2. Consent

People with mild to moderate dementia were recruited in the study and were expected to be able to give informed consent for participation provided that appropriate care was taken in explaining the research and sufficient time was allowed for them to reach a decision. Written informed consent was taken by the RDO at baseline from both the person with dementia and carer. Since the intervention required joint participation, it was likely that both participants would have consulted each other in making their decision. Therefore, it was possible that

any individual participant's decision to either participate or not participate with the research might be influenced by the other participant. However, it was important that individual participants were not forced to make a decision against their will and the RDO spent as much time as necessary in speaking to the participants individually about the research. It was made clear to both people with dementia and carers that no disadvantage would accrue in terms of the current care they received or any future research opportunities, if they chose not to participate or withdraw from the study.

Following guidance from the British Psychological Society (British Psychological Society, 2014), consent was regarded as a continuing process rather than a one-off decision, and willingness to continue participating was continually checked through discussions with participants during the assessments. Where the participant's level of impairment increased, so that they were no longer able to provide informed consent, the provisions of the Mental Capacity Act (2005) were followed. This meant that we aimed to continue the involvement of the participant after consulting with the involved carer. The Mental Capacity Act stipulates that the research may be carried out despite the participant's loss of capacity if, (i) the project satisfies prescribed requirements, (ii) any information or material related to the participant which is used in the research was obtained before the participant's loss of capacity, (iii) and the person conducting the project takes in relation to the participants such steps as may be prescribed for the purpose of protecting him/her (Department of Health, 2015).

The consent form was signed and dated by the participant and the RDO before they entered the study. One copy was given to the participant and one was retained at the local study site.

6.3.4.3. Data security and entry

HR attended a seminar to learn more about the General Data Protection Regulation (GDPR) provisions and to follow these during the study in addition to the GCP guidance. Each study site created their own password-protected spreadsheet containing participant identifiable information and allocation outcome for the dyad. This spreadsheet could only be accessed through a secure NHS trust computer.

After collection of the data by HR from each site, the data was stored in a secure cabinet at the University of Nottingham. Identifiable information including the consent forms were kept in a separate, locked cabinet. After reviewing the data and checking the scoring by HR, it was then entered manually into SPSS version 25 for Windows which was used for all the analyses.

6.3.5. Statistical analyses

6.3.5.1. Feasibility analyses

Regarding the primary aim of this trial, key feasibility outcomes are reported through frequencies and include the number of participants screened, recruited, randomised, and retained through the duration of the trial. Adherence to the intervention was assessed by calculating the average number of iCST app activities completed by the dyad. This data was logged in the weekly telephone calls but also through anonymous back-end tracking through analytics. In terms of feasibility, >75% of the participants in the experimental group were expected to complete the recommended minimum of two activities on average every week. This benchmark was adopted based on work in some previous feasibility trials including psychological treatments where benchmarks for successful adherence ranged between 75% to 80% (Horne, Hooban, Lincoln, & Logan, 2019; Orgeta et

al., 2019). The usability and acceptability of the iCST app were further investigated by examining data from the weekly telephone calls, post-trial interviews, and by calculating scores on the CUA with higher scores indicating higher levels of usability and acceptability. Data from the post-trial interviews was coded and summarised but not analysed thematically with specialised software considering the small sample size of participants partaking in the interviews and difficulty in reaching data saturation (Guest, Bunce, & Johnson, 2006). Lastly, outcome measures were assessed for appropriateness by calculating missing data rates within the measures and across the follow-ups.

6.3.5.2. Outcome analyses

Regarding the second aim of this trial, as this is a feasibility trial and null hypothesis significance testing is inappropriate due to a likely lack of power to detect significant effects of the intervention (Arnold et al., 2009; Sim, 2019; Tickle-Degnen, 2013), analyses mainly included descriptive statistics computed for each group and outcome measure including means, standard deviations, 95% confidence intervals and effect sizes (Eldridge et al., 2016; Vranceanu et al., 2019). However, in order to compare the outcomes on each of the questionnaires between the two groups, an analysis of covariance (ANCOVA) was undertaken. This allowed checking for any discernible differences that could be interpreted as potential signs of effectiveness, exploring the data in more detail, and better understanding any trends. The outcome at FU1 and FU2 served as a dependent variable and the outcome at the baseline assessment was fitted as a covariate as this may have influenced the FU1 or FU2 outcome. All analyses were based on the intention to treat principle in that all available data was included in the analyses. Rules for missing data were adapted from the main iCST trial (Orrell et al., 2017). Data was not imputed if outcome measures or assessments were missing in full,

and imputation (using pro-rating) was only used when fewer than 20% of cases were missing on any given measure.

6.4. Results

6.4.1. Recruitment and participant flow

6.4.1.1. Recruitment of participants

Recruitment for the feasibility trial took place between November 2018 and April 2019 with two sites (LPT and LPFT) starting recruitment one month later in December 2018. The last follow-up took place in July 2019 after which data on screening and recruitment was shared by each site with HR through email.

A total of 384 dyads were approached or referred across the four sites and, of these, 43 dyads were consented, completed the baseline assessment and were randomised to either the iCST app or TAU control group. Table 6.3 describes the response rates and the total numbers of participants lost before randomisation accompanied by reasons for loss.

Table 6.3. Response rates and loss of participants prior to randomisation.

Reason	**Total (%)**
Total approached/referred	384
Reason unknown or not disclosed	100 (26)
Exclusion criteria applied	90 (23)
Lack of availability correct device	80 (21)
Does not wish to take part	52 (14)
Dyad approached has not responded	14 (4)
Not interested in using technology	5 (1)
Total lost between approach/referral and randomisation	341 (89)
Total number randomised	43 (11)

Most frequently, the reason for not recruiting a dyad to the trial was unknown as not all sites registered dyads' reasons for not participating with the study when visiting support groups in particular. In most other cases, the lack of having a correct device for the study and the remaining study exclusion criteria led to dyads being ineligible. Participants who did not have the correct device, often did have access to technology such as personal computers (PCs), laptops, and mobile phones but not a device compatible with the iCST app such as a tablet with iOS version 10 or Android version 4.4.2.

Table 6.4 shows the referral and randomisation rates per site. Of all sites, Derby had the highest number of referrals and/or approaches, however Nottingham had the highest conversion rate from referral to randomisation.

Table 6.4. Recruitment rates per site.

Site	**Approached or referred**	**Randomised (%)**
Derby	151	11 (7)
Leicester	94	11 (12)
Lincoln	75	8 (11)
Nottingham	64	13 (20)
Total	384	43

Participants were most often referred from or approached through dementia support groups (n = 162), JDR (n = 76), the site's own research database (n = 69), or clinicians working in CMHTs or memory assessment services (n = 43). A small proportion of participants were approached through their GP (n = 13) or care home promotion (n = 2), and one other participant was referred through a leaflet advertising the study. For 18 participants, the source of referral or approach was unknown.

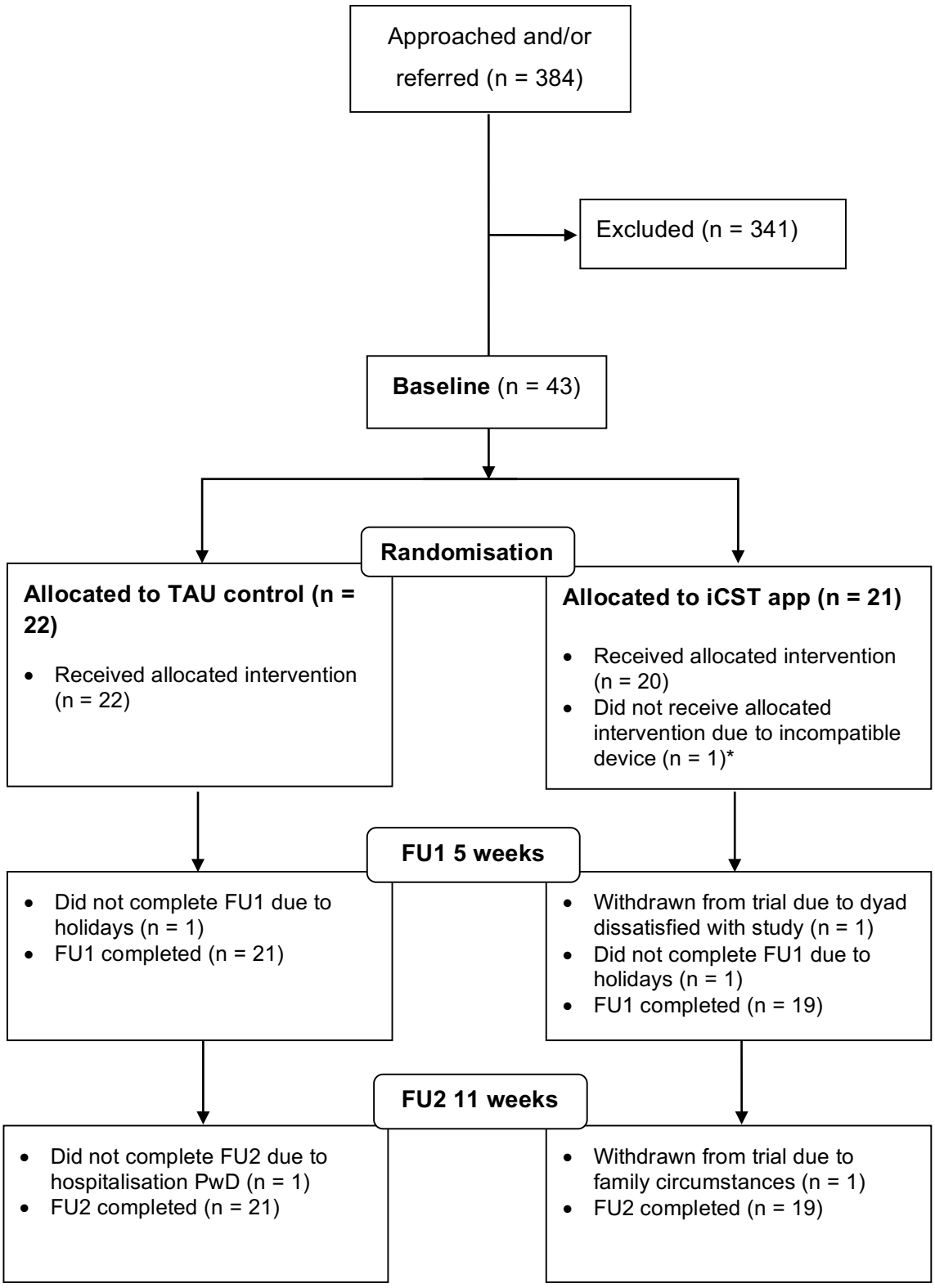
6.4.1.2. Participant flow and follow-up retention rates

Figure 6.2 shows the participant flow through the feasibility trial along with treatment allocation, number of withdrawals, and non-completion of either FU1 or FU2 per allocation group (Eldridge et al., 2016). Block randomisation led to an equal distribution of participants across the treatment groups with 21 dyads randomised to the iCST app group and 22 dyads randomised to the TAU control group. One dyad in the experimental group was not able to access the iCST app (see section 6.4.3.2. Issues related to the iCST app).

All participants accepted their allocation outcome to either the iCST app or TAU control group and no dyads dropped out after learning their randomisation results. Furthermore, retention rates were high with only two dyads from the experimental group withdrawn from the study (see section 6.4.5. Adverse events). One dyad in the experimental group and one dyad in the control group did not complete FU1 due to holidays but these dyads were both available for FU2. Another dyad in the control group did not complete FU2 due to the hospitalisation of the person with dementia. The hospitalisation was not study-related (see section 6.4.5. Adverse events).

6.4.1.3. Allocation disclosure

Unblinding occurred for eight dyads in the experimental group and one dyad in the control group. For seven dyads in the experimental group, unblinding happened at FU1 when the dyad inadvertently told the blinded researcher about their use of the iCST app. In one case, a dyad mistakenly made a telephone call to the blinded researcher with a query about their allocation outcome to the experimental group. The dyad in the control group also disclosed their allocation outcome to the blinded researcher while making a telephone call to schedule FU1.



*dyad who did not receive the intervention in the experimental group was subsequently withdrawn from the study.

Figure 6.2. CONSORT flow diagram: participant flow through feasibility trial.

6.4.2. Sample characteristics

Tables 6.5 and 6.6 show the demographic information of people with dementia and carers. Tests for homogeneity showed no differences in distributions on any of the characteristics between the iCST app and TAU control group. People with dementia overall had a mean age of 73.05 years (data missing for two participants), and the majority of people with dementia were male (n = 29), married (n = 34) and lived at home with their spouse or partner (n = 36) (data missing for one participant). Half of the people with dementia had no educational qualifications (n = 11) or had left school after their O-Levels/GCE (n = 10), and data for one participant was missing. Most people with dementia were taking AchEIs at the time of the baseline assessment (n = 30) with an almost equal distribution across the iCST app (n = 16) and TAU control group (n = 14). Data was missing for three participants. Lastly, the majority of people with dementia were not involved in any CST groups at the time of the study (n = 35) with data missing for one participant. Of the people with dementia participating in CST groups, five were in the control group and two were in the experimental group. Most people with dementia had a diagnosis of AD (n = 18) or vascular dementia (VaD) (n = 6). Fewer participants had a diagnosis of frontotemporal dementia (FTD) (n = 3), mixed dementia (n = 2), or another type of dementia such as Lewy-body, Parkinson's disease dementia or post cortical atrophy (n = 3). Data on the type of dementia was missing for 11 participants.

The mean age of carers was 66.21 years and the majority of carers were female (n = 33) and in terms of educational qualifications had either left school after their O-Levels/GCE (n = 14) or had a BSc/BA degree (n = 10). Data on age was missing for four participants and one participant did not provide information on educational qualifications. For both people with dementia and carers, the sample was

predominantly white with only one person with dementia from Asian descent. One carer preferred not to disclose their ethnicity. A total of 34 spousal dyads participated with the study and the non-spousal dyads consisted of partners (n = 2), children (n = 3) or the son/daughter-in-law (n = 1) of the person. Two dyads identified their relationship as 'other'.

Table 6.5. Demographics of people with dementia.

	Total	**iCST app**	**TAU**
Characteristic			
Age in years: mean, SD	73.05, 8.41 (range: 50-89)	73.43, 7.81	72.65, 9.20
Male (%)	29 (67)	13 (62)	16 (73)
Ethnicity white (%)	42 (98)	20 (95)	22 (100)
Relationship with carer: married (%)	34 (81)	18 (86)	16 (76)
Lives with spouse/partner (%)	36 (86)	18 (86)	18 (86)
Education: no qualifications or School Leaver O-Levels/GCE (%)	21 (50)	12 (57)	9 (43)
Taking AchEI medication (%)	30 (75)	16 (80)	14 (70)

Table 6.6. Demographics of carers.

	Total	**iCST app**	**TAU**
Characteristic			
Age in years: mean, SD	66.21, 12.11 (range: 27-83)	68.21, 9.90	64.30, 13.88
Female (%)	33 (77)	16 (76)	17 (77)
Ethnicity white (%)	42 (100)	21 (100)	21 (100)
Education: School Leaver O- Levels/GCE or Higher Education (BSc/BA) (%)	24 (59)	11 (52)	13 (65)

Table 6.7 shows the previous experience of participants with using technology

across the two treatment groups, data was missing for one person with dementia and one carer. Overall, carers were more experienced with using technology with over half indicating they had at least some experience with using technology. Whereas, people with dementia were less likely to have experience with using technology or their experience ranged from very limited to some experience.

Table 6.7. Previous experience of people with dementia and carers with using technology.

Experience with technology	**Person with dementia (n = 42)**			**Carer (n = 42)**		
	Total (%)	**iCST app (%)**	**TAU (%)**	**Total (%)**	**iCST app (%)**	**TAU (%)**
None	12 (29)	6 (29)	6 (29)	2 (5)	0 (0)	2 (10)
Very limited	10 (23)	3 (14)	7 (33)	6 (14)	3 (14)	3 (14)
Some experience	12 (29)	6 (29)	6 (29)	24 (57)	12 (57)	12 (57)
Quite a lot	6 (14)	6 (29)	0 (0)	5 (12)	4 (19)	1 (5)
Extensive	2 (5)	0 (0)	2 (9)	5 (12)	2 (10)	3 (14)

The iPad was the most familiar type of device for 32 dyads (74%), and 11 dyads owned an Android tablet including: Samsung, Lenovo and Amazon Kindle (26%).

6.4.3. Feasibility and acceptability of the iCST app

The feasibility of the iCST app was investigated through collecting information on adherence to and acceptability of the app. Data was gathered from participants in the experimental group through weekly telephone calls, analytics, post-trial interviews, and a usability and acceptability questionnaire at the end of the study.

6.4.3.1. Adherence

The iCST app consisted of 21 activities to be completed over the course of 11 weeks. Based on previous iCST research (Orrell et al., 2017), it was recommended to dyads that they completed 2-3, 30-minute activities per week. Telephone data showed that, of the 20 dyads, 40% (n = 8) were able to complete 21 or more activities over 11 weeks, 30% (n = 6) completed 14 to 21 activities, 25% (n = 5) completed 7 to 14 activities, and 5% (n = 1) completed six activities during the study. Some dyads reported doing more than one activity on one day and dividing their time across several activities (e.g. 10 minutes on Word Search and 20 minutes on The Price is Right). Dyads shared the amount of time they spent per activity and on average, they spent 24 minutes on each activity (Table 6.8).

Table 6.8. Adherence data from telephone calls and analytics.

Average activities completed	18.65 (SD = 8.67, range = 6 – 38)	
Average time per activity	23.63 (SD = 15.66, range = 0 – 90)	
Number of unique visits to each activity	Word Search: 129	Sudoku: 71
	Odd one Out: 54	Globe Trotter: 51
	Trivia Quiz: 51	Spaceman: 49
	Food: 49	The Price is Right: 46
	Sayings: 42	Brainstorm: 41
	In Pairs: 40	Sounds: 29
	Useful Tips: 29	Past Events: 24
	iSpy: 23	Old Wives' Tales: 21
	Toys Are Us: 17	Arts: 15
	My Life: 15	Being Creative: 13
	Being Active: 10	

This is slightly less than the recommended 30 minutes. The data for 55 phone calls out of 220 is missing as researchers could not always make contact. Raw analytics

for unique visits to the iCST app was explored to determine activity choice and is shown in Table 6.8 (data was missing for two dyads). If an activity was done multiple times during the same visit to the iCST app on one day, this was counted only once. This was necessary to display the data for unique visits to activities. The most popular activities included Word Search and Sudoku which was also confirmed through the telephone calls. The discussion-based activities proved to be less popular, and Being Active and Being Creative were visited the least. As the time needed to complete an activity differed among participants, it may be more informative to look at the average weekly time spent on the iCST app. The recommendation was to spend 60-90 minutes per week on the app. According to the analytics for 18 dyads, only 11% of the dyads (n = 2) had a weekly average between 60 and 90 minutes on the app, 33% (n = 6) spent 40 to 60 minutes, another 33% (n = 6) spent 20 to 40 minutes, and 23% (n = 4) spent less than 20 minutes on the iCST app. This data was corrected for technical issues making the iCST app unavailable for a few days (see section 6.4.3.2. Issues related to the iCST app) and the withdrawal of a dyad halfway through the study.

Reasons for not being able to complete iCST app activities on any given week are shown in Table 6.9. Frequent reasons included: holidays or family commitments, time constraints, and ill health of either the person with dementia or carer.

Table 6.9. Reasons for not completing iCST app activities.

Reason	**Number of dyads**	**Total amount of weeks affected**
iCST app unavailable	10	14
Holidays or family commitments	8	10
Time constraints	8	10
Ill health person with dementia or carer	7	9
Other	3	4

One dyad reported doing substitute activities for the iCST app while on holidays which included dancing, and word search puzzle books. Furthermore, issues related to the app (see section 6.4.3.2. Issues related to the iCST app), negatively affected adherence to the app as well.

6.4.3.2. Issues related to the iCST app

There was one case where the iCST app could not be installed, due to incompatibility with the dyad's device. The device was an iPad mini with iOS version 9, which is one version below the minimum requirement for the iCST app to operate. The dyad was initially retained in the trial but later withdrawn due to family circumstances. The remainder of the installations were successful and dyads were able to access the iCST app.

Throughout the trial, the app stopped working for five consecutive days on Apple devices only, during which dyads were unable to complete any activities. The issue was related to the licence expiration of the app we had used to trial the iCST app with. This was resolved by the software company by renewing the licence and hereafter, all unblinded researchers made an additional phone call to ensure all participants were successfully able to access the app again. No other failures of the iCST app were reported that prevented participants from using the app.

6.4.3.3. Acceptability of the iCST app

In addition to data on adherence, the acceptability of the iCST app was further assessed by investigating comments made by participants during the weekly telephone calls, the post-trial interviews, and results on the usability and acceptability questionnaire.

Weekly telephone calls and post-trial interviews

All dyads were contacted for weekly telephone calls and, of these, three dyads agreed to take part in a post-trial interview to provide more in-depth feedback on their experiences of using the iCST app during the study.

Content

Dyads reported diverse experiences of using the iCST app throughout the 11 weeks of the trial. Most dyads found the app to be engaging and fun. In general, the majority of the content was deemed appropriate. Depending on individual interests, most popular activities included: Word Search, Sudoku, Globe Trotter, Spaceman, In Pairs, the Price is Right, and the Trivia Quiz. Dyads found that Globe Trotter often led to pleasant conversations about holidays, and Word Search and Sudoku were enjoyable due to familiarity:

A lot of the places we'd been to. So that was nice to sort of talk about that then when we'd been there. – Carer, Interview 1.

There was a consensus about the need for more content as dyads would make their way through the app relatively quickly and did some activities multiple times leading to repetition of the content. In addition, not all activities were relevant depending on individual interests and one person with dementia from a black and minority ethnic background would like to see more culturally relevant content. For people with very mild dementia and who were reported to be high functioning, the app was often too easy and lacked challenge. Some activities such as Being Creative and other discussion-focused activities were therefore considered to be less appropriate. In addition, some carers found the discussion activities difficult to lead as they reported that the person they were caring for had never been very talkative or there were some difficulties due to the dementia e.g. low concentration:

I don't like talking. – Person with dementia, Interview 1.

Other dyads very much enjoyed the discussion activities such as My Life and Past Events as these led to long conversations between the pair. Similarly, even though Being Active was one of the least popular activities, a few dyads were happy to see it included and valued the effects of physical exercise, with one dyad using the activity as an inspiration to go dancing. Lastly, one person with dementia felt it was important to engage in a variety of activities despite not liking some of them:

Sometimes it (the app) has to have the ones that you don't actually like to see if that actually challenges you to do it. – Person with dementia, Interview 1.

Design

People were positive about the design of the app:

I think it is very well presented. – Person with dementia, Interview 2.

One carer found the navigation to be difficult while the majority found the app easy to use after getting used to it:

It was quite quick you know, precise once you clicked on welcome, which activities to choose. In that respect, that was good. – Carer, Interview 1.

As in the qualitative study with the iCST app prototype v2.0, there was no consensus on the use of colours and some people with dementia mentioned they did not find the colour scheme as important as other features of the app. Text and images were deemed appropriate with one carer suggesting to change the logo to make it more relevant to the purpose of the app and improve association.

Potential benefits

One carer clearly reflected on the need for the iCST app and went on to say she found it very useful as it made cognitive stimulation more accessible:

I think if these people had got the access to cognitive stimulation … I think there is a huge amount of potential life enjoyment being wasted, being lost, because people haven't got that stimulation. – Carer, Interview 2.

Dyads often reported enjoyment and spending time together while using the app, and mentioned they were looking forward to purchasing the app after the study:

It certainly uplifted me (…) Not only could I do this but it was actually pleasant to do this together. – Person with dementia, Interview 2.

The app was also used in different contexts with one dyad taking the tablet with them on holidays and while travelling on the train, and other dyads using the app with their grandchildren or independently at times:

Yeah together both of us were doing it. So the children were in the pool playing and we were on the sunbeds doing this (the iCST app). – Carer, Interview 3.

Other observed benefits for the person with dementia included increased concentration and memory (e.g. through remembering news headlines), and being able to engage in deeper conversations which was reported by two dyads:

Yeah it does make me think. Definitely. It makes me think yeah. – Person with dementia, Interview 3.

In addition, some carers noticed an increased confidence in the person they were caring for related to their own abilities or willingness to try new things (e.g. looking at older academic books, taking up maths tuition, becoming aware of their language skills):

I've seen an awakening in (…), it's like he has come to life, cognitive-wise and interested. Realising he can do things he struggled with. – Carer, Interview 2.

The iCST app was seen as a gateway into other things. Increased confidence in using technology was reported for both carers and people with dementia:

Sometimes you got to have confidence to use these things. And I haven't always had that, have I? I'm getting a bit better now aren't I? – Person with dementia, Interview 3.

I thought it was really good (…) I think it was a big step forward for (…). Because (…) she would not have picked this up off the table. – Carer, Interview 3.

Some benefits of the iCST app compared to paper-based iCST included its accessibility, speed, and modern feel.

Improvements and updates to the iCST app

There was a consensus on the need for more tailored content depending on the individual's interests. In addition, some dyads commented that there was a need for another, more intermediate level to better accommodate the different levels of abilities. Most dyads were keen on keeping track of exact progress within and across activities in terms of time. For some activities, there was a need for more guidance and clarity in some questions (e.g. Past Events, iSpy) and more feedback on exact correct and incorrect answers as the app was deemed to be a bit ambiguous (e.g. Food and Odd One Out) which could lead to frustration.

Regarding the lay-out and when choosing a new activity, some dyads would like to see a list of activities on the screen rather than swiping through three activities at a time. There was another suggestion to make switching between levels and activities more straightforward. Lastly, a few bugs needed to be resolved e.g. missing map from Globe Trotter, low volume of the musical instruments in Sounds.

Other minor technical difficulties were reported which were often related to slow connection or need for a software update on the tablet.

Usability and acceptability questionnaire

Results from the usability and acceptability questionnaire are shown in Table 6.10. The iCST app was rated particularly well on several aspects including learnability to use the app, being able to use it in different contexts, and the font/button sizes. Both people with dementia and carers felt confident about their ability to use the app and found the instructions to be easy. However, both groups gave their lowest rating to willingness to use the app frequently and people with dementia in particular gave a lower rating to the app's usefulness. Overall, the iCST app was rated better by carers than people with dementia on every aspect of the questionnaire, which reflects some of the findings from the telephone calls and post-trial interviews.

Table 6.10. Results from the usability and acceptability questionnaire.

Questionnaire item[1]	People with dementia (n = 16)	Carer (n = 18)
	% agree or strongly agree	% agree or strongly agree
1. I think most people could learn very quickly how to use Thinkability.	81	89
2. I felt confident about my ability to use Thinkability.	81	100
3. Overall, I knew what to do at all times.	69	94
4. Once I had learned to use Thinkability, I could perform tasks quickly.	63	94
5. Thinkability can be used anywhere and in any context.	81	94

Table 6.10 continued

6. The instructions in Thinkability are easy.	75	94
7. The font and button sizes are sufficient for me.	69	100
8. I would like to use Thinkability frequently.	50	56
9. Overall, I think Thinkability is very useful to me.	26	61
10. Overall, I think Thinkability is easy to use.	63	95

[1]Responses include: strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, strongly disagree.

6.4.4. Outcome data

6.4.4.1. Acceptability of outcome measures

The acceptability of the outcome measures was assessed through investigating the number of completed questionnaires and the number of questionnaires with missing data (Tables 6.11 and 6.12). Some participants did report that the assessments were lengthy and found the QCPR and CUSE in particular to be confusing due to the wording of some of the questions. However, the majority of participants did not report any difficulties. The CUSE was often not completed if the participant did not have any or little experience with using technology. This led to substantial missing data on the CUSE for both people with dementia (n = 31) and carers (n = 16), and the CUSE was therefore excluded from the tables. Furthermore, the CSDD included considerable missing data as it included items that participants were 'unable to evaluate'. Completion rates did not seem to differ greatly between FU1 and FU2 for both people with dementia and carers.

Table 6.11. People with dementia completion rates of assessments and amount of missing data on questionnaires.

	Baseline	FU1	FU2
Total assessments completed in full	30	35	32
Total assessments missing in full	0	3	3
Assessments with missing data	13	5	8
ADAS-Cog	4	2	3
QoL-AD	3	3	4
CSDD	9	3	2
EQ-5D	0	2	1
QCPR	1	2	1
QoL-AD [P]	5	4	5
CSDD [P]	6	7	7
BADLS [P]	0	0	0
NPI total [P]	1	0	0

Table 6.12. Carer completion rates of assessments and amount of missing data on questionnaires.

	Baseline	FU1	FU2
Total assessments completed in full	42	39	40
Total assessments missing in full	0	3	3
Assessments with missing data	1	1	0
EQ-5D	0	1	0
HADS – Anxiety	0	0	0
HADS – Depression	1	0	0
QCPR	0	0	0

6.4.4.2. Outcome scores

Following the application of data imputation, Tables 6.13 and 6.14 show the unadjusted mean scores and standard deviations of people with dementia and carers. The CUSE contained considerable missing data, mainly for people with dementia with roughly equal amount of missing data in both treatment groups. However, for people with dementia, the 12 participants in the experimental group scored higher (M = 125.33, SD = 31.41) than the 14 participants in the control group (M = 106.57, SD = 32.99). An independent samples t-test did not show any significant differences between the two groups (t(24) = -4.78, p = .153, two-tailed). On average, the scores of people with dementia were lower than the scores of carers. For carers, only two CUSE questionnaires were missing in full and the scores between the two treatment groups did not seem to differ greatly (M = 131.70, SD = 25.73 for the experimental group, M = 130.38, SD = 34.13 for the control group).

Regarding the other baseline outcome measures for people with dementia, the ADAS-Cog was missing for four participants and the NPI was missing for one participant. At FU1, the ADAS-Cog, QoL-AD, CSDD, EQ-5D, QCPR were missing for four participants, and the proxy-rated Qol-AD, CSDD, BADLS, and NPI were missing for three participants. At FU2, the ADAS-Cog, EQ-5D, QCPR were missing for four participants, and the QoL-AD, CSDD, proxy-rated QoL-AD, CSDD, BADLS, and NPI were missing for three participants.

For carers, no outcome measures were missing at baseline. At FU1, the EQ-5D was missing for one participant, and the HADS and QCPR were missing for three participants. Lastly, at FU2, the EQ-5D, HADS and QCPR were missing for three participants.

Table 6.13. Unadjusted means for outcome measures for people with dementia in the iCST app and TAU control group. *CI = confidence interval, [P] = proxy rated measure.*

	Baseline		FU1			FU2		
Outcome measure	iCST n = 21 Mean (SD)	TAU n = 22 Mean (SD)	iCST n = 19 Mean (SD)	TAU n = 21 Mean (SD)	Difference CI (95%)	iCST n = 19 Mean (SD)	TAU n = 21 Mean (SD)	Difference CI (95%)
ADAS-Cog	16.26 (7.48)	19.55 (9.40)	15.05 (7.56)	19.85 (10.09)	-1.01 to 10.61	15.74 (8.45)	18.30 (11.55)	-4.03 to 9.16
QoL-AD	37.67 (5.73)	39.18 (7.18)	37.53 (5.15)	35.65 (10.68)	-7.36 to 3.61	37.47 (7.31)	37.19 (6.11)	-4.58 to 4.02
CSDD	4.71 (5.76)	4.23 (4.20)	4.44 (4.57)	4.48 (3.44)	-2.57 to 2.63	5.11 (6.05)	4.52 (5.48)	-4.27 to 3.11)
EQ-5D	76.76 (21.82)	82.64 (16.03)	79.16 (14.39)	79.10 (19.83)	-11.35 to 11.24	80.26 (17.05)	81.90 (14.88)	-8.73 to 12.00
QCPR	56.52 (6.28)	59.18 (7.02)	57.68 (4.88)	59.70 (6.70)	-1.80 to 5.83	58.11 (7.84)	59.38 (6.37)	-3.34 to 5.88
QoL-AD [P]	34.95 (5.35)	34.36 (5.87)	35.26 (5.03)	35.24 (4.70)	-3.14 to 3.09	35.21 (7.01)	34.10 (5.34)	-5.08 to 2.85
CSDD [P]	5.19 (4.34)	5.95 (5.12)	3.89 (2.98)	3.86 (2.78)	-1.88 to 1.81	4.68 (5.24)	4.76 (3.56)	-2.77 to 2.92
BADLS [P]	9.57 (7.73)	8.73 (5.91)	9.11 (7.40)	8.81 (6.27)	-4.67 to 4.08	9.05 (8.09)	9.71 (6.84)	-4.12 to 5.44
NPI total [P]	14.35 (12.84)	12.00 (14.77)	12.26 (12.71)	11.38 (14.52)	-9.66 to 7.89	9.05 (16.27)	9.57 (9.26)	-7.85 to 8.89

Table 6.14. Unadjusted means for outcome measures for carers in the iCST app and TAU control group. *CI = confidence interval.*

	Baseline		**FU1**			**FU2**		
Outcome measure	iCST n = 21 Mean (SD)	TAU n = 22 Mean (SD)	iCST n = 19 Mean (SD)	TAU n = 21 Mean (SD)	Difference CI (95%)	iCST n = 19 Mean (SD)	TAU n = 21 Mean (SD)	Difference CI (95%)
EQ-5D	83.62 (17.36)	86.77 (13.63)	89.79 (7.74)	86.85 (13.99)	-10.33 to 4.45	88.74 (11.66)	83.19 (12.21)	-13.21 to 2.11
HADS – Anxiety	4.95 (4.48)	4.36 (3.62)	5.00 (4.42)	4.48 (4.05)	-3.23 to 2.19	4.95 (4.81)	5.33 (4.52)	-2.60 to 3.37
HADS - Depression	3.14 (3.01)	2.86 (3.50)	2.53 (3.41)	2.71 (3.74)	-2.11 to 2.49	2.42 (3.00)	5.33 (4.52)	-1.65 to 2.14
QCPR	56.38 (8.08)	57.27 (5.87)	54.79 (10.60)	58.67 (6.50)	-1.69 to 9.44	57.63 (7.66)	59.05 (6.55)	-3.13 to 5.96

Tables 6.15, 6.16, 6.17 and 6.18 show the results of the ANCOVA tests at FU1 and FU2 for people with dementia and carers which include the group means for the iCST app and TAU control group, the mean differences, 95% confidence intervals, effect sizes, and p-values after adjusting for baseline outcomes.

For the person with dementia, the analysis at FU1 and FU2 did not show any significant differences between the iCST app and TAU control group on any of the outcome measures. The estimated, adjusted mean on the QoL-AD at FU1 was marginally higher for participants in the iCST app group (MD = 2.66, SMD = .41) which could be a sign of improvement on this measure. However, this difference was smaller at FU2 (MD = 1.32, SMD = .20). In addition, the estimated, adjusted mean on the BADLS at FU2 was slightly better for participants in the iCST app group compared to the TAU control group (MD = -1.30, SMD = .19) which could potentially be a sign of increased independence while performing activities of daily living. Mean differences on the remainder of the measures were small.

For the carers, analysis showed a significant difference at the 5% level on the EQ-5D at FU2 between the iCST app and TAU control group with a higher estimated, adjusted mean for people in the iCST app group (MD = 6.34, 95% CI = .92 – 11.76, SMD = .41, p = .02). This is potentially indicative of the effectiveness of the iCST app on the QoL of carers, however, considering the small sample size and therefore large confidence interval, these results should be considered with caution. Furthermore, performing multiple statistical tests and comparisons, as in this study, may have increased the likelihood of randomly detecting a significant difference. Having had a slightly lower mean QCPR at baseline, the TAU control group displayed a higher estimated, adjusted mean on the QCPR than the iCST app group at FU1 (MD = -3.02, SMD = .43) and FU2 (MD = -1.62, SMD = .23).

Table 6.15. Adjusted means for outcome measures for people with dementia in the iCST app and TAU control group at FU1. *MD = mean difference, CI = confidence interval, SMD = standardised mean difference*, *[P] = proxy rated measure.*

FU1	iCST app	TAU	MD	Difference CI (95%)	Effect size (SMD)	p value
ADAS-Cog	17.55	17.75	-.20	-2.85 to 2.44	.02	.878
QoL-AD	37.93	35.27	2.66	-1.87 to 7.18	.41	.241
CSDD	4.45	4.55	-.10	-1.65 to 1.45	.02	.896
EQ-5D	80.57	77.76	2.81	-6.70 to 12.32	.02	.553
QCPR	58.47	58.95	-.48	-3.37 to 2.42	.07	.741
QoL-AD [P]	35.09	35.39	-.30	-2.54 to 1.95	.05	.790
CSDD [P]	3.99	3.77	.22	-1.33 to 1.75	.05	.781
BADLS [P]	8.93	8.97	-.04	-2.45 to 2.36	.01	.970
NPI total [P]	11.45	12.12	-.67	-6.40 to 5.07	.05	.815

Table 6.16. Adjusted means for outcome measures for carers in the iCST app and TAU control group at FU1. *MD = mean difference, CI = confidence interval, SMD = standardised mean difference*.

FU1	iCST app	TAU	MD	Difference CI (95%)	Effect size (SMD)	p value
EQ-5D	90.20	86.46	3.74	-2.19 to 9.66	.24	.209
HADS-Anxiety	4.72	4.73	-.01	-1.70 to 1.70	.00	.998
HADS-Depression	2.33	2.89	-.56	-1.81 to .69	.17	.372
QCPR	55.24	58.26	-3.02	-7.06 to 1.02	.43	.138

Table 6.17. Adjusted means for outcome measures for people with dementia in the iCST app and TAU control group at FU2. *MD = mean difference, CI = confidence interval, SMD = standardised mean difference*, *[P] = proxy rated measure.*

FU2	iCST app	TAU	MD	Difference CI (95%)	Effect size (SMD)	p value
ADAS-Cog	17.73	17.14	.59	-2.45 to 3.64	.07	.694
QoL-AD	38.02	36.70	1.32	-1.19 to 3.83	.20	.293
CSDD	4.66	4.93	-.27	-2.22 to 1.68	.05	.781
EQ-5D	81.13	81.08	.05	-9.48 to 9.59	.00	.991
QCPR	58.83	58.76	.07	-3.64 to 3.77	.01	.970
QoL-AD [P]	34.77	34.49	.28	-2.78 to 3.35	.05	.852
CSDD [P]	5.00	4.48	.52	-1.87 to 2.91	.11	.663
BADLS [P]	8.72	10.02	-1.30	-3.61 to 1.01	.19	.262
NPI total [P]	8.94	9.68	-.74	-6.64 to 5.16	.05	.801

Table 6.18. Adjusted means for outcome measures for carers in the iCST app and TAU control group at FU2. *MD = mean difference, CI = confidence interval, SMD = standardised mean difference*, **Significant at 5% level.*

FU2	iCST app	TAU	MD	Difference CI (95%)	Effect size (SMD)	p value
EQ-5D*	89.15	82.81	6.34	.92 to 11.76	.41	.020
HADS-Anxiety	4.76	5.51	-.75	-2.70 to 1.20	.18	.440
HADS-Depression	2.42	2.67	-.24	-1.33 to .84	.07	.655
QCPR	57.53	59.14	-1.62	-4.89 to 1.66	.23	.323

The remainder of the outcomes at FU1 and FU2 did not show any significant differences between the iCST app and the TAU control group.

6.4.5. Adverse events

One SAE, which occurred in the control group, was reported to the CI. The SAE included a hospitalisation of a person with dementia due to a broken hip, and was unrelated to the study. Two other AEs were reported to the CI, both of which occurred in the experimental group. This led to the withdrawal of both dyads. One dyad was withdrawn due to a death in the family. The other dyad was withdrawn due to a study related issue. For this dyad, completing the questionnaires at FU1 in a room apart from the carer, had led to some distress for the person with dementia later in the day. In order to prevent this from occurring again and after discussing this with the carer, the research team decided to withdraw the dyad from the study.

6.5. Discussion

This study set out to evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a TAU control group, and to assist the development of a protocol for a full-scale trial. A range of data was collected on relevant study-related aspects of a potential full-scale RCT including the study process, and the feasibility and acceptability of the iCST app. Data collection was supported by a mixed methods approach where quantitative data from questionnaires and analytics was complemented by qualitative data from telephone calls and interviews with people with dementia and carers.

6.5.1. Study findings

The study was designed as a randomised feasibility trial in order to be better informed about its appropriateness for a larger-scale study in terms of screening, recruitment, randomisation, retention, feasibility and acceptability of the iCST app, and choice of outcome measures.

6.5.1.1. Screening, recruitment, randomisation, and retention rates

In terms of recruitment, a total of 43 dyads out of the original target of 60 were recruited by four study sites in a timeframe of five to six months. This equals to roughly one to two dyads per week who met the inclusion criteria. Referrals most often came from dementia support groups or the study site's own research database. The Alzheimer's Society was initially involved through a partnership but unfortunately, this did not lead to any recruits. For a proportion of the referrals, the reason for exclusion was often unknown which will need to be better monitored in a future study. RDOs communicated that the technology-related inclusion criteria were the biggest challenge in recruitment. For instance, some participants did not have a compatible touch-screen tablet for accessing the iCST app despite having access to technology. Or participants did not have access to internet which further limited their participation in the study. Our original recruitment target was not met however, a previous review found this to be a common issue among trials. McDonald et al. (2006) found that out of 114 multi-site trials only 31% were able to achieve their original recruitment target, listing factors that may influence recruitment rates such as delays in the start of recruitment and overall slow recruitment due to ineligible participants. Furthermore, the involvement of a study partner, in this case a carer, may have led to an additional barrier towards recruitment as study participation then relies on the willingness of both the person with dementia and the carer (Bartlett, Milne, & Croucher, 2019). Also, there may be some concerns from either the person with dementia or carer about burdening

their study partner with participation in a study. Some strategies to improve recruitment for a future study include more regular visits or phone calls to recruiting sites, advertisements in newspapers or on the radio, and modifying the inclusion criteria (e.g. compatibility of the iCST app with more devices) (McDonald et al., 2006).

The chosen method for randomisation (block randomisation) was appropriate for the study as this led to equal group sizes. Sealed Envelope also worked well for the purpose of randomisation. Lastly, allocation outcome was also acceptable to participants as there were no drop-outs as consequence of having been randomised to either of the two groups. The attrition rate in general was low for the study as only two dyads out of 43 dropped out of the study (attrition rate of 4.7.%). Both dyads were in the experimental group however, reasons for drop out were unrelated to the intervention.

6.5.1.2. Feasibility and acceptability of the iCST app

Adherence was monitored through weekly telephone calls with dyads and through anonymous analytics. There seemed to be some discrepancies between these two types of data. Although 40% of the dyads reported being able to complete two or more activities per week which would amount to more than 60 minutes spent on the app per week, analytics showed that only 11% spent 60 to 90 minutes on the iCST app. This means that the previous benchmark set to determine the feasibility of the iCST app (>75% of dyads completing two or more activities per week) has not been met. It is important to note that completion times most likely differed across dyads e.g. one dyad may complete Past Events in 30 minutes while another participant may only take 10 minutes. Therefore, time spent on the iCST app may be a better indicator for the feasibility of the iCST app than the amount of activities

completed, and can also be used to inform the recommended dose in future research. Telephone calls were also helpful in monitoring any challenges with using the iCST app and reasons for not completing activities. Challenges related to low levels of adherence were also reported in previous iCST research where less than half of the participants (40%) in the iCST group completed at least two activities per week and a smaller proportion (22%) did not complete any activities (Orrell et al., 2017). However, as this included participant reported data, actual levels of adherence may have been lower. This study aimed to remedy this by verifying the telephone data through analytics and therefore tracking the time spent on the iCST app. In the previous iCST study, reasons for low adherence included difficulties with fitting iCST in the daily routine due to a lack of time and also difficulties with engaging the person with dementia in the activities due to for instance poor health or the activities being too easy (Orrell et al., 2017). This is similar to findings from this study where low adherence to the app was most often detected among people with very mild dementia and who reported to be high functioning. These participants often found the content too easy and would spend less time on the app as they completed the activities relatively quickly. More tailored and appropriate content for its users may perhaps increase adherence to the iCST app. Other reasons for not being able to use the iCST app included technical difficulties with the app or family/holiday commitments.

In terms of usability and acceptability, carers rated the iCST app better than people with dementia. Despite giving a positive rating to its usability and most notably its design, roughly half of the people with dementia and carers were less willing to use it frequently and people with dementia gave a low rating to the usefulness of the app. Usefulness of the iCST app may have been comprised by the lack of

relevance and range of the activities for some people with dementia. Carers judged the app to be more useful than people with dementia.

6.5.1.3. Appropriateness of outcome measures

The majority of the outcome measures were acceptable to most participants however, some participants found the assessments too lengthy which at times led to fatigue. The CSDD may not be appropriate for assessing symptoms of depression as participants found some areas difficult to evaluate leading to less meaningful data. This is also the case for the CUSE which was included to investigate any differences between computer user self-efficacy between the two groups. Given the length of the assessments and that data on both the CUSE and CSDD was often missing, a future study could potentially reduce the amount of outcome measures or modify the current selection. As this study did not find any differences in computer user self-efficacy between the experimental and TAU control group and the lack of suitable questionnaires in this area for older people with cognitive impairments, it may be advisable to omit such a questionnaire entirely. The Geriatric Depression Scale-15 (GDS-15), which has been used in the previous large-scale iCST study, may be another suitable questionnaire to measure depression among people with dementia rather than the CSDD (Moniz-Cook et al., 2008).

6.5.1.4. Outcome data

Considering the small sample size of the study and therefore lack of statistical power to detect effectiveness, no definite conclusions can be drawn from the results of the outcome measures which should be interpreted with caution. However, potential signs of improvements can be identified which can be relevant for future research.

For people with dementia, there were no significant differences on any of the outcome measures between the iCST app and TAU control group. Considering the small to medium effect size for QoL (Qol-AD) at FU1, there may be a relationship between improvements in QoL and use of the iCST app which is an encouraging finding in relation to a full-scale trial. Previous iCST research did not find any significant effects for the person with dementia in terms of cognition or QoL. However, people with dementia receiving iCST rated their relationship with their carer more positively than participants in the TAU control group (Orrell et al., 2017). We did not find such an effect in this study which may partly be explained by the differing lengths of the interventions. Paper-based iCST runs for 26 weeks compared to the iCST app which includes activities for 11 weeks leading to less time spent together on the app before the final assessment took place. In terms of computerised cognitive stimulation, there are few feasibility or large-scale trials that have investigated such interventions for people with dementia (Garcia-Casal et al., 2017). A small pilot study found benefits on the cognition and QoL of people with dementia if a computerised cognitive stimulation programme was combined with a paper-based, group cognitive stimulation programme (Tarraga et al., 2006). In addition, Astell, Smith, Potter, and Preston-Jones (2018) conducted a study using a within-participants design in which they investigated the effectiveness of a group-based, computerised reminiscence and conversation tool (CIRCA). Similar to the findings of previous CST research (Spector et al., 2003), results from Astell et al. (2018) showed significant improvements in the cognition and QoL of people with dementia following the intervention. This potentially suggests that elements such as a group setting or a structured approach towards delivery may be essential in obtaining such benefits on cognition and QoL.

For the carer, a significant difference with a small to medium effect size in favour of participants in the iCST app group was found for QoL (EQ-5D). This is in accordance with results from the previous iCST study which also found significant improvements for the carer's QoL on the same outcome measure. This suggests that a carer-led cognitive stimulation programme may be helpful to the carer him/herself. However, the possibility of a type I error needs to be considered as well as the small sample size and large number of tests of probability which may have generated a spurious result. There were no significant differences on any of the other outcome measures.

In the post-trial interviews, two dyads mentioned that the iCST app had helped the person with dementia to feel more confident in their cognitive abilities and their abilities to use technology. For one dyad, this increase in confidence subsequently led the person with dementia to engage with other cognitive activities which he had previously not done. A systematic review by Tyack and Camic (2017) found similar findings whereby mastery of a touch-screen intervention for people with dementia led to increased confidence in own abilities, feelings of empowerment, and pride.

Both quantitative and qualitative findings suggest that the iCST app may be as effective as paper-based iCST especially considering the potential benefits for the QoL of carers, and feelings of confidence and empowerment for some people with dementia. Though this does not fully support the hypothesis of the iCST app leading to better outcomes than paper-based iCST, these findings do confirm that the iCST app may have certain advantages over paper-based iCST. For instance, the iCST app allows for improved monitoring of adherence, and a broader scope for updates and new activities. In addition, interactive, touch-screen technology may be better placed to promote engagement as all participants in the iCST app

group actively completed a proportion of the activities whereas, for paper-based iCST, the RCT found that 22% of the participating dyads did not complete any activities (Orrell et al., 2017). The content of the iCST app offered on a novel platform may therefore make it more appealing than paper-based iCST.

6.5.2. Strengths and limitations

A strength of this study was that it allowed for the comprehensive investigation of multiple aspects related to the study process and the intervention to better prepare for a full-scale trial. In addition, the combination of different types of data from multiple sources supported data triangulation and helped to increase the validity of the data. For instance, data from telephone calls was supported both by analytics and post-trial interviews. The addition of analytics in particular provided valuable insights in the adherence to the iCST app. Furthermore, this study had a relatively low attrition rate leading to minimal data loss. Lastly, the inclusion of the CRN for study delivery support proved to be integral.

In terms of limitations, the sample was mainly made up of white British participants which led to the underrepresentation of other minority ethnic groups in the study. The iCST app was only compatible with certain touch-screen tablets and software versions which provided an additional challenge to recruitment for all study sites. In addition, the relatively low adherence to the iCST app and variance in its use were limitations of the study. Technical difficulties also impacted adherence negatively. This may be remedied by offering the iCST app in a more standardised manner and providing more guidance within the app on its use. My role as an unblinded researcher in setting up and undertaking the randomisation procedure, and conducting the post-trial interviews may have led to a degree of bias in the obtained results. The interviews included a small sample of dyads who only had a

positive experience with using the app. This led to a lack of insights from dyads who found the app to be less useful. Lastly, another limitation was the lack of frequent data monitoring which led to some missing data on outcome measures as these had been completed incorrectly.

6.5.3. Recommendations for a full-scale RCT

Based on the findings from the current study, it is recommended to conduct a full-scale trial with the iCST app but with the necessary modifications. Table 6.19 includes the Acceptance Checklist for Clinical Effectiveness Pilot Trials (ACCEPT) which consists of several trial components ranging from trial design and interventions to randomisation and data procedures (Charlesworth, Burnell, Hoe, Orrell, & Russell, 2013). The table also includes how the various trial components have been monitored in this study and what the outcomes are in terms of recommendations for a full-scale RCT. ACCEPT has been developed to assess whether data from pilot studies can be pooled with data from a main trial however, for this study, it has been used to determine which components of the trial will need amendments prior to conducting a full-scale RCT and how this can be achieved. It is recommended to make amendments to the majority of the trial components including: sample, intervention, participants, blinding, data, research governance, data analysis and trial management. The design, consent procedures, randomisation process, and Health & Safety regulations were deemed appropriate.

As the iCST app was used with a high level of flexibility, this may have led to the lack of any potential signs of effectiveness for people with dementia. In order to better understand the impact of the iCST app in terms of effectiveness, it may need to be offered using a more structured approach. For instance, the iCST app could

Table 6.19. ACCEPT for a full-scale RCT with the iCST app (Charlesworth et al., 2013).

Component of trial		**Monitoring methods**	**Amend?**	**Outcomes**
Trial design		Reviewed suitability of and adherence to research protocol.	No	Trial design and related components are appropriate.
Sample size		Tested assumptions within protocol on: number of sites; recruitment rates; retention rates; & SD of primary outcomes.	Yes	Revision necessary in terms of sample size calculation; recruiting capacity; trial period; & funding.
Interventions	Clinical governance	Assessed compliance with formal training in intervention through contact with local PIs.	Yes	Enhance formal training and supervision of local researchers and/or research nurses at each site e.g. by additional training visits and/or catch-ups.
	Intervention fidelity	Measured & assessed adherence to intervention through weekly telephone calls and analytics.	Yes	Enhance supervision of intervention using identifiable analytics. Extend the iCST app with more relevant activities and provide more guidance in its use e.g. through the involvement of a formal carer.
Participants	Recruitment strategy	Assessed participant flow per recruitment source.	Yes	Refine recruitment strategy e.g. by promoting engagement within recruitment sources (e.g. memory clinics) and include other sources such as the Alzheimer's Society.
	Eligibility criteria	Assessed reasons for ineligible participants and any barriers to recruitment.	Yes	Refine eligibility criteria e.g. by making the iCST app compatible with a maximum number of devices.

Table 6.19 continued

Consent procedures	Participant information sheets (PIS)	Monitored PIS distribution and emergence of questions related to the PIS through contact with PIs at local site.	No	PIS are appropriate.
	Taking informed consent	Monitored consent documentation and appropriateness of forms through contact with PIs at local site.	No	Consent process and accompanying forms are appropriate.
Randomisation process		Checked randomisation procedures including use of Sealed Envelope, randomisation sequences and accessibility by researchers.	No	Randomisation procedure & training of research team are appropriate.
Blinding		Checked occurrences of unblinding by participants and whether unblinded researchers can keep other researchers blind.	Yes	Extend blinding procedures, e.g. by checking whether blinded assessors can predict individual allocations.
Data	Data collection	Assessed adherence to assessments and weekly telephone calls/questionnaires.	Yes	Refine schedules to reduce assessment burden and modify outcome measure selection. Enhance training of research team data collection tools such as outcome measures to minimise errors and missing data.

Table 6.19 continued

Data	Data quality	Tested missing data procedures listed within the analysis plan.	Yes	Refine missing data procedures in case of assessments missing in full e.g. through statistical analyses.
	Data management	Tested suitability of trial database, storage of data, related procedures & software.	Yes	Refine trial database & data monitoring procedures considering the amount of data in larger trial.
Research Governance	Research protocol adherence	Tested adherence to research protocol as widely as possible through regular contact with local PIs.	Yes	Enable quality assurance officer (QAO) to test adherence as widely as possible. Refine protocol to enhance quality assurance plan & training of team.
	Adverse events (AE)	Assessed occurrences and severity of AEs, and reporting procedures.	Yes	Refine AE reporting & assessment procedures through the addition of a QAO.
	Health & Safety (H&S)	Monitored H&S procedures, e.g. during installation and assessment visits.	No	Refinement to H&S procedures not necessary.
Data analysis		Tested an analysis plan on the obtained data.	Yes	Refine analysis plan to address research aims in full in terms of effectiveness on outcomes.
Trial management		Reviewed role descriptions of research team including at local sites.	Yes	Extension of research team will be necessary through a Trial Steering Committee and a Data Monitoring Committee. Refine roles e.g. depending on workloads.

be offered by a formal carer as part of the care routine which has now been done with paper-based iCST (Gibbor et al., 2020). In addition, participants in a future study could be given more guidance on its use to promote a more standardised approach to the app. This would need to be supported with more sophisticated adherence measures such as the use of analytics which can be linked to the individual user in combination with regular telephone calls. By standardising the 'dose' across the participants, a future study may provide different study findings. As some participants in this study completed the iCST app quicker than anticipated, extending the iCST app with more content would allow them to spend more time on it and may also provide different results.

6.6. Conclusion

This study gave insights in the feasibility of conducting a full-scale RCT with the iCST app compared to a TAU control group. In terms of the study process, recruitment proved to be challenging due to a lack of eligible participants, randomisation measures were adequate, attrition was low throughout the study, and some inadequate outcome measures were identified for which alternatives were found. In terms of the intervention, adherence to the iCST app and variability in its use were additional challenges. Participants largely judged the iCST app to be usable and most found it enjoyable. Lastly, despite the lack of signs of effectiveness on any of the outcome measures for people with dementia, there are some promising findings in terms of benefits for the QoL of carers following use of the iCST app. Based on the findings, it is recommended to conduct a full-scale RCT with the necessary modifications which include an increase in capacity to better support a larger sample size, recruitment and study monitoring, a more structured and guided approach towards offering the iCST app supported by

adherence monitoring, an extension to the iCST app in terms of content, and an increase in device compatibility to ensure the iCST app can be accessed on more touch-screen tablets or other devices. These modifications will help to create a more suitable version of the intervention and will strengthen the design of a full-scale RCT to better understand the effectiveness and impact of the iCST app.

Chapter 7 – Investigating the feasibility of implementing the individual Cognitive Stimulation Therapy application (iCST app) in Indonesia

This chapter was based on a journal article: Rai, H. K., Prasetya, V. G. H., Sani, T. P., Theresia, I., Tumbelaka, P., Turana, Y., Schneider, J., & Orrell, M. Exploring the feasibility of an individual Cognitive Stimulation Therapy (iCST) application and related technology for use by people with dementia and carers in Indonesia. *Dementia* (under review).

7.1. Introduction

More than two-thirds of people with dementia live in low and middle income countries (LMIC). One of the largest increases in the number of people with dementia is expected to take place in the Asia Pacific region with Indonesia ranking fourth after China, India, and Japan (Alzheimer's Disease International, 2014). For Indonesia, the number of people with dementia is expected to increase fourfold from 1.2 million in 2015 to almost 4 million in 2050 (Prince et al., 2015). Moreover, there is little information on the current health and social care services provision for people with dementia. Psychosocial interventions may be particularly useful because the costs of anti-dementia drugs are relatively high making them hard to access for many people, added to which they are unsuitable for some people with dementia due to side effects (Prince et al., 2016).

Cognitive Stimulation Therapy (CST) has been translated to Bahasa Indonesia and is offered at several day centres in Jakarta, but it has yet to be a routinely, accessible programme. A pilot study among people with dementia in Indonesian

nursing homes suggested possible cognitive improvements after attending CST groups. However, the numbers were small (N = 5) and more research is warranted (Komalasari, 2014). Individual CST (iCST) has not been culturally adapted yet and is therefore not available in Indonesia.

The iCST application (iCST app) seems to be a promising approach for people with dementia in Indonesia as it aims to improve accessibility to the intervention for people unable to access CST groups. In addition, as most people with dementia in Indonesia live among their family, the involvement of a carer in the iCST app may encourage intergenerational activities. The population of internet users in Indonesia is expected to boom in the next five years, reaching a penetration rate of 53%, meaning that technology will play an increasingly important part in the daily lives of the residents (Das, Gryseels, Sudhir, & Tan, 2016). However, not much is known about the application of technology in the health industry, compared to more developed countries - particularly in the care of people with dementia.

Considering the existing use of CST in Indonesia and the expected technology boom, there is a need to investigate the potential for adapting and implementing the iCST app and related technology in Indonesia. By exploring the willingness of people with dementia and carers to adopt technology, steps towards offering technology-based interventions such as the iCST app can be made in order to combat the lack of resources for the care of people with dementia in Indonesia and perhaps other LMIC.

7.2. Aims and hypothesis

The aims of this study were to explore the attitudes of people with dementia, carers, and healthcare professionals towards the iCST app, and the use and implementation of related technology in their daily lives.

It was hypothesized that evaluating the iCST app in Indonesia would provide evidence for its feasibility and applicability in an alternative cultural context, and therefore contribute to its overall quality with a better understanding of different cultural needs which may support global accessibility to the iCST app.

7.3. Methods

7.3.1. Sample

People with dementia, family and paid carers, and healthcare professionals were recruited for different parts of this study. The inclusion criteria were adapted from previous CST and iCST research (Orrell et al., 2017; Spector et al., 2003). People with dementia needed to (1) have a formal diagnosis of dementia, (2) have some ability to communicate and understand the research (e.g. ability to give informed consent), (3) see/hear well enough to participate, (4) have a minimum age of 50 years with no maximum age limit, (5) and have a carer (or friend/befriender) available to participate in the research activities. For family and paid carers, and healthcare professionals the criteria included (1) a minimum age of 21 years, (2) see/hear well enough to participate, and (3) sufficient experience of working in the field of dementia for healthcare professionals only.

People with dementia and carers were recruited as familial dyads through the Indonesian Alzheimer's associations in Jakarta and Depok (Alzheimer Indonesia). The research team advertised the study through leaflets and promoted it during Alzheimer Indonesia events for people with dementia and carers. People

expressed their interest in the study through approaching and/or contacting the research team directly. They were then provided with separate information sheets for the person with dementia and the carer. Alzheimer Indonesia also supported the recruitment of healthcare professionals through distributing leaflets to their list of contacts.

7.3.2. Study design

This was an exploratory, qualitative study, which took place in Jakarta and Depok, Indonesia. Methods consisted of focus group discussions with people with dementia and carers followed by a short testing session of the iCST app, and a stakeholder meeting. These methods were used to gather diverse and in-depth data regarding the attitudes of people with dementia and carers towards the use of technology in daily life with the iCST app serving as an example of such technology. A discussion guide was developed by the researcher (HR) which included semi-structured questions to explore key areas related to the different uses for technology and its usefulness for people with dementia (see Appendix 20).

The stakeholder meeting was organised with professionals working in the field of dementia to gather their views on how technology can be used in dementia care, and on the feasibility of adapting and implementing the iCST app in Indonesia. Aguirre et al. (2014) recommend the early inclusion of healthcare workers such as psychologists, socials workers, and local health workers in the adaptation process of CST. Their knowledge and experience of working with people with dementia in their cultural context help to uncover potential cultural barriers for adaptation and their feedback can be useful in making the necessary changes to the intervention (Aguirre et al., 2014).

7.3.3. Intervention – iCST app

The intervention was a third version of the iCST app prototype as described in Chapter 4. It included a welcome section and the full range of 21 activities in English including interactive word, picture, and number games as well as discussion activities (Table 7.1 and Figure 7.1).

Table 7.1. List of iCST app activities.

Activity name		
Sounds	Past Events	Being Creative
Spaceman	Odd One Out	The Price is Right
Useful Tips	iSpy	Trivia Quiz
Word Search	Sudoku	Globe Trotter
Sayings	My Life	Being Active
Food	Brainstorm	Arts
Old Wives' Tales	Toys Are Us	In Pairs

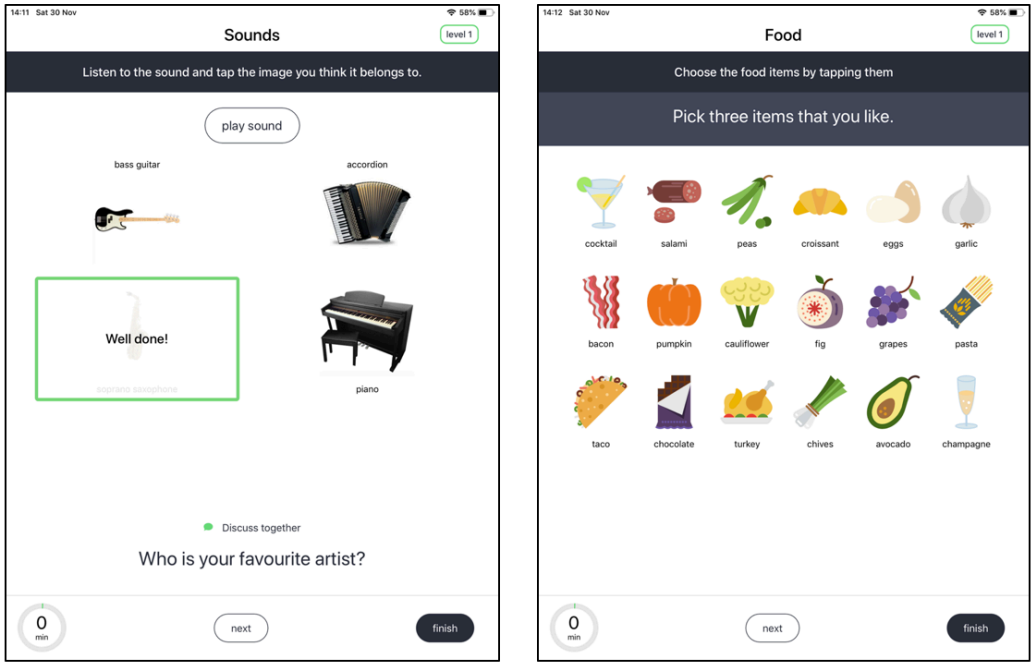


Figure 7.1. Screenshots of the Sounds (left) and Food (right) activities in the iCST app.

Each activity comes with a choice between two levels with more challenging and in-depth content provided in level two. Considering the differences in cultural contexts, a sub-set of activities with a focus on interactivity and culturally relevant content was presented to the participants. These activities included Food and Sounds (Figure 7.1).

7.3.4. Procedure

All study related documents were translated from English to Bahasa Indonesia by the research team before any research activities took place.

7.3.4.1. Focus groups

Four focus groups were organised: two mixed groups with people with dementia and carers (n = 12), one with family carers only (n = 3), and one other with both family and paid carers (n = 3). Different types of focus groups were organised in order to gain the perspectives of multiple stakeholders and therefore increase the richness of the data (Morgan, 1996). Participants completed a short demographics form prior to the focus group discussion. Three researchers (HR, PT, IT) and one student were present at each group. Two researchers (HR, PT) facilitated the discussion while a student made notes, written observations, and provided translations where necessary. One researcher (IT) provided assistance with any practical needs of the participants. Each focus group lasted approximately 30-45 minutes followed by a 20-minute try-out with the iCST app in pairs. A brief explanation was given about the app prior to the try-out. Hereafter, one touch-screen tablet was given to each pair with the app already open and presented on the screen. Given that the activities were in English, activities were trialled at level one and there were a minimum of three facilitators present who spoke both Bahasa Indonesia and English in order to provide translations to the participants. Support

and guidance from the researchers was given as participants made their way through each activity. Detailed notes and written observations were made during the session. Lastly, all participants completed a short usability and acceptability questionnaire (Castilla et al., 2018).

The focus groups discussions were audio-recorded, transcribed, and translated from Bahasa Indonesia to English. The transcripts were anonymized and stored on a password protected computer at Atma Jaya Catholic University.

7.3.4.2. Stakeholder meeting

The stakeholder meeting was organised with professionals working in the field of dementia (n = 21). One researcher (HR) gave a brief introductory presentation covering the purpose of the day, technology for people with dementia, the iCST app, and led the subsequent discussion. Another researcher (TS) provided support for simultaneous translation from English to Bahasa Indonesia. Findings from the focus group discussions with people with dementia and carers were also shared. This was followed by a structured group discussion on key topics set in advance by the research team. Topics included current experience with technology in dementia care, potential uses for technology, any limitations, and the feasibility of the iCST app. Data was not audio-recorded but detailed notes of the emerging thoughts and ideas were taken throughout the group discussion by two undergraduate students from Atma Jaya Catholic University.

7.3.5. Ethical approval

Ethical approval was obtained through the Division of Psychiatry and Applied Psychology Ethics Committee at the University of Nottingham in March 2019 (reference number 0280) (see Appendix 15). For the focus groups, a researcher explained the purpose of the research on the day of the event and written informed

consent was obtained from each participant hereafter. Wherever necessary, the carer sat with the person with dementia during the consenting process. Each consent form was checked by a researcher to ensure it was completed in full. No informed consent was taken for the stakeholder meeting, as the purpose of the meeting was to gain insights in the group's views rather than the view of an individual.

7.3.6. Analysis

The data from the focus groups was coded and analysed thematically using NVivo software by two researchers (HR, VP). The data was analysed independently to ensure reliability of the analysis. An inductive approach was chosen as it allows for the analysis to be driven by the data leading to the generation of new ideas and themes rather than testing a preconceived theory (Thomas, 2006). This approach was best suited for the current study as the aim was to gather exploratory data on the views and opinions of participants on using the iCST app and related technology in daily life. The approach included detailed readings and interpretation of the raw data in the transcripts. The objectives of the study served as key domains for investigation and helped guide the coding and process of analysis. Observational notes were reviewed to support the analysis and provide clarifications.

7.4. Results

The sample included 18 participants: six people with dementia and 12 carers (Table 7.2). The sample was mostly made up of female participants and included a mix of spousal and adult child caring dyads. In addition, all participants except for one person with dementia had some experience with using technology in their daily lives ranging from assistive technology (AT) such as mobile phones to touch-

screen apps such as YouTube or WhatsApp to support activities in daily living. More details on the exact usage are included in the thematic analyses below.

Table 7.2. Demographics of people with dementia and carers in the focus groups.

Demographics		Focus groups (%)	
		Person with dementia (n = 6)	Carers (n = 12)
Gender	Female	5 (83.3)	12 (100)
Age	Mean age (years)	74.5 (*SD* = 8.41, range 60 - 83)	53.33 (*SD* = 13.2, range 35 - 72)
Living status of person with dementia	Person lives with family	5 (83.3)	
	Person lives alone	1 (16.7)	
Relationship	Spouse		3 (25)
	Child		5 (41.7)
	Neighbour		2 (16.7)
	Paid carer		2 (16.7)
Experience with technology	Yes	5 (83.3)	12 (100)

Thematic analysis of the data led to the formation of three main themes ('perceptions of technology', 'using technology to support daily life', and 'technology for mental stimulation and interaction'), and three subthemes.

7.4.1. Theme 1 – Perceptions of technology

Due to the advancement of technology in Indonesia, use of technology in all forms is quickly becoming more widespread in both urban and rural areas. Most participants had a positive attitude towards technology to support activities in their daily life. Carers found this kind of technology to be very helpful and beneficial for themselves, and also for people with dementia:

At the end of the day, I see that technology helps them. – Family carer, Focus group 2.

Although they also agreed that people should not solely rely on technology as the interaction between people is an important aspect:

For me, how advanced the technology is, there should be a human touch. The purpose of the technology is to help us. (…) At the end of the day, the human touch and affection is more effective than screen touch. – Family carer, Focus group 1.

When asked how they perceived technology in general, most people with dementia responded by saying that technology makes them feel happy.

7.4.2. Theme 2 – Using technology to support daily life

Perceived benefits of using technology

Participants described a range of different benefits for the usage of technology of which communication was mentioned most often. Others mentioned using technology for religious purposes in order to listen to prayer, which could help to remedy tense moments between the person with dementia and carer.

For me it is easy to contact my children who live abroad for three years. So, if I don't have a mobile phone it will be very hard. With that, I can make a video call and see my children and grandchildren's faces. – Person with dementia, Focus group 3.

A carer mentioned she uses it to access information about Alzheimer's disease (AD). Information sharing was further reflected upon by a person with dementia:

I have a group of ex co-workers from the office (on WhatsApp) and there are many members, so we share information or news such as health articles. – Person with dementia, Focus group 3.

Yes, and I love to read regarding health. I spend my time reading rather than just sleeping. I do not feel comfortable if I do nothing. – Person with dementia, Focus group 2.

Some carers mentioned they did not use technology specifically in their interactions or care for people with dementia. However, one carer used technology to look at pictures together and to play games. Another carer valued the use of YouTube:

For me, I like YouTube because I can find everything there, such as my favourite art and craft. I will find the tutorial or other creative video that I can use as an activity for my mother. For now, it is very important and I cannot live without it. – Family carer, Focus group 4.

Other beneficial uses for technology included transportation and shopping e.g. ordering groceries. In terms of platforms, the majority used smartphones or another type of mobile phone, and some additionally used computers. Use of a touch-screen tablet was less popular especially among the older participants.

Barriers

Participants also felt like there were several challenges and barriers towards using technology. Some of these could be explained through a lack of experience with technology even prior to receiving the diagnosis of dementia or challenges related to operating systems:

Before (being) diagnosed with dementia, my mother always refused to use gadgets. We try to convince her to use mobile phone, but she did not want it. So, since then she rarely used technology and even now, when she has dementia, she never wants to use it. – Family carer, Focus group 1.

Oh, sometimes when I want to type something, a different letter pops out. So I have to erase all and start again. – Person with dementia, Focus group 3.

Visual impairments were also mentioned as making it more difficult to use technology. Other concerns included privacy and safety:

For me the negative side is … because the information can be accessed easily by everybody, we have difficulties in differentiating between true information and hoax. – Paid carer, Focus group 4.

Need of support

Both people with dementia and carers acknowledged the need of support when using technology in daily life. This was especially the case for people with dementia and older carers. Participants most frequently reached out to either their children or grandchildren as they were considered to be more 'technology savvy':

No, I go upstairs and ask help from my grandchildren. They are experts on this. I try to ask for help first rather than switching it off. – Person with dementia, Focus group 3.

Others mentioned reaching out to friends and one carer reached out to her younger co-workers for support. Some did not reach out for support in case of difficulties with technology but rather tried to find a solution themselves or would switch the piece of technology off if the problem persisted.

7.4.3. Theme 3 – Technology for mental stimulation and interaction

Family carers in particular valued mental stimulation for the person they were caring for and expressed a need for more resources:

However, at the end the stimulation is very important because it can be a habit if we do it repeatedly. – Family carer, Focus group 2.

I want to know what we as a caregiver can do for our person with dementia, such as a game, to stimulate their brain so they can interact, play and communicate more. – Family carer, Focus group 4.

One carer wanted more resources to keep her husband's brain active and felt she was relying too much on medication. Others expressed already taking part in some mentally stimulating activities such as doing crosswords or discussing the news on TV. One person with dementia reflected on the use of music to promote mental stimulation and interaction with others:

Or we can interact through music. Through memorising the lyrics, our brain can be stimulated as well. We can memorise songs from different areas: Java, Sunda, Padang, Betawi. – Person with dementia, Focus group 3.

When asked about using something like the iCST app for both mental stimulation and interaction, participants responded positively:

That would be great if there is an application like that, because that is what we need. Sometimes it is difficult to find an activity that can be done together. In my case, since my husband is bored easily, it is difficult to interact. So, I'm happy if there is an application that can foster interaction together. – Family carer, Focus group 1.

Some carers mentioned that such an app would be most helpful in the early stages of dementia and would need to be fully adapted to the Indonesian cultural context

in order for people to be able to use it, and the involvement of a relative or friend in using the app is necessary as it would make the experience more useful but also more meaningful.

7.4.4. Usability and acceptability questionnaire

Table 7.3 contains the usability and acceptability ratings of the iCST app as given by 17 participants of the focus groups. Carers gave uniformly high ratings to each aspect of the app but ratings by people with dementia were more dispersed.

Table 7.3. Results from the usability and acceptability questionnaire.

Questionnaire item[1]	People with dementia (n = 6)	Carer (n = 11)
	% agree or strongly agree	% agree or strongly agree
1. I think most people could learn very quickly how to use Thinkability.	50	91
2. I felt confident about my ability to use Thinkability.	33	91
3. Overall, I knew what to do at all times.	83	91
4. Once I had learned to use Thinkability, I could perform tasks quickly.	17	100
5. Thinkability can be used anywhere and in any context.	67	91
6. The instructions in Thinkability are easy.	67	91
7. The font and button sizes are sufficient for me.	50	64
8. I would like to use Thinkability frequently.	67	91
9. Overall, I think Thinkability is very useful to me.	50	91
10. Overall, I think Thinkability is easy to use.	50	100

[1]Responses include: strongly agree = 4, somewhat agree = 3, neither agree or disagree = 2, somewhat disagree = 1, strongly disagree = 0

For example, carers found the app useful and were also more willing to use the app frequently. Most people with dementia found the instructions easy and agreed that the app could be used in multiple contexts however, there was no strong consensus in other areas including suitability of font and button size, and usefulness of the app. Both people with dementia and carers indicated they knew what to do at all times while using the app but people with dementia felt less confident about their ability to do so. This suggests people with dementia may need more support and encouragement to use new technology. While using the app participants reflected on the content of the Sounds and Food activities and how these could be adapted for the Indonesian version of the app. A carer mentioned different Indonesian musical instruments whereas a person with dementia talked about different Indonesian dishes or ingredients useful for the Foods activity such as rice or tempe (a soy-based food).

7.4.5. Stakeholder meeting

The stakeholder meeting was attended by 21 participants: seven nurses, six social workers, three medical doctors, two care home staff members, one psychologist, one community leader, and one researcher. Their experience of working in dementia care ranged from two months to 33 years. When asked about experiences with technology in dementia care, participants mentioned various tools such as a community-based tracking app to report missing people but also technology in the workplace such as electronic patient systems. However, only one care home manager described how she used technology together with her residents to promote communication through video calls with family members, stating that this often helped to reduce anxiety among residents:

It is quite helpful for people with dementia. For example, when they are missing their family, we can play a video from the family. – Care home manager.

All participants mentioned multiple barriers in the implementation of technology for people with dementia. On a structural level, a social worker shared that the health and social sectors are currently not integrated in Indonesia. This leads to a lack of clarity on which sector should support people with dementia in their care and needs. In addition, due to a lack of awareness of dementia in Indonesia, some participants emphasized a need for technology to support the diagnostic and screening process of people with dementia rather than technology for post-diagnostic support. Other barriers included practical issues such as access to a stable internet connection for data and the relative lack of development of technology in Indonesia especially in more rural areas. This was seen as an important issue because older people in retirement from work may move out of the city to more rural areas. This may mean that they have poor access to the internet compared to more developed areas such as Jakarta. A care home manager mentioned that residents at her nursing home were often unfamiliar with technology, which she said was because residents often came from lower socio-economic backgrounds.

Participants shared some insights on how to overcome some of these barriers. For instance, like in the iCST app, combining technology with face-to-face interaction could be helpful. There was a consensus that it would be good to involve members of the family in the use of technology for people with dementia to provide support whenever needed:

In Indonesia it is better to combine technology and face-to-face (approaches). For example, a family support programme, the support comes from family of the older person who can already use apps. – Care home worker.

This would include the younger generation as they often take care of their grandparents and tend to be more 'technology-savvy'. When discussing the benefits of offering CST on a computerised platform, one person mentioned:

There is a benefit of that: it is more standardized, and can be done earlier/quicker without much training. But the carer would still need guidance in its use (of the iCST app). – Medical doctor.

With regard to the iCST app in particular, participants felt it could be useful as it includes various audio-visual stimuli, which may be interesting for people with dementia. However, the content would need adaptation to the Indonesian context, and people with dementia would need to be involved in this process.

Participants also felt that the following measures would need to be in place for successful implementation of the app: electricity, access to internet connection and appropriate devices, and adoption in current policy. Finally, a range of stakeholders would need to be informed about the app including caregivers, family members, physiotherapists, occupational therapists, and other medical professionals in order to promote awareness.

7.5. Discussion

This is the first study in Indonesia to explore the attitudes of people with dementia, carers, and healthcare professionals towards the use and implementation of technology to support daily life and dementia care, and in particular the iCST app. Carers described a need for additional resources to keep the brain active and

welcomed the idea of an app for the mental stimulation and interaction of people with dementia. Healthcare professionals reflected on structural and practical barriers, which prevent the implementation of technology-based interventions for people with dementia, such as the iCST app, and shared ideas on how to overcome these.

7.5.1. Perceptions of technology

All participants had a positive attitude towards technology. Carers were especially positive about how it can be beneficial to themselves and the person they were caring for but also pointed out that technology should support the interaction between people with dementia and carers rather than replace it. People with dementia provided less elaboration than carers and said that using technology makes them feel happy. This is in line with a previous review which found that people with dementia valued being able to use technology for fun and for more enjoyable activities (van Boekel, Wouters, Grimberg, van der Meer, & Luijkx, 2019). The review also found that healthcare professionals such as general practitioners (GPs) had concerns about the loss of face-to-face interactions due to technology (van Boekel et al., 2019). In this study, similar concerns were voiced by family carers. The findings from this study are also consistent with the United Kingdom (UK) qualitative evaluation of the iCST app (see Chapter 5), which found that people with dementia and carers welcomed the idea of using such technology together and found it to be enjoyable. Healthcare professionals in Indonesia were receptive to implementing technology within dementia care but were more concerned about the need for technology to strengthen the diagnostic process of dementia rather than providing post-diagnostic support.

7.5.2. Using technology in daily life

All participants used technology in some way in their daily lives and found it to be beneficial. Uses ranged from communication and transportation to leisure such as listening to music or watching videos. Few had experience of using technology in dementia care.

Despite having positive attitudes towards technology, participants also encountered a range of barriers towards its use including reluctance to use technology, physical limitations, lack of familiarity with technology, limited accessibility, and current organisation of dementia care. Carers stated that the people they were caring for were at times unwilling to use technology. This was supported by people with dementia but they identified additional barriers related to difficulties with operating technology. These included physical limitations (e.g. visual impairments) or lack of familiarity with technology of which the latter was also identified by healthcare professionals. Previous research found similar results where people with dementia who lived alone, stated they had difficulties with operating different kinds of technology (e.g. alarm clocks, computers) (Nygard & Starkhammar, 2007). Healthcare professionals discussed some structural barriers such as the organisation of dementia care, and limited accessibility due to poor internet networks and older people living in more remote areas. Lastly, inadequate knowledge and understanding of the potential of technology can be an additional problem (Nygard & Starkhammar, 2007).

All participants in this study agreed that it would be best to use technology, which has been designed for people with dementia, together with family members. Most people with dementia and carers already involved family members or friends when using technology. Participants from the stakeholder meeting found that this, and especially the involvement of the younger generation, could help overcome some of the barriers mentioned before. In addition, more than 51% percent of the older

population in Indonesia has less than six years of formal education and the additional support from a family member or friend could help them to better navigate the iCST app (Maylasari, Sulistyowati, Ramadani, & Annisa, 2017). This involvement could be helpful for the successful implementation of resources such as the iCST app, which are meant to be used together.

7.5.3. Technology for mental stimulation and interaction

A previous systematic review has shown that computerised cognitive interventions can have moderate, positive effects on the cognition of people with dementia (Garcia-Casal et al., 2017). The availability of such resources could be helpful as some carers in this study described a need for alternatives to medication to help keep the brain of people with dementia active. This indicates the importance of mental stimulation, which was a common theme in previous paper-based iCST research (Yates, Orrell, et al., 2015). Especially when discussing the potential of technology, carers were keen on using something like the iCST app. This is supported by the findings from the usability and acceptability questionnaire as almost all carers gave high ratings to the usefulness of the iCST app and indicated they would like to use it frequently. People with dementia rated the iCST app slightly lower which can possibly be explained by the barriers to using technology such as limited familiarity or overall difficulty with operating devices. However, people with dementia were keen to try-out the iCST app, were engaged while using it, and liked to use technology to make themselves feel happy and for other leisure activities. This indicates that the iCST app could be a welcome resource for people with dementia. Healthcare professionals were positive about the interactive features of the iCST app. To implement the iCST app successfully, it would need to be carefully adapted to the cultural contexts of various users and there would

need to be awareness among not only people with dementia and carers, but also healthcare professionals so they could recommend use of the app.

These findings from people with dementia, carers, and healthcare professionals have provided evidence for the feasibility and applicability of the iCST app in an alternative cultural setting and therefore confirmed the hypothesis for this study. The iCST app has good applicability as carers found the iCST app to be useful. Further observations showed that the interactive features and content of the iCST app supported engagement among people with dementia. The feasibility of the iCST app can be improved by the cultural adaptation of individual activities and by overcoming barriers to accessibility e.g. through improved awareness and infrastructure for technology.

7.5.4. Limitations and strengths

Participants were unfamiliar with technology specifically for people with dementia and at times, facilitators had to provide more support and examples to guide the discussion. This led to a more structured discussion than anticipated. More carers than people with dementia participated in this study, which reflects low and often delayed diagnosis rates. Therefore, it can be difficult to recruit people with dementia for research as they may lack capacity by the time they are diagnosed, making participation more challenging. At times in this study, people with dementia did not fully participate in the discussion and required lots of support from their carers. These factors may have limited the richness of the data. There were limited activities that participants could try-out due to differing cultural contexts and language barriers, of which the latter also limited my own involvement in directing the discussions. Therefore, participants were not able to comment on the full app.

The presence of multiple bilingual facilitators did help to remedy some of the cultural barriers.

The strengths of this study lie in the in-depth data from a variety of stakeholders. This is reinforced by observations and a usability and acceptability questionnaire. Combining research methods can help to confirm findings across the methods but more importantly, provide complementary data (Small, 2011). By including a diverse sample of people with dementia, carers, and healthcare professionals, we were able to gather a variety of opinions and a well-rounded view on the iCST app and technology for people with dementia in general. It also helped to uncover more structural barriers towards implementation from the perspective of healthcare professionals with experience in the field. The sample included a mix of spousal and adult child caring dyads and therefore, carers were included from a wide age range with different levels of familiarity with technology. Lastly, the focus groups were organised in different parts of Java, Indonesia and included both an urban (Jakarta) and rural area (Depok). This further improved the richness of the data by including a more diverse population and allowed participants with different backgrounds to share their ideas and opinions.

7.5.5. Implications for future research

Overall, more research in the area of technology for people with dementia is needed to better understand its potential in Indonesia and to develop the evidence-base. Future research could include the development and piloting of technology-based interventions tailored to the needs of the Indonesian population e.g. mental stimulation apps which can be used on mobile devices.

Considering that group CST is already being used on a small scale in Indonesia and the need for additional resources for mental stimulation and interaction, there

may be some potential for the iCST app to be implemented as well. Future research activities could include stakeholder workshops to better understand how the content can be adapted to the various Indonesian cultural contexts. However, access to and awareness of available technology will need to be improved across the country, and the dementia care system should be strengthened. Indonesia is already taking steps towards this by launching its National Dementia Plan in 2016. It includes key aspects such as awareness, access to information and quality services, strengthening human resources and overall system – infrastructure, and supporting research on cognitive and dementia issues. Through this plan and the continued work of Alzheimer Indonesia, which includes awareness raising and capacity building, there will be an opportunity to adapt the iCST app to the cultural contexts in Indonesia and to implement it successfully in the future.

7.6. Conclusion

This is the first study in a LMIC to investigate the attitudes of people with dementia, carers, and healthcare professionals towards the iCST app, and the use and implementation of related technology in their daily lives. Most participants were positive about the use of technology and shared various beneficial uses such as communication and other leisure activities. Some barriers included difficulties with operating the devices, lack of familiarity with technology, limited accessibility and overall readiness for technology adoption in Indonesia. Participants acknowledged the need for support when using technology which could help remedy some of the challenges.

There is a need for more resources to keep people with dementia mentally stimulated and to promote interaction. The iCST app was viewed as useful tool for this and participants rated it well in terms of usability and acceptability. In addition

to improving the awareness of dementia and technology, there is a need to consider the various cultures across Indonesia and adapt the iCST app using the existing CST adaptation guidelines.

Chapter 8 – Discussion and conclusion

This research project set out to develop and evaluate a computerised version of individual Cognitive Stimulation Therapy (iCST) in the form of a touch-screen application (app) for people with dementia and carers, and to investigate its potential for wider implementation internationally. It allowed for the application of an array of research activities supported by a range of methods leading to the collection of rich and in-depth data. The development work was first guided by a narrative synthesis systematic review to investigate how involvement of people with dementia in developing technology could be optimised. Hereafter, while adopting an agile methodology and adhering to the Medical Research Council (MRC) Framework and Centre for eHealth Research (CeHRes) roadmap, additional research activities included the identification of the evidence-base and theory behind Cognitive Stimulation Therapy (CST) and technology, patient and public involvement (PPI) consultation meetings, review of existing iCST materials, and a qualitative study with people with dementia and carers in the United Kingdom (UK). This led to the development of three iterative prototypes of the iCST app of which the third was introduced to stakeholders in Indonesia where an exploratory, qualitative study took place to investigate the attitudes of people with dementia, carers, and healthcare professionals towards using technology to support daily life, and the potential of the iCST app to be adapted and implemented into a different cultural context. Finally, the third iCST app prototype was also taken forward in a feasibility trial in the UK to evaluate the feasibility of conducting a full-scale randomised controlled trial (RCT) with the iCST app compared to a treatment as usual (TAU) control group, and to further inform the usability and acceptability of the iCST app.

8.1. Summary of the findings

Prior to any development activities, a brief review of the literature surrounding dementia, use of technology, and technology-based interventions for older people with and without dementia was undertaken. As dementia has a multi-level impact on the individual, society and the economy, and given the lack of a range of suitable treatments, there is a need for more resources to help keep people with dementia mentally stimulated and engaged. Technology may be able to provide such resources and over the last decade, use of technology and access to the internet has grown among all age groups (Office for National Statistics, 2020). Despite some barriers for older people aged 65 and over such as inappropriate technology designs and lack of awareness (Delello & McWhorter, 2017), there are advantages to using novel technologies such as a decrease in social isolation and the availability of technology-based interventions for people with dementia (Delello & McWhorter, 2017). In addition, there seem to be some promising effects from the use of touch-screen interventions for people with dementia such as increased well-being (Tyack & Camic, 2017), however more research is warranted as there is a lack of such technologies for the mental stimulation and leisure activities for people with dementia and the field of computerised cognitive stimulation in particular is underdeveloped (Garcia-Casal et al., 2017). In addition, the current research surrounding the effects of computerised cognitive stimulation for people with dementia seems to be inconclusive (see section 8.2. Findings in the context of previous research). CST is the only non-pharmacological treatment recommended for people with dementia as it has shown to benefit cognition and quality of life (QoL) (Spector et al., 2003). Therefore, a literature review was conducted to better understand the evidence-base and mechanisms behind the various CST-based approaches including iCST. The effectiveness of CST is

derived from its multifaceted approach such as a group environment, and its key principles which reinforce mental stimulation, use of reminiscence, enjoyment and more. Moreover, it targets specific neuropsychological domains such as memory and language which is helpful in supporting the cognition (Yates et al., 2018). Different results were found for iCST including improvements in both the QoL of carers and the quality of the relationship between the person with dementia and carer (Orrell et al., 2017). However, the researchers stressed the need for more research as adherence to the intervention was low, making it challenging to investigate effectiveness in terms of cognition and QoL for the person with dementia. Furthermore, researchers suggested that a novel platform such as a technological tool may lead to different results as this would allow for better adherence monitoring and there may be some mentally stimulating effects of regularly engaging with technology.

8.1.1. Development of the iCST app

The primary objective of this research was to develop an interactive (touch-screen) app as a mode of delivery of iCST for people with dementia and carers, which can be used on touch-screen tablets. This objective has been met by adopting a highly systematic and rigorous approach towards the development of the iCST app resulting in three iCST app prototypes. This process started with a narrative synthesis systematic review to better understand the current involvement of people with dementia in developing technology and how this could be optimised. The obtained evidence was synthesised through the use of narrative synthesis and evidence-based frameworks such as the MRC Framework and the CeHRes roadmap. The review found that people with dementia were involved in various stages of technology development using an array of quantitative and qualitative methods. The results led to the development of 12 evidence-based best practice

guidelines on how to better involve people with dementia in developing technology which were also reviewed in two consultation meetings by PPI members to ensure relevance and suitability. The review was an integral starting point as the majority of the guidelines in terms of user-involvement were imbedded in the development and evaluation process of the iCST app. As such, I will reflect on how some of these were applied in the research activities described below.

The narrative synthesis systematic review was followed by development activities for the iCST app. The hypothesis in Chapter 1 stated that a development approach supported by evidence-based frameworks and stakeholder involvement would result in a well-designed and suitable iCST app because an effective design process can contribute to the usefulness and usability of an intervention. To test this hypothesis, like with the development of CST and iCST, the development of the iCST app adhered to evidence-based frameworks such as the MRC Framework. The addition of the CeHRes roadmap provided insights in aspects of eHealth development in particular. Principles from action research also supported the development process through including active participation from relevant stakeholders including people with dementia. Finally, we were also guided by recommendations of Eumedianet who introduced us to the concept of working agile which helped organise the development according to three sprints. Prior to any development activities, frequent meetings took place with Eumedianet over Skype and in person to discuss the project in more detail including aims, the intervention, timelines and available resources. Cross-national barriers and the lack of familiarity with interventions for people with dementia among Eumedianet required more time to ensure the company fully understood the purpose of the study and essence of CST and iCST. Matching the timelines between research and development proved to be more challenging than anticipated and the

difference between the two sectors (academia and industry) became more apparent. Agile development requires a quick turn-around meaning that when a prototype is developed, it should be evaluated by users as soon as possible. In practice, this was not always possible due to the time that was needed for recruitment and activity set-up (e.g. location, travel). In addition, at times, these activities would require additional ethical approval for amendments to the protocol leading to more time lost. A solution would be to involve the software development company in the development of the research protocol and ensure all necessary sprints are captured before obtaining ethical approval. The need for amendments would thus be minimised. Another solution is to simply factor in more time for each sprint. Prior to any user-involvement, care was taken to ensure we followed guidelines from the systematic review. For instance, for the planned research activities, we set the goal of user-involvement for each of these and made sure participants were made aware of the purpose of their involvement through initial contact (telephone, email), the participant information sheet (PIS) and on the day itself (recommendation 2 and 3). We also decided to involve users across multiple stages of development (recommendation 4) and aimed for a combination of methods to collect feedback from users throughout the different studies e.g. interviews, questionnaires and observations (recommendation 5).

We started with sprint 1 which included two PPI consultation meetings with people with dementia and carers. Most participants found the iCST manual to be interesting and welcomed the idea of an iCST app. Needs for personalisation, flexibility in its use, and support while using the iCST app were identified early in the development process. Furthermore, participants felt people with dementia would need to be empowered to use technology which was confirmed by participants from the qualitative study in sprint 3. Lastly, in terms of converting

paper-based iCST to an app, participants recommended reducing the amount of content significantly in order to create a suitable lay-out. A further review of the paper-based iCST materials by both the research and software development teams led to the final selection of 21 activities to be included in the iCST app. Disagreements between both teams on which activities to include were overcome by making compromises and carefully reviewing the amount of time and resources needed to develop each activity (e.g. more time is needed to create videos). The addition of LY, who completed her PhD on paper-based iCST, in the selection process was also favourable as she provided unique insights on each iCST activity.

Eumedianet suggested we present working prototypes to users rather than paper wireframes, which was further confirmed through the findings from the systematic review as previous research recommended the use of working prototypes as well (recommendation 9). Therefore, for sprint 2, a working prototype v1.0 of the iCST app was developed consisting of two activities, a welcome section, and the timeline. This was then evaluated during a small PPI consultation meeting with two people with dementia and a carer. A working prototype made it easier to gain feedback as it better resembled the end product. Most feedback pertained to the lay-out of the app which led to amendments in text size, reduction of complicated language, and the removal of small bugs. These were incorporated in prototype v2.0 of the iCST app along with an additional five activities, which was evaluated more in-depth by people with dementia and carers in four focus groups and 10 interviews as part of sprint 3.

In sprint 3, following the advice from Eumedianet, we decided to incorporate a short test session paired with observations prior to any discussions with participants. During the try-out, participants were able to choose from a selection

of activities and spend 15 to 20 minutes on the app which was key in obtaining detailed and more relevant feedback. Findings from the qualitative research activities were further supported by a usability and acceptability questionnaire in order to enhance data triangulation. The iCST app was considered to be intuitive and the lay-out in particular was rated positively. Feedback included additional minor changes to the lay-out, the expansion of the content, and we obtained a better understanding of the perceived benefits (e.g. mental stimulation) and feasibility of using the iCST app. Based on this feedback, the iCST app was extended to include the full 21 activities to be taken forward in the feasibility trial. Some of these activities were directly based on ideas given by participants from the qualitative study such as a Word Search or a Trivia Quiz. Interestingly, these activities were quite popular among participants in the feasibility trial. During each of the sprints, it was not always possible to adopt all the feedback received from the participants as some suggestions would have had a negative effect on the usability of the iCST app (e.g. the addition of multiple control buttons on the screen). Each piece of feedback was therefore carefully considered by both teams before implementing or rejecting it.

Feedback from the three development sprints have underpinned the hypothesis of the development study, which is a direct result of using a rigorous development approach for effective design. People with dementia and carers shared that the iCST app could have a range of potential benefits indicating that it could be a useful tool in daily life, and further highlighted the attractive design features of the app such as the lay-out and images which provides further evidence for its usability.

The final objective of this research was to investigate the feasibility of adapting the iCST app for users in Indonesia according to their cultural context. Therefore, after the qualitative study in the UK, prototype v3.0 of the iCST app was taken forward

in a small exploratory study in Indonesia with people with dementia, carers, and healthcare professionals. This was preceded by substantial preparation work including frequent online meetings between members of Alzheimer's Disease International and Alzheimer Indonesia, a set-up visit to Alzheimer Indonesia a few months prior to the placement, and the drafting of necessary documents for the research activities and ethical approval. Despite the short time frame of two months and therefore a relatively small sample size, we were able to conduct four focus groups (n = 18) and a stakeholder meeting (n = 21). The hypothesis in Chapter 1 stated that evaluating the iCST app in Indonesia would provide evidence for its feasibility and applicability in an alternative cultural context, and therefore contribute to its overall quality with a better understanding of different cultural needs which may support global accessibility to the iCST app. During the work in Indonesia, we found that most participants had positive attitudes towards using technology to support daily life and welcomed the idea of an iCST app providing support for the hypothesis of this study. Through the usability and acceptability questionnaire, we found that carers considered the iCST app to be useful and also usable. Through observations, we found that people with dementia were engaged while using the app. These findings provide evidence for the applicability of the iCST app in Indonesia. We learned more about different cultural needs regarding the iCST app in terms of content adaptation, the need for family support for people with dementia while using the app, and other barriers towards accessing technology which would need to be overcome before implementing such an intervention e.g. increase in awareness, capacity to support technology. This feedback further confirms the aforementioned hypothesis by providing the necessary insights into the feasibility of the iCST app in Indonesia. Furthermore, differences in the dementia care system compared to the UK had an impact on the

study e.g. participants often had a more advanced level of dementia before receiving a diagnosis and there was a general lack of awareness of technology for dementia care. Despite these challenges, this study was one of the first of its kind in Indonesia and set a good example of both cross-cultural and cross-sectorial collaboration.

8.1.2. Evaluation of the iCST app

The secondary objective of this research was to evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a TAU control group. This objective was met by taking iCST app prototype v3.0 forward in a feasibility trial with people with dementia and carers (n = 43) to investigate a range of study-related aspects for a full-scale RCT, and the usability and acceptability of the intervention. The hypothesis in Chapter 1 stated that the iCST app would lead to better outcomes for people with dementia and carers compared to paper-based iCST because the benefits of computer use on cognitive functioning and QoL may add to the overall effectiveness of the intervention as a result of engaging with novel and stimulating activities, increased confidence, and feelings of empowerment. To test this hypothesis, the trial was supported by different data collection methods such as weekly telephone calls, questionnaires, and post-trial interviews. In addition, based on recommendations from previous iCST research, we were able to better monitor adherence through analytics. Similarly, keeping in line with recommendations from the systematic review and despite some minor technical issues, we ensured the app met an acceptable standard of stability and reliability before presenting it to users for evaluation (recommendation 10). Regarding the study-related aspects, it is recommended to proceed with a larger trial given that the necessary modifications as set out in the Acceptance Checklist for Clinical Effectiveness Pilot Trials (ACCEPT) have been met. These include

changes to recruitment, the intervention, design and more. Recruitment especially proved to be challenging which was partly due to the specific, technology-related eligibility criteria but also the lack of capacity in terms of recruiting sites and the supporting staff members. Regarding the iCST app, tablet compatibility proved to be an issue as some Android tablets negatively influenced the lay-out and consequently the usability of the app due to the size of the tablet or an older software version. For instance, tablets with a small screen size (less than 8 inches) such as an iPad mini or an Amazon Kindle did not display the full content of the iCST app and were therefore unsuitable. Other devices such as iPads (Pro or Air) and Galaxy Tabs with a minimum screen size of 8.9 inches worked well and allowed for a more optimal experience while using the iCST app. Also, adherence was relatively lower than expected and use of the app varied substantially across the participants as observed through analytics. There is also a need to re-examine the content of the iCST app as some game-like activities such as Word Search were more popular than the discussion-based activities, of which the latter better resemble traditional CST and iCST activities. The majority of the participants found the iCST app to be enjoyable however, for people who had milder dementia, the activities were found to be less challenging and therefore, less mentally stimulating. Two dyads who were interviewed mentioned increased confidence in using the touch-screen tablet or in undertaking other mentally stimulating activities such as maths tuition. This reflects a recommendation from the systematic review which includes the importance of offering people with dementia the opportunity to learn a new skill such as using technology (recommendation 11). In terms of the outcomes, the results show that there seems to be a relationship between using the iCST app and potential improvements in the QoL of people with dementia. The relationship was stronger at follow-up 1 (FU1) than at follow-up 2 (FU2) which may

be attributed to lower adherence to the app later in the trial. We also found improvements in the QoL of carers after using the iCST app. No other significant effects were found for both the person with dementia and carers. These findings from the feasibility trial partly confirm the hypothesis for this study as it seems that the iCST app may be similar in effectiveness to paper-based iCST given the small indications of benefits for the carer's QoL. Qualitative findings also suggest that feelings of empowerment and increased confidence are potential benefits for people with dementia which may lead to better outcomes if the iCST app is expanded with a better range of activities and used on a more regular basis. Finally, the findings also suggest that, in comparison to paper-based iCST, the iCST app may work better for people with dementia and carers as it allows for improved monitoring of adherence, offers scope for updates and new activities, and can promote increased engagement through interactive, touch-screen technology. While the hypothesis cannot fully be accepted, the preliminary results suggest that the iCST app may potentially lead to better outcomes than paper-based iCST when investigated in a full-scale RCT.

Lastly, following the final recommendation of the systematic review, we ensured that all participants across the studies received updates on the results and any further developments of the iCST app (recommendation 12).

8.2. Findings in the context of previous research

8.2.1. Development of the iCST app

Findings from the narrative synthesis systematic review corroborated a previous systematic review by Span et al. (2013) who also concluded that it is both feasible and necessary to involve people with dementia in developing technology. However, where Span et al. (2013) found a relative lack of involvement across the

development process, our review found multiple studies that involved people with dementia more elaborately in developing technology from identifying user-needs to evaluating devices. A novelty of our review was the generation of best practice guidelines, supported by previous studies providing good examples of end user involvement, which were reviewed by PPI members, and thus informed the development of the iCST app. Our recommendations are largely in line with the design guidelines for people with dementia created by the MinD project (Dening, Gosling, Craven, & Niedderer, 2020). These highlight the importance of the involvement of people with dementia throughout the research process using mindful co-design and co-production.

The use of evidence-based frameworks in previous research also led the development of the iCST app. For instance, the MRC Framework heavily supported the development and evaluation of CST and iCST (Spector et al., 2003; Yates, Leung, et al., 2015). The CeHRes roadmap however, is more novel and has therefore not been adopted as commonly in previous research apart from in the development of a shared decision-making tool for people with dementia and carers (Span et al., 2017). Furthermore, the agile methodology is a common approach towards technology development and it worked well for the development of the iCST app. It has been applied in previous dementia research for example in the development of dementia care models or other technology-based interventions such as FindMyApps: a selection tool for people with dementia to support them while choosing apps that are useful for them (Kerkhof et al., 2019). Like the iCST app, it was developed over the course of three sprints leading to iterative prototypes, and involved multiple stakeholders such as people with dementia, informal carers, developers, and researchers (Kerkhof et al., 2019). However, the combination of the MRC Framework, CeHRes roadmap, and the agile

methodology led to a novel and more rigorous approach for the development of the iCST app which has, to the best of our knowledge, not been done before.

The choice of a touch-screen tablet as a platform for a computerised version of iCST was informed by the Office for National Statistics (2018) who found that 42% of older people in Great Britain (GB) (aged 65 years and over) use a tablet computer to access the internet. Moreover, previous research suggests that a touch-screen tablet is intuitive and has a high level of acceptance among people with dementia (Joddrell & Astell, 2016; Lim et al., 2013). This is in accordance with findings from our qualitative study and feasibility trial in the UK in which we found that most people with dementia were able to handle the touch-screen device independently or with support from the carer. Regarding the design of the iCST app, Tyack and Camic (2017) have previously recommended that a touch-screen intervention should be kept intuitive, should include an error-free interface and some guidance on what to do. This is supported by Delello and McWhorter (2017) who found that an inappropriate technology design can be a barrier for older people to using technology. The features recommended by Tyack and Camic (2017) were all embedded within the iCST app and the majority of the participants from our PPI consultation meetings, qualitative study and feasibility trial, found the iCST app to be intuitive. This was also likely due to the type of navigation included in the app which was a linear one rather than a hypertextual navigation as recommended by Castilla et al. (2016). There was a need for better signposting across the iCST app including better button placement and an increase in text size. The usability and acceptability across the various prototypes of the iCST app was rated well but slightly better by carers than people with dementia. Tyack and Camic (2017) also provide recommendations in terms of the content of a touch-screen intervention such as it should be tailored where appropriate to the user, including

the level of dementia, and should include a slight challenge so the user is invited to apply more complex cognitive skills rather than simpler ones. This is in accordance with findings from the majority of our interactions with end users: participants were keen on seeing more relevant content tailored to individual needs and interests. One carer in the qualitative study in particular suggested to include more levels in the iCST app so the content would be more appropriate according to the individual's progression of dementia. Furthermore, we also found that both people with dementia and carers would like the iCST app to include activities that could be done both together with a carer and separately by the person with dementia.

Finally, the development of the iCST app also included the perspectives of multiple stakeholders such as people with dementia, carers, and healthcare professionals from a different cultural context namely Indonesia which allowed for a more novel and comprehensive view on the intervention. Perspectives on use of technology to support daily life of people with dementia and carers were largely in line with findings from van Boekel et al. (2019). For instance, we found that people with dementia primarily used technology to make them feel happy and van Boekel et al. (2019) found that fun and pleasure facilitates use of technology among people with dementia. Perspectives on the iCST app were also similar to those from our qualitative study in the UK. Like with the UK study, participants in Indonesia valued the design of the app but there was a need for more tailored content e.g. according to the appropriate cultural context. In Indonesia, we also found there was a stronger need for someone to support people with dementia while using the app. In terms of facilitators and barriers towards accessing assistive technology (AT) in low and middle income countries (LMIC), the World Health Organisation (WHO) has identified the following gaps: (1) despite a high need for such resources, there

is a low demand due to lack of awareness among stakeholders, (2) lack of transfer of technological resources to low-resource settings and subsequent lack of user-involvement in the process, (3) barriers to supply including financial constraints and lack of capacity, and (4) lack of high-quality evidence on effectiveness of such technologies (Tangcharoensathien, Witthayapipopsakul, Viriyathorn, & Patcharanarumol, 2018). Most of these gaps were highlighted by healthcare professionals in our study who emphasized the need for awareness of such technologies across stakeholders and the need for end user involvement when adapting the iCST app to the Indonesian cultural context but also more structural issues such as poor internet connection. The WHO proposes several solutions to these gaps which are similar to solutions mentioned by our healthcare professionals such as a national policy framework for the adoption of AT, capacity building of personnel and training of (informal) carers, and an increase in awareness of AT (Tangcharoensathien et al., 2018). The WHO also proposed enhancing provision of AT through integrating it with current health services which can be further supported by involving carers while using AT as suggested by participants from our study.

8.2.2. Evaluation of the iCST app

There is a strong evidence-base behind the benefits of paper-based group cognitive stimulation for people with dementia (Spector et al., 2003; Woods et al., 2012). Earlier research has shown some promising findings regarding the benefits of computerised cognitive stimulation for people with dementia despite the general lack of research in this area (Garcia-Casal et al., 2017). For instance, both Zaccarelli, Cirillo, Passuti, Annicchiarico, and Barban (2013) and Tarraga et al. (2006) found improvements in the cognition of people with Alzheimer's disease (AD) after using a computerised cognitive stimulation programme for 12 and 24

weeks respectively. This is further supported by Astell et al. (2018) who found improvements in both the cognition and QoL of people with dementia after engaging in eight computerised cognitive stimulation activities. Unlike the iCST app, which is a carer-delivered cognitive stimulation programme, all the aforementioned studies encompass group-based computerised cognitive stimulation offered to participants using a standardised approach which may explain the differing results compared to those of the iCST app. Based on these studies, it seems that the effects of group computerised cognitive stimulation are more in accordance with the benefits of paper-based group CST (Spector et al., 2003). The iCST app is one of the first computerised, carer-delivered programmes of cognitive stimulation for people with dementia. But preliminary results from our feasibility trial, albeit based on a small sample making direct comparisons with larger RCTs difficult, are still more in line with paper-based, carer-delivered cognitive stimulation programmes. For instance, like with previous iCST research, we found improvements in the QoL of carers after using the iCST app. However, where paper-based iCST also led to benefits in the relationship quality from the person with dementia's perspective (Orrell et al., 2017), the iCST app did not lead to such effects nor on any of the other outcome measures for the person with dementia and carer. It should be noted that the feasibility trial was not powered to identify a difference if there was one. The findings are also consistent with Milders et al. (2013) who found that none of the cognition, except for verbal fluency, or well-being measures changed over the course of the study for people with dementia and carers after engaging in a paper-based, carer-delivered cognitive stimulation programme. Similar to findings from the iCST trial, the authors stressed that carers completed fewer than the number of recommended exercises (Milders et al., 2013). This was also the case for the iCST app but with the addition of

analytics to better monitor adherence, we were able to gain more reliable insights in the actual usage of the iCST app compared to paper-based programmes of individual cognitive stimulation. In terms of qualitative findings, the iCST app was deemed to be enjoyable and with some activities considered to be more mentally stimulating than others. These effects were also highlighted in qualitative research with paper-based iCST (Leung et al., 2017). In addition, in this study, offering the iCST app on a touch-screen tablet helped a small proportion of people with dementia to feel more confident in their cognitive abilities, and also to feel more comfortable with using the device over time. This is in accordance with findings from a systematic review by Tyack and Camic (2017) who found that using a touch-screen intervention could help enhance the sense of mastery of people with dementia.

8.3. Methodological problems

This complex project consisted of a considerable amount of research and development activities for which effective project and time management were required to successfully develop and evaluate the iCST app. I will reflect on some of the challenges I encountered during the project and how these were overcome.

As the project consisted of multiple stages, there were various overlapping timelines which led to some conflicts in the project activities. For example, the development of the iCST app overlapped with the narrative synthesis systematic review making it difficult to fully embed all of the best practice guidelines in the development process. I aimed to incorporate guidelines whenever these emerged in the app development especially relating to the ongoing involvement of people with dementia. Unfortunately, I was not able to involve a person with dementia and/or carer as a co-researcher who could provide consistent feedback on the

app. Despite having advertised the need for co-researchers on PPI communication channels, there was little to no response. This was partly remedied by organising multiple development sprints where feedback from end users including people with dementia and carers could be collected on several occasions.

Furthermore, delays in research led to delays in development and vice versa. For development, the creation and fine tuning of activities prior to testing them with end users required more time than anticipated. Delays in research were often caused by awaiting ethical approval for amendments or challenges in recruiting participants making it difficult to undertake the research. Recruitment proved to be more challenging than anticipated throughout the project. This could partly be attributed to time constraints (e.g. for the exploratory study in Indonesia). For the feasibility trial, difficulties in recruitment were often due to the eligibility criteria making it harder to recruit participants e.g. people who did not have an appropriate device for the iCST app. Originally, the iCST app was meant to be compatible with a wider range of devices but it became apparent that this would require significant development work for which there was a lack of time. There was also a need to explore the usefulness of the intervention prior to investing additional resources in its development. Regarding the trial, I was able to extend recruitment to ensure there was enough data for the analyses. However, this meant that part of the feasibility trial had to be managed while I was in Indonesia which is another example of conflicting project activities. The inclusion of the Indonesian perspective was a valuable addition as it enabled a more diverse perspective on the iCST app which was difficult to obtain in the UK considering our sample consisted of mainly white British participants.

Finally, adapting the content of the iCST app from paper-based iCST was challenging as a highly selective process was needed to significantly reduce the

content to fit with the app. Considering that paper-based iCST was already adapted from group CST, this may have led to the loss of key components that contribute to the benefits of CST e.g. a rich, social environment. This became apparent in the trial where some carers found it difficult to elicit conversation with the person they were caring for as they were not very talkative and enjoyed the game-like activities more. Furthermore, participants indicated that there was a need for a wider range of relevant activities tailored to the level of dementia as well. However, this feedback on the existing activities has given us good insights in the type of activities that are most appealing and how the app can be improved.

8.4. Future research

It is recommended to conduct a full-scale RCT with the iCST app with the necessary modifications to aspects of the study process and the intervention. These include refining the iCST app with more relevant content, inclusion of a sample size calculation based on intended power of the study and the smallest effect size of interest drawn from previous large-scale CST research, building capacity to support recruitment, and modifying the outcome measure selection including a better alternative for the Cornell Scale for Depression in Dementia (CSDD). In addition, adherence monitoring could be improved by analysing identifiable analytics during the study as in this study, anonymous analytics was analysed after study completion. This would make it easier to identify participants who have a lower adherence to the iCST app earlier in the study and provide them with more guidance on its use. This in combination with more content, could perhaps encourage participants to spend more time on the app. It would further help to determine the optimal dose of the iCST app in terms of achieving effectiveness.

CST has already been implemented in over 25 countries and future research could also include exploratory work with the iCST app in other countries while adhering to the CST adaptation guidelines. This could help to investigate the feasibility of implementing the app more internationally and thus improving accessibility for more people with dementia and carers. Furthermore, like with previous CST and iCST research, future research with the iCST app could examine its cost-effectiveness and also any facilitators and barriers to its implementation in policy and practice.

The iCST app must be kept 'live' meaning there will be a need for regular updates in terms of software and content making the iCST app highly dynamic for users. These will need to be supported by appropriate research activities to determine suitability of the updates and continued collaboration between the research and software development teams.

Lastly, while the iCST app has originally been developed for people with dementia, some feedback from stakeholders in the community suggested that the app has a broader applicability e.g. for people who feel isolated looking for activities to do together or for people learning English as it would encourage them to have conversations.

8.5. Implications for research, practice and policy

The study contributes to the existing, limited body of research surrounding computerised cognitive stimulation and will therefore be relevant for multiple stakeholders looking to develop or participate in such interventions. Its rigorous and evidence-based approach to the development of the iCST app with consistent involvement of people with dementia also sets an example and may be useful for future researchers and technology developers.

There is also a lack of apps for mental stimulation, leisure and enjoyment for people with dementia of which the latter is a common unmet need (Joddrell & Astell, 2016; Smith & Mountain, 2012). By developing a touch-screen version of iCST and making it commercially available in the Apple and Google Play stores, we have provided an additional resource to meet the needs of people with dementia which can also be used to spend meaningful time together as a dyad. We have aimed to increase the accessibility to a CST-based intervention both nationally and internationally, given appropriate cultural adaptation, for people with dementia who are unable to attend groups. This will give them an additional choice between paper-based and computerised iCST.

CST is widely used but there is an increased need for remote access to CST resources considering the COVID-19 pandemic. On the 11th of June 2020 I presented during a webinar on remote CST research which included CST by Zoom and the iCST app. This webinar was attended by 270 staff members from the National Health Service (NHS) and memory services, and generated a lot of interest in the iCST app in the UK but also New Zealand where the iCST app will be investigated in a small, exploratory study. Considering this interest in the iCST app and that it has been well-received along with its potential qualitative and quantitative benefits, national policy makers should consider supporting remote CST approaches including the iCST app. This could be done through adoption in NHS app library and the National Institute for Health and Care Excellence (NICE) guidelines following more research on effectiveness of the iCST app. This would help increase awareness and therefore the uptake of the app within the community.

8.6. Conclusion

To the best of our knowledge, this is the first study to develop and investigate a computerised, carer-delivered version of a cognitive stimulation programme for people with dementia. It is also the first study to develop and evaluate a touch-screen version of iCST and to investigate its potential for implementation internationally in Indonesia. An innovative, mixed methods approach to its development and evaluation led to the creation of the iCST app which was supported by active user-involvement. Feedback from people with dementia and carers indicated that the iCST app was useful and had good usability. Preliminary results are in accordance with previous iCST research and show improvements in the QoL of carers in a small sample. Furthermore, it has been deemed to be an enjoyable app appropriate for mental stimulation and engagement.

Based on results from the feasibility trial, its recommended to conduct a full-scale RCT with the iCST app including the necessary modifications to better understand its potential for effectiveness for people with dementia and carers. More research is also warranted to determine its cost-effectiveness, and to support its successful implementation and adoption in both policy and practice. The iCST app has a wider potential to be implemented internationally after careful adaptation to the appropriate cultural context and given other barriers towards accessing technology have been overcome where necessary. The iCST app has been released on the Apple and Google Play stores as ‘Thinkability’ and it is therefore hoped that it can become a routine, accessible intervention, like CST, for people with dementia globally who are in need of cognitive stimulation at home with the support of interactive technology.

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Appendices

Appendix 1: REC approval letter

Health Research Authority
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
Jarrow Business Centre
Rolling Mill Road
Jarrow
NE32 3DT
Telephone: 0207 104 8081

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

05 February 2018

Prof. Martin Orrell
Institute of Mental Health, Jubilee Campus
Triumph Road
Nottingham
NG7 2TU

Dear Prof. Orrell

Study title:	**Adapting individual Cognitive Stimulation Therapy for delivery by a web-application**
REC reference:	**17/YH/0405**
Protocol number:	**17064**
IRAS project ID:	**216780**

Thank you for your letter of 23rd January, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier

than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Clause 5 needs to be removed from the Interview Carer Consent Form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission 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 sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

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 [Feasibility Study Poster]	1.0	31 October 2017
Copies of advertisement materials for research participants [Feasibility Study Leaflet]	1.0	31 October 2017
Covering letter on headed paper [Covering Letter]	1.0	31 October 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Letter]	1.0	26 July 2017
GP/consultant information sheets or letters [GP Study Information Letter]	1.0	31 October 2017
Interview schedules or topic guides for participants [Focus Group Discussion Guide]	1.0	31 October 2017
Interview schedules or topic guides for participants [Interview Discussion Guide]	1.0	31 October 2017
IRAS Application Form [IRAS_Form_06112017]		06 November 2017
IRAS Application Form XML file [IRAS_Form_06112017]		06 November 2017
IRAS Checklist XML [Checklist_17012018]		17 January 2018
Letter from funder [Funding Award Letter]	1.0	12 May 2015
Letter from sponsor [Sponsor Letter]	1.0	03 November 2017
Non-validated questionnaire [CUA-Brief]		
Other [Specification iCST web-application]	1.0	31 October 2017
Other [Letter of contest]		15 December 2017
Other [Rebecca Griffiths CV (MSc student)]		07 January 2018
Other [Dr. Lauren Yates CV (supervisor MSc student)]		07 January 2018
Participant consent form [Focus Group Carer Consent Form]	1.0	31 October 2017
Participant consent form [Focus Group Participant Consent Form]	1.0	31 October 2017
Participant consent form [Interview Carer Consent Form]	1.0	31 October 2017
Participant consent form [Interview Participant Consent Form]	1.0	31 October 2017
Participant consent form [Study Carer Consent Form]	1.0	31 October 2017
Participant consent form [Study Participant Consent Form]	1.0	31 October 2017
Participant consent form [Post Trial Interview Carer Consent Form]	1.0	07 January 2018
Participant consent form [Post Trial Interview Participant Consent Form]	1.0	07 January 2018
Participant information sheet (PIS) [Focus Group Carer PIS]	2.0	07 January 2018
Participant information sheet (PIS) [Focus Group Participant PIS]	2.0	07 January 2018
Participant information sheet (PIS) [Interview Carer PIS]	2.0	07 January 2018
Participant information sheet (PIS) [Interview Participant PIS]	2.0	07 January 2018

Participant information sheet (PIS) [Study Carer PIS]	2.0	07 January 2018
Participant information sheet (PIS) [Study Participant PIS]	2.0	07 January 2018
Participant information sheet (PIS) [Post Trial Interview Carer PIS]	1.0	07 January 2018
Participant information sheet (PIS) [Post Trial Interview Participant PIS]	1.0	07 January 2018
Research protocol or project proposal [iCST web-application for people with dementia]	2.0	07 January 2018
Summary CV for Chief Investigator (CI) [Summary CV Martin Orrell]	1.0	31 October 2017
Summary CV for student [Harleen Rai CV]	1.0	31 October 2017
Summary CV for supervisor (student research) [Prof. Justine Schneider CV]	1.0	31 October 2017
Summary CV for supervisor (student research) [Prof. Martin Orrell CV]	1.0	31 October 2017
Validated questionnaire [ADAS-Cog]		
Validated questionnaire [QoL-AD]		
Validated questionnaire [CSDD]		
Validated questionnaire [NPI]		
Validated questionnaire [BADLS]		
Validated questionnaire [QCPR]		
Validated questionnaire [EQ-5D]		
Validated questionnaire [HADS]	1.0	31 October 2017
Validated questionnaire [CUSE]		
Validated questionnaire [SUS]		

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.

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

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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/qualityhttp://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/YH/0405	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Janet Holt Chair

Email:nrescommittee.yorkandhumber-bradfordleeds@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Ms. Angela Shone, University of Nottingham*
Ms. Shirley/S. Mitchell, Nottinghamshire Healthcare NHS Foundation Trust

Appendix 2: HRA approval letter

Health Research Authority

Prof. Martin Orrell
Institute of Mental Health, Jubilee Campus
Triumph Road
Nottingham
NG7 2TU

Email: hra.approval@nhs.net

09 March 2018

Dear Prof. Orrell

Letter of HRA Approval

Study title:	**Adapting individual Cognitive Stimulation Therapy for delivery by a web-application**
IRAS project ID:	**216780**
Protocol number:	**17064**
REC reference:	**17/YH/0405**
Sponsor	**University of Nottingham**

I am pleased to confirm that **HRA 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 from the HRA.

How should I continue to work with participating NHS organisations in England?

You should now provide a copy of this letter to all participating NHS organisations in England, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of HRA assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a

'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland, Scotland and Wales?

HRA Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland, Scotland and Wales.

If you indicated in your IRAS form that you do have participating organisations in one or more devolved administration, the HRA has sent the final document set and the study wide governance report (including this letter) to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with Northern Ireland, Scotland and Wales.

How should I work with participating non-NHS organisations?

HRA 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 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.

I am a participating NHS organisation in England. What should I do once I receive this letter? You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Ms. Angela Shone

E-mail sponsor@nottingham.ac.uk
Telephone 01158467906

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 **216780**. Please quote this on all correspondence.

Yours sincerely

Catherine Adams

Senior Assessor

Email: hra.approval@nhs.net

Copy to: Ms. Angela Shone, Sponsor's Representative

Ms. Shirley Mitchell, Nottinghamshire Healthcare NHS Foundation Trust

List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Feasibility Study Poster]	1.0	31 October 2017
Copies of advertisement materials for research participants [Feasibility Study Leaflet]	1.0	31 October 2017
Covering letter on headed paper [Covering Letter]	1.0	31 October 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Letter]	1.0	26 July 2017
GP/consultant information sheets or letters [GP Study Information Letter]	1.0	31 October 2017
HRA Schedule of Events	1	04 October 2017
HRA Statement of Activities	1	04 October 2017
Interview schedules or topic guides for participants [Focus Group Discussion Guide]	1.0	31 October 2017
Interview schedules or topic guides for participants [Interview Discussion Guide]	1.0	31 October 2017
IRAS Application Form [IRAS_Form_06112017]		06 November 2017
Letter from funder [Funding Award Letter]	1.0	12 May 2015
Letter from sponsor [Sponsor Letter]	1.0	03 November 2017
Non-validated questionnaire [CUA-Brief]		
Other [Specification iCST web-application]	1.0	31 October 2017
Other [Letter of contest]		15 December 2017
Other [Rebecca Griffiths CV (MSc student)]		07 January 2018
Other [Dr. Lauren Yates CV (supervisor MSc student)]		07 January 2018
Other [Response form Chair re condition of Favourable Opinion]		08 March 2018
Participant consent form [Post Trial Interview Carer Consent Form]	1.0	07 January 2018
Participant consent form [Post Trial Interview Participant Consent Form]	1.0	07 January 2018
Participant consent form [Focus Group Carer Consent Form]	1.0	31 October 2017
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Participant information sheet (PIS) [Post Trial Interview Participant PIS]	1.0	07 January 2018
Research protocol or project proposal [iCST web-application for	2.0	07 January 2018
people with dementia]		
Summary CV for Chief Investigator (CI) [Summary CV Martin Orrell]	1.0	31 October 2017
Summary CV for student [Harleen Rai CV]	1.0	31 October 2017
Summary CV for supervisor (student research) [Prof. Justine Schneider CV]	1.0	31 October 2017
Summary CV for supervisor (student research) [Prof. Martin Orrell CV]	1.0	31 October 2017
Validated questionnaire [QoL-AD]		
Validated questionnaire [CSDD]		
Validated questionnaire [NPI]		
Validated questionnaire [BADLS]		
Validated questionnaire [QCPR]		
Validated questionnaire [EQ-5D]		
Validated questionnaire [HADS]	1.0	31 October 2017
Validated questionnaire [CUSE]		
Validated questionnaire [SUS]		
Validated questionnaire [ADAS-Cog]		

Summary of HRA assessment

The following information provides assurance to you, the sponsor and the NHS in England that the study, as assessed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing, arranging and confirming capacity and capability.

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	At the time of submission an estimated 10 sites were expected, two have confirmed hence the discrepancy with Part C and the number of organisations detailed in IRAS.
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities will act as agreement of an NHS organisation to participate. The sponsor is not requesting and does not expect any other site agreement.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study

4.3	Financial arrangements assessed	Yes	No funding is to be provided to participating organisations as detailed in the Statement of Activities.
Section	**HRA Assessment Criteria**	**Compliant with Standards?**	**Comments**
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All organisations will be undertaking the same activity (i.e. there is only one 'site-type') as detailed in the study documents and protocol.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Principal Investigator is expected at sites to facilitate the recruitment process for our feasibility study. Activities will consist of checking the eligibility of potential participants against the criteria which will be provided by the research team, and facilitate the communication between potential participants (people with dementia and their carers) and the research team.

GCP training is not a generic training expectation, in line with the HRA/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.

It is expected that interviews will be undertaken at patient's homes or on University premises. No access arrangements are therefore required however DBS and OH checks are expected.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 3: Search strategy for the narrative synthesis systematic review (EMBASE)

Search Strategy:

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1 exp dementia/ (291039)

2 exp Alzheimer disease/ (158874)

3 (dement* or alzheimer*).ti,ab. (234814)

4 1 or 2 or 3 (330517)

5 exp INFORMATION TECHNOLOGY/ or exp TECHNOLOGY/ or exp ASSISTIVE TECHNOLOGY/ (211555)

6 exp human computer interaction/ (5488)

7 (HCI* or multimedia* or "touch screen*" or "self help device" or "mobile application*" or device* or application* or tablet* or mobile* or ehealth* or telehealth* or prototype* or "user computer interface" or "virtual systems" or "digital" or "web-based" or online* or internet*).ti,ab. (1814345)

8 5 or 6 or 7 (1975929)

9 exp product development/ (4411)

10 ("user participatory development" or "patient participation*" or "participatory research*" or "field test*" or "person with dementia" or "people with dementia" or "patient involvement" or user-validated or co-design or "participatory design" or "user involvement").ti,ab. (26611)

11 exp patient participation/ (21736)

12 9 or 10 or 11 (50207)

13 4 and 8 and 12 (515)

****

Appendix 4: Screenshot of activity priority list in Excel

page in book			Session	new unique name	what is the activity in the book?	Interactivity tablet	possible content	priority for Nottingham (scale 1-10)	priority for EUM (scale 1-10)
28	Instruction video		Being Creative I	Being creative 1	gardening, knitting, baking, making music, painting, dancing, flower arranging etc	instructions on tablet	-	1	10
29	Instruction video		Being Creative I	Being creative 2	gardening, knitting, baking, making music, painting dancing, flower arranging etc	instructions on tablet	-	1	10
30	Match		Number Games I	Put a price on it	put price on items in pictures (bread, book, pull, carr, house). Give hints ("money") with amounts of £1, £10, £100, £1000 etc	pictures of bread, book etc. Swipe the right "banknotes" to the pictures. Also: small house (and others) and villa (and others): which "banknote" combines with which picture?	Which price on what? Pictures of -House for sale -fast food menu? -newspaper -television -car	9	10
33	Game		Number Games II	Dots & boxes	play dots and boxes (pens in 2 colors and the empty grid are in book)	dots & boxes grid, draw with fingers and use 2 colors		9	8
34	Categorize		Quiz Games I	Old wives tales	Serie of old wives tales. Discuss whether they are they true or false. Did you ever hear them? Where do these tales come from? Why do we have them?	old wives tales with picture. Button "true" and "false" and a button for a short explanation on the answer.	This activity is an opportunity to explore ideas, and perhaps recall some fond memories! The old wives tale is just a first step to discussion: • Do you think any of the old wives' tales	8	
36	Select One		Quiz Games I	Quiz	answer the quiz questions, but don't care about right/wrong. Discuss topics in the questions.	Questions with ABC answers beneath. click right answer. Questions with audio/video/animation?	Can you guess the answers to the questions in the General Knowledge Quiz? Don't worry about the score, this is just for fun!	7	8
41	Fill in missing part		Quiz Games II	Song Quiz			Sound = Don't sit under the apple tree boxes: nice song / not so nice song Question to start discussion: What makes you like/dislike this song? Sound = On the street where you live boxes: nice song / not so nice song Question to start discussion: Do you like	8	10
42	Categorize		Sounds I	(un)pleasant sounds	write down which sounds are pleasant, which are irritating, where would you expect to hear them (use pictures), make categories (animal, machine, outdoor). Do these sounds bring back memories?	each picture has a sound (press to hear). Pictures can be moved to a "box" with category on it. Each sound has new choices	categories : outdoor/ indoor, animal/human, human/machine, young/old. Sounds: -goose -people talking in a large group -washing machine -children on playground	8	10

Appendix 5: PIS focus group – person with dementia

Participant Information Sheet – FOCUS GROUPS
(Final Version 3.0: 23-05-2018)
IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in our focus group about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have been shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

Why have I been invited?

You are being invited to take part in this focus group because you have had a memory assessment at some point.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

You will be part of a small group of six people, and will be given a presentation about the study by a researcher, who will show you a video clip of an iCST session, and some examples of activities and games to be administered during the sessions on a computer or tablet. In addition, you will be able to try some sessions out yourself. You will then have an opportunity to discuss your ideas and opinions on what you have seen with the group (e.g. ease of use and the look and feel of the program). Your feedback and views are very important in helping us to create the most suitable and relevant computerised programme of cognitive stimulation for people with dementia.

The focus groups will be held at the University of Nottingham (or a venue that is more local to you, exact location to be confirmed depending on focus group participants). Your participation in the focus group will last for approximately one and a half hour. Before you take part, you will be asked to sign a consent form. The focus groups will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The focus groups will begin around April 2018 and end no later than June 2018. During this time, four focus groups are planned. You are not obliged to attend more than one focus group. If you are unable to attend, or have a prior commitment, that will not be a problem. The minimum number of participants for a focus group will be six, plus the researcher. If this number cannot be reached, the focus group will be re-arranged. Once participants have expressed interest in taking part, they will be asked their preferences regarding focus group timings, for example days of week, time of day etc.

The focus groups will be organised by Harleen Rai who is a PhD student and Rebecca Griffiths who is an MSc student at the University of Nottingham.

Expenses and payments

Any travel expenses incurred by yourself will be reimbursed the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. The computerised version of iCST aims to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the focus group at any point.

What are the possible benefits of taking part?

Taking part in a focus group will be an enjoyable experience. You will meet people like yourself, and will be making a worthwhile contribution the research study. Previously, people participating in focus groups have reported that they have enjoyed the experience greatly. The advice and feedback we get from participants in the focus groups may help us to find new and effective ways to help people with dementia in the future.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations

to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the focus groups will appear in Harleen Rai's PhD thesis (submission in August 2019), Rebecca Griffiths' MSc thesis (submission in September 2018), and will be published in relevant academic journals.

Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Rebecca Griffiths
Institute of Mental Health – address as above
Email: msxrg9@exmail.nottingham.ac.uk

Thank you for considering taking part in the focus group!

Appendix 6: PIS focus group – carer

Carer Information Sheet – FOCUS GROUPS

(Final Version 3.0: 23-05-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in our focus group about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have been shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

Why have I been invited?

You are being invited to take part in this focus group because you support a person who has had a memory assessment at some point.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

You will be part of a small group of six people, and will be given a presentation about the study by a researcher, who will show you a video clip of an iCST session, and some examples of activities and games to be administered during the sessions on a computer or tablet. In addition, you will be able to try some sessions out yourself. You will then have an opportunity to discuss your ideas and opinions on what you have seen with the group (e.g. ease of use and the look and feel of the program). Your feedback and views are very important in helping us to create the most suitable and relevant computerised program of cognitive stimulation for people with dementia.

The focus groups will be held at the University of Nottingham (or a venue that is more local to you, exact location to be confirmed depending on focus group participants). Your participation in the focus group will last for approximately one and a half hour. Before you take part, you will be asked to sign a consent form. The focus groups will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The focus groups will begin around April 2018 and end no later than June 2018. During this time, four focus groups are planned. You are not obliged to attend more than one focus group. If you are unable to attend, or have a prior commitment, that will not be a problem. The minimum number of participants for a focus group will be six, plus the researcher. If this number cannot be reached, the focus group will be re-arranged. Once participants have expressed interest in taking part, they will be asked their preferences regarding focus group timings, for example days of week, time of day etc.

The focus groups will be organised by Harleen Rai who is a PhD student and Rebecca Griffiths who is an MSc student at the University of Nottingham.

Expenses and payments

Any travel expenses incurred by yourself will be reimbursed by the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you or the person you are caring for in taking part in this study. The computerised version of iCST aims

to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the focus group at any point.

What are the possible benefits of taking part?

Taking part in a focus group will be an enjoyable experience. You will meet people like yourself, and will be making a worthwhile contribution to the research study. Previously, people participating in focus groups have reported that they have enjoyed the experience greatly. The advice and feedback we get from participants in the focus groups may help us to find new and effective ways to help people with dementia in the future.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the focus groups will appear in Harleen Rai's PhD thesis (submission in August 2019), Rebecca Griffiths' MSc thesis (submission in September 2018), and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Rebecca Griffiths
Institute of Mental Health – address as above
Email: msxrg9@exmail.nottingham.ac.uk

Thank you for considering taking part in the focus group!

Appendix 7: Consent form focus group – person with dementia

PARTICIPANT CONSENT FORM – FOCUS GROUPS
(Final Version 1.5: 29-05-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 3.0 dated 23-05-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that focus groups will be facilitated and observed by the researcher who will make written notes about the discussion. Observations made during the sessions may be used in the study reports but these will be anonymised and kept confidential. ☐

4. I understand that the focus groups will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

5. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

6. I agree to take part in the above focus group. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Carer	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 8: Consent form focus group – carer

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Nottinghamshire Healthcare NHS
NHS Foundation Trust

CARER CONSENT FORM – FOCUS GROUPS
(Final Version 1.5: 29-05-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Carer:

Please initial box

1. I confirm that I have read and understand the information sheet version number 3.0 dated 23-05-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative/friend being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that focus groups will be facilitated and observed by the researcher who will make written notes about the discussion. Observations made during the sessions may be used in the study reports but these will be anonymised and kept confidential. ☐

4. I understand that the focus groups will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

5. I understand that relevant sections of my or my relative/friend's data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that personal details will be kept confidential. ☐

6. I agree to take part in the above focus group. ☐

Name of Carer	Date	Signature

Name of Relative/Friend

Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 9: Focus group discussion guide

Focus Group Discussion Guide – Final v1.5

1. Introduce ourselves, hand out information sheets and do consent forms

2. Present the research and the purpose of the focus group (incl. practicalities)

3. Explain ground rules and that we would like feedback regarding the iCST web-app in particular.

4. Ask if anyone has questions before the session begins

(10 min)

Start the tape:

1. Introductions

- Ask people to introduce themselves and tell the group how they feel today

(5 min)

2. iCST web-app introduction: we will have three touch screen tablets (and 1 laptop) available with the iCST web-app. Participants can use these devices in pairs and they will get the time to explore the application for themselves. Facilitators will give some instructions beforehand and will provide support wherever needed.

(5 – 7 min)

iCST web-app lay-out:

- What do you think about the size and font of the text?
- What do you think about the images e.g. size?
- Is the lay-out clear?
- What do you think about the use of colours?

(10 min)

iCST web-app content:

- What do you think about the content of the current sessions? E.g. diversity, relevance, enjoyment?
- Are concepts and terms explained well?
- Is the language used appropriate and easy to understand?
- Any mistakes in spelling / grammar?
- Are there any other features you think could benefit the iCST web-app?

(20 min)

3. Using the iCST web-app together:

- Are there any activities you do together?
- Would you consider using this application at home with one of your relatives or a close friend?
- If yes, what do you think about using this application together with the person you are caring for/you carer?
- What are some of the benefits or disadvantages you can think of while using the iCST web-app together?

(20 min)

4. Practical issues related to using the iCST web-app

- Would you have the time to spend 1.5 hours on the iCST web-app a week at home?
- Can you forsee any practical difficulties/challenges the participants might face if they were to use this application?
- What kind of support do you think you might need if you were to use this application?

(7 min)

5. General points about the iCST web-app:

- Overall, what do you like / dislike about the iCST web-app?
- Do you think it would be easy to use? Why or why not?
- Compared to a paper-based version, what do you think could be the additional benefits of computerised iCST?
- Are there any other comments you would like to make?

(7 min)

STOP TAPE

6. Finish with thanks, and information on what will happen next

Materials needed:

- *Consent forms + information sheets*
- *Three or four tablets (apple/android)*
- *1 laptop*

- *Pens and paper*
- *Projector in case bigger screen is needed*
- *White board*
- *Possibly iCST manuals*

Appendix 10: PIS interview – person with dementia

Participant Information Sheet - INTERVIEW
(Final Version 3.0: 23-05-2018)
IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in a one-to-one interview about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have been shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

Why have I been invited?

You are being invited to take part in this interview because you have at some point had a memory assessment.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

A researcher from the University of Nottingham will visit you in your home to explain the therapy in more detail and to show you a video clip of an iCST session, and some examples of activities and games to be administered during the sessions. You may try some of these activities and games yourself on a device such as a touch-screen tablet. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the researcher. We will ask you to reflect on your enjoyment and comprehension while interacting with the programme. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of computerised cognitive stimulation for people with dementia. At the end you will be asked to complete a short questionnaire relating to the programme.

The interview will last for approximately one and a half hour. Before you take part, you will be asked to sign a consent form. The interview will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The interviews will begin around April 2018 and end no later than June 2018. During this time, it is envisaged that 10 interviews will be held (five with people with dementia and five with carers). You do not have to attend more than one interview. If you are unable to attend, or have a prior commitment, that will not be a problem. Once participants have expressed a desire to take part, they will be asked their preferences regarding timing of the interview, for example days of week, time of day etc.

The interviews will be organised by Harleen Rai who is a PhD student and Rebecca Griffiths who is an MSc student at the University of Nottingham.

Expenses and payments

No travel expenses will be incurred by yourself as the researcher will visit you at home, but in the event that they are, you will be reimbursed by the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. The computerised version of iCST aims to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the interview at any point.

What are the possible benefits of taking part?

Taking part in an interview will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from people who take part in the interviews may help us to find new and effective ways to help people with dementia in the future.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of

confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the interviews will appear in Harleen Rai's PhD thesis (submission in August 2019), Rebecca Griffiths' MSc thesis (submission in September 2018), and will be published in relevant academic journals.

Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Rebecca Griffiths
Institute of Mental Health – address as above
Email: msxrg9@exmail.nottingham.ac.uk

Thank you for considering taking part in the individual interviews!

Appendix 11: PIS interview – carer

Carer Information Sheet - INTERVIEW

(Final Version 3.0: 23-05-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in a one-to-one interview about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have been shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

Why have I been invited?

You are being invited to take part in this interview because you support a person who has had a memory assessment at some point.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

A researcher from the University of Nottingham will visit you in your home to explain the therapy in more detail and to show you a video clip of an iCST session, and some examples of activities and games to be administered during the sessions. You may try some of these activities and games yourself on a device such as a touch-screen tablet. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the researcher. We will ask you to reflect on your comprehension and any practical issues while interacting with the programme. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of computerised cognitive stimulation for people with dementia. At the end you will be asked to complete a short questionnaire relating to the programme.

The interview will last for approximately one and a half hour. Before you take part, you will be asked to sign a consent form. The interview will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The interviews will begin around April 2018 and end no later than June 2018. During this time, it is envisaged that 10 interviews will be held (five with people with dementia and five with carers). You do not have to attend more than one interview. If you are unable to attend, or have a prior commitment, that will not be a problem. Once participants have expressed a desire to take part, they will be asked their preferences regarding timing of the interview, for example days of week, time of day etc.

The interviews will be organised by Harleen Rai who is a PhD student and Rebecca Griffiths who is an MSc student at the University of Nottingham.

Expenses and payments

No travel expenses will be incurred by yourself as the researcher will visit you at home, but in the event that they are, you will be reimbursed by the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you or the person you are caring for in taking part in this study. The computerised version of iCST aims to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the interview at any point.

What are the possible benefits of taking part?

Taking part in an interview will be a worthwhile experience. You will be making an important contribution to an important research study. The advice and feedback we get from people who take part in the interviews may help us to find new and effective ways to help people with dementia in the future.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of

confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the interviews will appear in Harleen Rai's PhD thesis (submission in August 2019), Rebecca Griffiths' MSc thesis (submission in September 2018), and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any

publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Rebecca Griffiths
Institute of Mental Health – address as above
Email: msxrg9@exmail.nottingham.ac.uk

Thank you for considering taking part in the individual interviews!

Appendix 12: Consent form interview – person with dementia

PARTICIPANT CONSENT FORM – INTERVIEWS
(Final Version 1.5: 29-05-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Please initial box

Name of Participant:

1. I confirm that I have read and understand the information sheet version number 3.0 dated 23-05-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential. ☐

4. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

5. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my ☐

participation in this study. I understand that my personal details will be kept confidential.

6. I agree to take part in the above interview. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____	_____	_____
Name of Carer	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 13: Consent form interview – carer

CARER CONSENT FORM – INTERVIEWS
(Final Version 1.5: 29-05-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Carer:

Please initial box

1. I confirm that I have read and understand the information sheet version number 3.0 dated 23-05-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or relative/friend being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential. ☐

4. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

5. I understand that relevant sections of my or my relative/friend's data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that personal details will be kept confidential. ☐

6. I agree to take part in the above interview. ☐

Name of Carer	Date	Signature

Name of Relative/Friend

Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 14: Interview discussion guide

Interview Guide – Final v1.5

1. Introduction, hand out information sheets and do consent form

2. Present the research and the purpose of the interview (incl. practicalities)

3. Explain the process of the interview and that we would like feedback regarding the iCST web-app in particular.

4. Ask if the participant has any questions before the interview begins

5. Try-out: the person with dementia and the carer will try-out a session together on the iCST web-application for about 15 to 20 minutes). The researchers will make some field notes. Hereafter, the person with dementia and carer will be interviewed separately.

(30 min)

Start the tape:

1. Introductions

- Short introduction and ask the participant to tell how he/she feels today.

(5 min)

2. iCST web-application: after the try-out session, we will ask the following questions.

iCST web-app lay-out:

- What do you think about the size and font of the text?
- What do you think about the images e.g. size?
- Is the lay-out clear?
- What do you think about the use of colours?

(5 min)

iCST web-app content:

- What do you think about the content of the current sessions? E.g. diversity, relevance, enjoyment?
- Are concepts and terms explained well?
- Is the language used appropriate and easy to understand?
- Any mistakes in spelling / grammar?
- Are there any other features you think could benefit the iCST web-app?

(15 min)

3. Using the iCST web-app together:

- Are there any activities you do together?
- Would you consider using this application at home with one of your relatives or a close friend?
- If yes, what do you think about using this application together with the person you are caring for/you carer?
- What are some of the benefits or disadvantages you can think of while using the iCST web-app together?

(15 min)

4. Practical issues related to using the iCST web-app

- Would you have the time to spend 1.5 hours on the iCST web-app a week at home? Would you like to as well?
- Can you forsee any practical difficulties/challenges you might face if you were to use/deliver (for the carer) this application?
- What kind of support do you think you might need if you were to use/deliver (for the carer) this application?

(10 min)

5. General points about the iCST web-app:

- Overall, what do you like / dislike about the iCST web-app?
- Do you think it would be easy to use? Why or why not?
- Compared to a paper-based version, what do you think could be the additional benefits of computerised iCST?
- Are there any other comments you would like to make?

(10 min)

STOP TAPE

6. Participant will be presented with a short usability questionnaire (CUA-Brief)

(5 min)

7. Finish with thanks, and information on what will happen next

Materials needed:

- *Consent form + information sheet*
- *Two touch screen tablets (apple/android or laptop)*
- *Internet access*
- *Pen and paper*
- *Possibly an iCST manual*
- *CUA Brief*

Appendix 15: Divisional ethical approval letter for study in Indonesia

University of Nottingham
UK | CHINA | MALAYSIA

DPAP Committee

20/03/2019

Supervisor: Martin Orrell

Applicant : Harleen Rai

Project: Project Id Exploring the attitudes of people with dementia and carers in Jakarta towards the CST application and related technology

A favourable opinion is given to the above named study on the understanding that the applicants conduct their research as described in the above numbered application. Applicants need to adhere to all conditions under which the ethical approval has been granted and use only materials and documentation that have been approved. If any amendments to the study are required, an amendment should be submitted to the committee for approval. An end of study form will be required once the study is complete.

yours

Professor David Daley

Co-Chair of DPAP Ethics Subcommittee

Professor Amanda Griffiths

Co-Chair of DPAP Ethics Subcommittee

Page 1 of 1

Appendix 16: PIS focus group Indonesia – person with dementia

University of Nottingham
UK | CHINA | MALAYSIA

School of Medicine
University of Nottingham
Medical School
Nottingham
NG7 2UH

PARTICIPANT INFORMATION

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: Determining the feasibility of implementing technology in the daily lives of people with dementia and carers in Indonesia

Researcher/Student: Miss Harleen Rai, Harleen.Rai1@nottingham.ac.uk

Supervisor/Chief Investigator: Prof. Martin Orrell, m.orrell@nottingham.ac.uk

Ethics Reference Number: 0280

We would like to invite you to take part in a research study about using technology in daily life for people with dementia and carers. Before you begin, we would like you to understand why the research is being done and what it involves for you.

What is the purpose of this study?

It can be difficult for people with dementia to stay mentally stimulated and engaged. Therefore, there are several psychological treatments in place to help relieve some of these symptoms. An example of such a treatment is Cognitive Stimulation Therapy (CST). It has shown to be an enjoyable and beneficial therapy for people with dementia and it is also offered in some memory clinics in Indonesia.

More recently, a computerised version of CST has been developed which can be used on touch-screen tablets such as iPads. This CST application can be used at home together with a relative/friend and consists of a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. This application is currently being tested in the United Kingdom.

We are interested to see if an application like this could be useful for people with dementia in Indonesia. However, at the moment we do not know much about the use of technology in the care for people with dementia. In order to explore this, we need to talk to people with dementia and their relatives/friends to uncover opinions/views about using technology as part of daily life. We would like to use the CST application as an example of a potential technology which could be

implemented in Indonesia. By doing so, we can take steps towards offering technology in the care of people with dementia.

Why have I been invited?

You have been invited to take part in this research study because you have lived experience with dementia. In addition, you have been invited because you attend a day centre and the centre has given permission to the research team to approach participants. If a staff member at the day centre has mentioned you should take part, you will not be under any obligation to do so.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You may change your mind about being involved at any time, or decline to answer a particular question. You are free to withdraw at any point before or during the study without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will I be asked to do?

If you choose to take part, you will participate in two research activities. One will be a focus group discussion and the other a try-out session with the CST application.

For the discussions, you will be part of a small group of four people and will be given an introduction about the study by a researcher. Hereafter, we will discuss various topics within the group for about one hour such as using technology in daily life, how it can be implemented in care for people with dementia, and the advantages and disadvantages of using technology.

For the try-out session, you will be paired up with your relative/friend and asked to try-out the CST application on an iPad (to be provided). This application consists of several game-like activities and under the guidance of the researchers you will be able to try it out for about 20 to 30 minutes. After, you will be asked to fill in a short questionnaire about the usefulness and ease of use of the application. This information will be helpful for us to understand whether something like this could be useful for people with dementia in Indonesia.

The research activities will be held at the day centre. Before you take part, you will be asked to sign a consent form and to answer some questions relating to demographics. The focus groups will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis and any potential publications in scientific journals. The try-out sessions will not be audio-recorded but some observations might be recorded by the researchers.

Will the research be of any personal benefit to me?

We cannot promise the study will help you but the advice and feedback we get from participants in this study may help may help us to find new and effective ways to help people with dementia in Indonesia in the future. More specifically, we will gain more knowledge on whether technology can be applied in the care for people with dementia.
In addition, taking part in a focus group can be an enjoyable experience. You will meet people
like yourself, and will be making a worthwhile contribution the research study. You will also have the opportunity to try out a new application which has not been used in Indonesia before.

Are there any possible disadvantages or risks in taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. However, in some cases the topics within the discussions could be upsetting. If this is the case for you, you will be free to leave the focus group at any point. In addition, you will be able to contact the researcher team for any additional support and questions.

What will happen to the information I provide?

We will follow ethical and legal practice and all information will be handled in confidence.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All personal details will be removed when the recordings from the focus group discussions are transcribed. Transcription will take place on a password protected computer by a member of the research team. The recordings will be deleted after the transcription process has been completed.
The data and findings from the research study will appear in Harleen Rai's PhD thesis and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example,

'carer' etc. We will keep you informed about the findings from the research study by providing you with a newsletter when the results have been analysed. Should you wish to have some more information about the findings, please do not hesitate to contact members of the research team directly.

At the end of the project, all raw data will be kept securely by the University under the terms of its data protection policy after which it will be disposed of securely. The data will not be kept elsewhere.

If you have any questions or concerns, please don't hesitate to ask. We can be contacted before and after your participation at the email addresses above.

What if there is a problem?

If you have any queries or complaints, please contact the student's supervisor/chief investigator in the first instance. If this does not resolve your query, please write to the Administrator to the Division of Psychiatry & Applied Psychology's Research Ethics Sub-Committee adrian.pantry1@nottingam.ac.uk who will pass your query to the Chair of the Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU, UK
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Dr. Tara Sani
Atma Jaya Catholic University – Neurology department
Jl. Pluit Raya No.2, RT.21/RW.8, Penjaringan, Kota Jkt Utara, Daerah Khusus Ibukota Jakarta 14440
Email: tara.sani@atmajaya.ac.id

Thank you for considering taking part in the research study!

Appendix 17: PIS focus group Indonesia – carer

University of Nottingham
UK | CHINA | MALAYSIA

School of Medicine
University of Nottingham
Medical School
Nottingham
NG7 2UH

PARTICIPANT INFORMATION – Carer (Relative/Friend)

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: Determining the feasibility of implementing technology in the daily lives of people with dementia and carers in Indonesia

Researcher/Student: Miss Harleen Rai, Harleen.Rai1@nottingham.ac.uk

Supervisor/Chief Investigator: Prof. Martin Orrell, m.orrell@nottingham.ac.uk

Ethics Reference Number: 0280

We would like to invite you to take part in a research study about using technology in daily life for people with dementia and carers. Before you begin, we would like you to understand why the research is being done and what it involves for you.

What is the purpose of this study?

It can be difficult for people with dementia to stay mentally stimulated and engaged. Therefore, there are several psychological treatments in place to help relieve some of these symptoms. An example of such a treatment is Cognitive Stimulation Therapy (CST). It has shown to be an enjoyable and beneficial therapy for people with dementia and it is also offered in some memory clinics in Indonesia.

More recently, a computerised version of CST has been developed which can be used on touch-screen tablets such as iPads. This CST application can be used at home together with a relative/friend and consists of a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. This application is currently being tested in the United Kingdom.

We are interested to see if an application like this could be useful for people with dementia in Indonesia. However, at the moment we do not know much about the use of technology in the care for people with dementia. In order to explore this, we need to talk to people with dementia and their relatives/friends to uncover

opinions/views about using technology as part of daily life. We would like to use the CST application as an example of a potential technology which could be implemented in Indonesia. By doing so, we can take steps towards offering technology in the care of people with dementia.

Why have I been invited?

You have been invited to take part in this research study because you are a relative/friend of a person with dementia and provide care for him/her. #

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You may change your mind about being involved at any time, or decline to answer a particular question. You are free to withdraw at any point before or during the study without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will I be asked to do?

If you choose to take part, you will participate in two research activities. One will be a focus group discussion and the other a try-out session with the CST application.

For the discussions, you will be part of a small group of four people and will be given an introduction about the study by a researcher. Hereafter, we will discuss various topics within the group for about one hour such as using technology in daily life, how it can be implemented in care for people with dementia, and the advantages and disadvantages of using technology.

For the try-out session, you will be paired up with your relative/friend and asked to try-out the CST application on an iPad (to be provided). This application consists of several game-like activities and under the guidance of the researchers you will be able to try it out for about 20 to 30 minutes. After, you will be asked to fill in a short questionnaire about the usefulness and ease of use of the application. This information will be helpful for us to understand whether something like this could be useful for people with dementia in Indonesia.

The research activities will be held at a venue that is local to you (exact location to be confirmed depending on focus group participants). Before you take part, you will be asked to sign a consent form and to answer some questions relating to demographics. The focus groups will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis and any potential publications in scientific journals. The try-out sessions will not be audio-recorded but some observations might be recorded by the researchers.

Will the research be of any personal benefit to me?

We cannot promise the study will help you but the advice and feedback we get from participants in this study may help may help us to find new and effective ways to help people with dementia in Indonesia in the future. More specifically, we will gain more knowledge on whether technology can be applied in the care for people with dementia.
In addition, taking part in a focus group can be an enjoyable experience. You will meet people
like yourself, and will be making a worthwhile contribution the research study. You will also have the opportunity to try out a new application which has not been used in Indonesia before.

Are there any possible disadvantages or risks in taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. However, in some cases the topics within the discussions could be upsetting. If this is the case for you, you will be free to leave the focus group at any point. In addition, you will be able to contact the researcher team for any additional support and questions.

What will happen to the information I provide?

We will follow ethical and legal practice and all information will be handled in confidence.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All personal details will be removed when the recordings from the focus group discussions are transcribed. Transcription will take place on a password protected computer by a member of the research team. The recordings will be deleted after the transcription process has been completed.
The data and findings from the research study will appear in Harleen Rai's PhD thesis and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example,

'carer' etc. We will keep you informed about the findings from the research study by providing you with a newsletter when the results have been analysed. Should you wish to have some more information about the findings, please do not hesitate to contact members of the research team directly.

At the end of the project, all raw data will be kept securely by the University under the terms of its data protection policy after which it will be disposed of securely. The data will not be kept elsewhere.

If you have any questions or concerns, please don't hesitate to ask. We can be contacted before and after your participation at the email addresses above.

What if there is a problem?

If you have any queries or complaints, please contact the student's supervisor/chief investigator in the first instance. If this does not resolve your query, please write to the Administrator to the Division of Psychiatry & Applied Psychology's Research Ethics Sub-Committee adrian.pantry1@nottingam.ac.uk who will pass your query to the Chair of the Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU, UK
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Dr. Tara Sani
Atma Jaya Catholic University – Neurology department
Jl. Pluit Raya No.2, RT.21/RW.8, Penjaringan, Kota Jkt Utara, Daerah Khusus Ibukota Jakarta 14440
Email: tara.sani@atmajaya.ac.id

Thank you for considering taking part in the research study!

Appendix 18: Consent form focus group Indonesia – person with dementia

University of Nottingham
UK | CHINA | MALAYSIA

School of Medicine
University of Nottingham
Medical School
Nottingham
NG7 2UH

PARTICIPANT CONSENT FORM – PERSON WITH DEMENTIA

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: Determining the feasibility of implementing technology in the daily lives of people with dementia and carers in Indonesia

Researcher: Miss Harleen Rai, Harleen.Rai1@nottingham.ac.uk

Supervisor: Prof. Martin Orrell, m.orrell@nottingham.ac.uk

Ethics Reference Number: 0280

- Have you read and understood the Participant Information? YES/NO
- Do you agree to take part in a focus group discussion that will be recorded about using technology in daily life? YES/NO
- Do you agree to take part in a try-out session with a touch-screen application and participate in a short questionnaire about the application? YES/NO
- Do you know how to contact the researcher if you have questions about this study? YES/NO
- Do you understand that you are free to withdraw from the study without giving a reason? YES/NO
- Do you understand that observations made during the sessions may be used in the study reports but these will be anonymised and kept confidential? YES/NO
- Do you understand that once you have been interviewed it may not be technically possible to withdraw your data? YES/NO
- Do you give permission for your data from this study to be shared with YES/NO

other researchers in the future provided that your anonymity is protected?

- Do you understand that non-identifiable data from this study including quotations might be used in academic research reports or publications? YES/NO
- I confirm that I am 18 years old or over YES/NO

_____		_____
Name of Participant	Date	Signature

_____
Name of Carer

_____		_____
Name of Person taking consent	Date	Signature

This consent form will be detached from the completed questionnaire and stored separately. Your answers will not be identifiable

Appendix 19: Consent form focus group Indonesia – carer

University of Nottingham
UK | CHINA | MALAYSIA

School of Medicine
University of Nottingham
Medical School
Nottingham
NG7 2UH

PARTICIPANT CONSENT FORM - CARER

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: Determining the feasibility of implementing technology in the daily lives of people with dementia and carers in Indonesia

Researcher: Miss Harleen Rai, Harleen.Rai1@nottingham.ac.uk

Supervisor: Prof. Martin Orrell, m.orrell@nottingham.ac.uk

Ethics Reference Number: 0280

- Have you read and understood the Participant Information? YES/NO
- Do you agree to take part in a focus group discussion that will be recorded about using technology in daily life? YES/NO
- Do you agree to take part in a try-out session with a touch-screen application and participate in a short questionnaire about the application? YES/NO
- Do you know how to contact the researcher if you have questions about this study? YES/NO
- Do you understand that you are free to withdraw from the study without giving a reason? YES/NO
- Do you understand that observations made during the sessions may be used in the study reports but these will be anonymised and kept confidential? YES/NO
- Do you understand that once you have been interviewed it may not be technically possible to withdraw your data? YES/NO
- Do you give permission for your data from this study to be shared with other researchers in the future provided that your anonymity is protected? YES/NO

- Do you understand that non-identifiable data from this study including quotations might be used in academic research reports or publications? YES/NO
- I confirm that I am 18 years old or over YES/NO

_____		_____
Name of Participant - Carer	Date	Signature

_____
Name of Relative/Friend

_____		_____
Name of Person taking consent	Date	Signature

This consent form will be detached from the completed questionnaire and stored separately. Your answers will not be identifiable

Appendix 20: Focus group discussion guide for study in Indonesia

Focus Group Discussion Guide

1. Introduce ourselves, hand out information sheets and do consent forms

2. Present the research and the purpose of the focus group (incl. practicalities)

3. Explain ground rules and that we would like feedback regarding the use of technology in particular.

4. Ask if anyone has questions before the session begins

(10 min)

Start the tape:

1. Introductions

- Ask people to introduce themselves and tell the group how they feel today

(5 min)

2. Attitudes towards technology

- How do you feel about using technology as part of your daily life? Is it a good thing or does it have more negatives?
- Do you think technology has the potential to assist you in certain areas? If so, which ones? If not, why not?
- What do you think the benefits of using technology could

be for you, if any?

(15 min)

3. Current use of technology

- Are there any pieces of technology you currently already use? If so, which ones?
- Do you see other people using technology around you e.g. children, friends?

(5 – 7 min)

4. Potential uses of technology

- What would you like to use technology for? E.g. games, communication, help around the house. Why?
- Would you need to support in order to use technology? What kind?

(5 – 7 min)

4. Practicalities of using technology

- What are some of the barriers you face in using technology?
- What would make it easier for you to use technology?
- How do you think access to technology can be improved?
- Are there any other points you would like to make?

(10 min)

STOP TAPE

5. Finish with thanks, and information on what will happen next

Materials needed:

- *Consent forms + information sheets*
- *Pens and paper*
- *Audio recorder*
- *Observation sheets*
- *iPad if necessary*

Appendix 21: Information leaflet feasibility study

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Nottinghamshire Healthcare NHS
NHS Foundation Trust

We are looking for participants with dementia for our research study

We are creating a computer application for people with dementia and carers. This application is based on individual Cognitive Stimulation Therapy (iCST). The idea is to keep the mind active and stimulated through fun activities and discussions all while using a computer device.

We are looking for participants with dementia and their carers (relative/friend) for our research study in which we will test this computer application over the course of a few weeks.

If you are interested in being part of this study or would like some more information, please do not hesitate to contact:

Harleen Rai, PhD student
Harleen.Rai@nottingham.ac.uk
07949 171 868

David Trevor, Research Delivery Officer
01158 231282

Appendix 22: PIS feasibility study – person with dementia

Participant Information Sheet – FEASIBILITY STUDY
(Final Version 2.5: 01-06-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in our research study about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have been shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

What happens in computerised iCST?

We recommend to using computerised iCST for 1.5 hours a week on a personal computer or a touch screen device such as a tablet. For example, this can be split into two sessions a week, each lasting 45 minutes, or three sessions a week each lasting 30 minutes. The intervention will last for 11 weeks and will be led by your relative/friend. The programme will include activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person.

Why have I been invited?

You are being invited to take part in this research study because you have had a memory assessment at some point.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

This study is a randomised trial. We need to see whether computerised iCST is better than receiving usual care, so we need to compare any changes experienced by people receiving computerised iCST to those receiving their usual care. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving computerised iCST. This means there is a 50% chance of you receiving computerised iCST and a 50% chance of not receiving computerised iCST or any other additional treatment to what you or your friend/relative are currently receiving. The decision is made by a computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of about 11 weeks. Following discussion of any questions you may have with a researcher, and signing the consent form, all participants will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours for an interview and to complete some questionnaires covering your quality of life, cognition (e.g. memory) and mood. The time stated to complete the interviews and questionnaires is an estimate; you and your relative/friend may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.

2. Repeat these questionnaires with the researcher after five weeks and then after another six weeks. This is to see whether any of these factors change as a result of the computerised iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

If you are allocated to the group which will not receive computerised iCST then you will not be asked to do anything beyond the aforementioned activities. You and your friend/relative will continue to receive the same treatment which you were receiving prior to this study.

However, if you are allocated to deliver the computerised iCST intervention, you and your friend/relative will continue to receive the same treatment which you were receiving prior to this study and you will additionally be asked to engage with computerised iCST for over 11 weeks. Your friend/relative will receive information on how to deliver the intervention.

Expenses and payments

No travel expenses will be incurred by yourself as you will not be required to travel for the purpose of this study, but in the event that they are, you will be reimbursed by the University of Nottingham.

What if I experience difficulties with understanding the research and making a decision?

All participants in research are invited to complete a consent form before the research commences. Sometimes it can be difficult to make a decision to consent to a research project. This is because there can be some challenges in understanding or retaining the information provided about the project. Sometimes it is possible to make a decision at the beginning of the project, but later this may become more difficult. In either of these circumstances, the research team is required to consult with someone who is involved in your care, such as a family member or friend, regarding whether your (continued) participation in the project is a good idea. If you have previously made an advance statement or advanced decision that is relevant, we would not do anything to go against this.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. The computerised version of iCST aims to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. Your relative/friend will be given guidance on what to do if you become anxious or distressed during sessions. If the intervention really does not suit you, you are free to finish at any point.

What are the possible benefits of taking part?

If you decide to take part and receive computerised iCST, we hope that it might be enjoyable for you. We also anticipate that the stimulating activities might improve some of your skills, including memory and language, and improve your quality of life. Such changes have been demonstrated through group CST. If you are not involved in computerised iCST but rather in the other group, you will still gain some valuable experience with participating in research and the outcomes of the questionnaires might be of interest to you. The information that we get from this study may help us to find new and effective ways to help people with dementia in the future, so you will be making a valuable contribution. In addition, both groups will get access to computerised iCST after the conclusion of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of

confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Involvement of the General Practitioner/Family doctor (GP)

We will ask for your permission to send your GP a letter explaining that you have agreed to take part in the study. A description of the study and practicalities will be given in this letter.

What will happen to the results of the research study?

The data and findings from this research study will appear in the student's PhD thesis (submission in August 2019) and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications without written consent.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Professor Martin Orrell
Institute of Mental Health – address as above
Phone: 0115 823 1291
Email: M.Orrell@nottingham.ac.uk

Thank you for considering taking part in the research study!

Appendix 23: PIS feasibility study – carer

Carer Information Sheet – FEASIBILITY STUDY
(Final Version 2.5: 01-06-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in our research study about a computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. More recently an individualised (one-on-one) version of CST (iCST) was developed, which is delivered by a carer (e.g. friend or family member) and involves taking part in a variety of activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person. A study showed iCST can improve the relationship between the person with dementia and the carer.

As a next step, we would like to explore a computerised version of iCST since technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial. Rather than a paper-based manual, a computerised version could be used on a computer, a touch-screen device such as a tablet (iPad) or a smartphone. We are interested to know whether a computerised version could be beneficial in improving cognition and quality of life for the person with dementia.

What happens in computerised iCST?

We recommend using computerised iCST for 1.5 hours per week on a personal computer or a touch screen device such as a tablet. For example, this can be split into two sessions a week, each lasting 45 minutes, or three sessions a week each lasting 30 minutes. The intervention will last for 11 weeks. You will deliver the sessions, and will receive training and ongoing support to help you with this. The programme will include activities such as being creative, word games and discussion of current affairs. The idea is to keep the mind active through enjoyable activities tailored to the interests and abilities of the person.

Why have I been invited?

You are being invited to take part in this research study because you support a person who has had a memory assessment at some point.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

This study is a randomised trial. We need to see whether computerised iCST is better than receiving usual care, so we need to compare any changes experienced by people receiving computerised iCST to those receiving their usual care. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving computerised iCST. This means there is a 50% chance of you receiving computerised iCST and a 50% chance of not receiving computerised iCST or any other additional treatment to what you or your friend/relative are currently receiving. The decision is made by a computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of about 11 weeks. Following discussion of any questions you may have with a researcher, and signing the consent form, all participants will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours for an interview and to complete some questionnaires. These will concern both the person you are caring for (asking questions about their quality of life, behaviour, mood, and activities of daily living) and yourself (asking questions about your general health, mood, and quality of life). The time stated to complete the interviews and questionnaires is an estimate; you and your relative/friend may take as many breaks as you want or

feel necessary, and even complete the process over two sessions if preferred.

2. Repeat these questionnaires with the researcher after five weeks and then after another six weeks. This is to see whether any of these factors change as a result of the computerised iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend if you live separately, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

If you are allocated to the group which will not receive computerised iCST then you will not be asked to do anything beyond the aforementioned activities. You and your friend/relative will continue to receive the same treatment which you were receiving prior to this study.

However, if you are allocated to deliver the computerised iCST intervention, you and your friend/relative will continue to receive the same treatment which you were receiving prior to this study and you will additionally be asked to:

1. Have a researcher visit you at home before the programme starts, and go through the sessions with you, helping to plan what you will be doing. This will include thinking about the interests and abilities of the person you are caring for and adapting the programme to suit their needs. The resources you have available at home will also be discussed. You will receive support from the research team throughout the study in the form of weekly telephone support (you will be able to indicate if this is necessary). At the end of each session, you will be asked for your reflections including how much you think the person is interested in and enjoying the sessions. This will be done on the computerised platform within the programme itself.

2. Some people will additionally be asked to be interviewed (alongside the person with dementia), to investigate the impact of the computerised iCST on the person with dementia's experience, both during the sessions and any generalised effects into everyday life, the carer role and carer relationship. Participation in this part of the study is entirely voluntary and whether or not you take part will have no impact on the rest of the study.

Expenses and payments

No travel expenses will be incurred by yourself as you will not be required to travel for the purpose of this study, but in the event that they are, you will be reimbursed by the University of Nottingham.

What if my relative/friend is unable to consent to take part, or loses the ability to consent?

All participants in research are invited to complete a consent form before the research commences. Sometimes people with dementia are unable to make a decision to consent to a research project because they have difficulty in understanding or retaining the information provided about the project. Sometimes people with dementia are able to do this at the beginning of the project, but later may not be able to provide their consent. In either of these circumstances, the research team is required to consult with someone who is involved in the person's care, such as a family member, regarding whether the person should participate, or continue to participate, in the project. If concerns do arise regarding your relative/friend's ability to consent, we would seek your advice regarding whether the person should participate and what you think the person's feelings and wishes would be regarding taking part. If the person has previously made an advance statement or advanced decision that is relevant, we would not do anything to go against this.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you or your relative/friend in taking part in this study. The computerised version of iCST aims to be stimulating and enjoyable and the level of risk in taking part is therefore minimal. During the support you will be given guidance on what to do if the person with dementia becomes anxious or distressed during sessions. If you face any difficulties with the programme or your computer device, we will support you in this as well. If the intervention really does not suit you or the person with dementia, you are free to finish at any point.

What are the possible benefits of taking part?

If you decide to take part, and your relative/friend is involved in computerised iCST, we hope that this may be of some help to them. We hope to see improvements in some of their skills including memory and language, and improve their quality of life. Such changes have been demonstrated through group CST. If you are not involved in computerised iCST but rather in the other group, you will still gain some valuable experience with participating in research and the outcomes of the questionnaires might be of interest to you. The information that we get from this study may help us to find new and effective ways to help people with dementia in the future, so you will be making a valuable contribution. In addition, both groups will get access to computerised iCST after the conclusion of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by

contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of

the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Involvement of the General Practitioner/Family doctor (GP)

We will ask for your permission to send your relative/friend's GP a letter explaining that you have both agreed to take part in the study. A description of the study and practicalities will be given in this letter.

What will happen to the results of the research study?

The data and findings from this research study will appear in the student's PhD thesis (submission in August 2019) and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications without written consent.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health (University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been

reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Professor Martin Orrell
Institute of Mental Health – address as above
Phone: 0115 823 1291
Email: M.Orrell@nottingham.ac.uk

Thank you for considering taking part in the research study!

Appendix 24: Consent form feasibility study – person with dementia

PARTICIPANT CONSENT FORM
(Final Version 1.5: 01-06-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Please initial box

Name of Participant:

1. I confirm that I have read and understand the information sheet version number 2.5 dated 01-06-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I agree to my GP being informed of my participation in this study. ☐

5. I understand that my carer and I may each participate in interviews with a member of the research team as part of this study. ☐

6. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential. ☐

7. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Carer	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix 25: Consent form feasibility study – carer

CARER CONSENT FORM
(Final Version 1.5: 01-06-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Carer:

Please initial box

1. I confirm that I have read and understand the information sheet version number 2.5 dated 01-06-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative/friend being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that relevant sections of my own data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that personal details will be kept confidential. ☐

4. I understand that my relative/friend and I may each participate in interviews with a member of the research team as part of this study. ☐

5. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential. ☐

6. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by ☐

name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc.

7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Carer	Date	Signature

_____
Name of Relative/Friend

_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix 26: PIS post-trial interview – person with dementia

Participant Information Sheet – POST TRIAL INTERVIEW

(Final Version 1.5: 01-06-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in a one-to-one interview about your experiences of using the computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

We developed a computerised version iCST in the hope of uncovering if this could potentially be beneficial in improving cognition and the quality of life of the person with dementia. We set out to investigate this as previous research on CST showed the intervention to be both enjoyable and beneficial, and it is now a recommended treatment. In addition, technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial as well.

Now that people have had a chance to use this computerised version of iCST, we would like get some valuable feedback from the users. This will help us better understand the effects of computerised iCST and we will also be able take into account what people liked or disliked about it. Hearing about first-hand experiences will help us improve the treatment and make it better suitable for future use.

Why have I been invited?

You are being invited to take part in this interview because you have completed 11 weeks of computerised iCST.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

This will be a joint interview with you and your relative/friend who helped using computerised iCST. A researcher from the University of Nottingham will visit you in your home (or your relative/friend's home) to talk about your experiences while using computerised iCST. You will be given the opportunity to discuss what you liked/disliked or what you might change to make computerised iCST better. A touch-screen tablet will be available for you and your relative/friend to point out any specific features you would like to talk about.

The interview will last for approximately one hour. Before you take part, you will be asked to sign a consent form. The interview will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The interviews will begin around September 2018 and end no later than December 2018. During this time, it is envisaged that five joint interviews will be held. You do not have to attend more than one interview. If you are unable to attend, or have a prior commitment, that will not be a problem. Once participants have expressed a desire to take part, they will be asked their preferences regarding timing of the interview, for example days of week, time of day etc.

The interviews will be organised by Harleen Rai who is a PhD student at the University of Nottingham.

Expenses and payments

No travel expenses will be incurred by yourself as the researcher will visit you at home, but in the event that they are, you will be reimbursed by the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. As you will have completed the intervention, the researcher will only ask you about your experiences, the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the interview at any point.

What are the possible benefits of taking part?

Taking part in an interview will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from people who take part in the interviews may help us to understand the effects of computerised iCST a bit better. In addition, sharing your experiences will help us improve the computerised version of iCST.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can

recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the interviews will appear in the student's PhD thesis (submission in August 2019) and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health

(University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Professor Martin Orrell
Institute of Mental Health – address as above
Phone: 0115 823 1291
Email: M.Orrell@nottingham.ac.uk

Thank you for considering taking part in the individual interviews!

Appendix 27: PIS post-trial interview – carer

Carer Information Sheet – POST TRIAL INTERVIEW

(Final Version 1.5: 01-06-2018)

IRAS Project ID: 216780

Title of Study: **Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application**

Name of Researcher: Harleen Rai

We would like to invite you to take part in a one-to-one interview about your experiences of using the computerised version of individual Cognitive Stimulation Therapy (iCST). Before you decide we would like you to understand why the research is being done and what it would involve for you. One researcher from our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Thank you for reading this information sheet.

What is the purpose of the study?

We developed a computerised version iCST in the hope of uncovering if this could potentially be beneficial in improving cognition and the quality of life of the person with dementia. We set out to investigate this as previous research on CST showed the intervention to be both enjoyable and beneficial, and it is now a recommended treatment. In addition, technology is increasingly becoming a bigger part of our daily lives and regular use of technology can be beneficial as well.

Now that people have had a chance to use this computerised version of iCST, we would like get some valuable feedback from the users. This will help us better understand the effects of computerised iCST and we will also be able take into account what people liked or disliked about it. Hearing about first-hand experiences will help us improve the treatment and make it better suitable for future use.

Why have I been invited?

You are being invited to take part in this interview because you have completed 11 weeks of computerised iCST.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or the standard of care you receive.

What will happen to me if I take part?

This will be a joint interview with you and your relative/friend with whom you have used computerised iCST. A researcher from the University of Nottingham will visit you in your home (or your relative/friend's home) to talk about your experiences while using computerised iCST. You will be given the opportunity to discuss what you liked/disliked or what you might change to make computerised iCST better. A touch-screen tablet will be available for you and your relative/friend to point out any specific features you would like to talk about.

The interview will last for approximately one hour. Before you take part, you will be asked to sign a consent form. The interview will be audio recorded and then the conversation will be transcribed and recorded for research purposes. This information will be held securely, and any remarks you make will be anonymised in the final PhD thesis.

The interviews will begin around September 2018 and end no later than December 2018. During this time, it is envisaged that five joint interviews will be held. You do not have to attend more than one interview. If you are unable to attend, or have a prior commitment, that will not be a problem. Once participants have expressed a desire to take part, they will be asked their preferences regarding timing of the interview, for example days of week, time of day etc.

The interviews will be organised by Harleen Rai who is a PhD student at the University of Nottingham.

Expenses and payments

No travel expenses will be incurred by yourself as the researcher will visit you at home, but in the event that they are, you will be reimbursed by the University of Nottingham.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks to you in taking part in this study. As you will have completed the intervention, the researcher will only ask you about your experiences, the level of risk in taking part is therefore minimal. Should you wish to, you are free to leave the interview at any point.

What are the possible benefits of taking part?

Taking part in an interview will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from people who take part in the interviews may help us to understand the effects of computerised iCST a bit better. In addition, sharing your experiences will help us improve the computerised version of iCST.

What if there is a problem?

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting Service Liaison Department / PALS (Local Services), Moorgreen House, Highbury Hospital, Bulwell, Nottingham, NG6 9DR.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof. Martin Orrell) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can

recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth.

Your contact information will be kept by the University of Nottingham for one year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The data and findings from the interviews will appear in the student's PhD thesis (submission in August 2019) and will be published in relevant academic journals. Participants' contributions will be anonymised and will not be identified in any publications, but verbatim quotes may be used and attributed to the type of participant, for example, 'carer' etc.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is led by Professor Martin Orrell who is Director of the Institute of Mental Health

(University of Nottingham). The research is being funded by H2020 Marie Skłodowska Curie Actions – Innovative Training Networks, 2015.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

Further information and contact details

For further information about the study please contact:

Harleen Rai
Division of Psychiatry and Applied Psychology, Institute of Mental Health
University of Nottingham, Triumph Road, Nottingham, NG7 2TU
Phone: 0115 748 4252
Email: Harleen.Rai@nottingham.ac.uk

Or

Professor Martin Orrell
Institute of Mental Health – address as above
Phone: 0115 823 1291
Email: M.Orrell@nottingham.ac.uk

Thank you for considering taking part in the individual interviews!

Appendix 28: Consent form post-trial interview – person with dementia

PARTICIPANT CONSENT FORM – POST TRIAL INTERVIEWS
(Final Version 1.5: 01-06-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Participant:

	Please initial box
1. I confirm that I have read and understand the information sheet version number 1.5 dated 01-06-2018 for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission.	☐
3. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential.	☐
4. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc.	☐
5. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my	☐

participation in this study. I understand that my personal details will be kept confidential.

6. I agree to take part in the above interview. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Carer	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 29: Consent form post-trial interview – carer

CARER CONSENT FORM – POST TRIAL INTERVIEWS
(Final Version 1.5: 01-06-2018)

Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application

IRAS Project ID: 216780

Name of Researcher: Harleen Rai

Name of Carer:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.5 dated 01-06-2018 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or relative/friend being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis with my permission. ☐

3. I understand that the interview will be facilitated by the researcher who will make written notes about the discussion. Observations made during the interview may be used in the study reports but these will be anonymised and kept confidential. ☐

4. I understand that the interview will be audio recorded. Participants' contributions will be anonymised and individuals will not be identified by name in the final PhD thesis or any publications, but verbatim quotes may be used and attributed to the identity of the participant, for example carer etc. ☐

5. I understand that relevant sections of my or my relative/friend's data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that personal details will be kept confidential. ☐

6. I agree to take part in the above interview. ☐

Name of Carer	Date	Signature

Name of Relative/Friend

Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 30: Post-trial interview discussion guide

Post-Trial Interview Guide – Final v1.0

1. Introduction, hand out information sheets and do consent forms

2. Present the purpose of the interview (incl. practicalities)

3. Explain the process of the interview and that I would like feedback regarding the iCST application in particular.

4. Ask if the participants have any questions before the interview begins

(15 min)

Start the tape:

1. Introductions

- Short introduction and ask the participants to tell how they feel today.

(5 min)

2. iCST application lay-out

- Overall, what do you think about the way the iCST application looks?
- What do you think about the way it is organized? E.g. was it easy to find your way through the iCST application?
- Any thoughts on included text and images? E.g. size, clarity.
- Are there any changes you would like to suggest? If so,

which ones?

(10 min)

3. iCST application content

- What do you think about the content of the current sessions? E.g. diversity, relevance, enjoyment?
- Are there any activities you particularly liked or disliked? Why?
- What would you like to see included in the iCST application?

(10 min)

4. Experience of using the iCST application:

- How would you describe your experiences of using the iCST application? (including using it together with your relative)
- Have you noticed any changes as a result of using the iCST application?
- Have you experienced any changes in your everyday life?
- Have you experienced any changes in your relationship with your relative?
- Bonus: did you find the iCST application mentally stimulating?

(15 min)

5. Practical issues related to using the iCST application

- How did you find embedding the iCST application within your daily/weekly routine? Did you have a particular

approach?

- Were there any practical difficulties/challenges over the last 11 weeks in using the iCST application?

(10 min)

5. General points about the iCST application:

- Overall, what do you like / dislike about the iCST application?
- Would you continue to use the iCST application? Would you find it valuable?
- Compared to a paper-based version, what do you think could be the additional benefits of using the iCST application?
- Are there any other comments you would like to make?

(10 min)

STOP TAPE

6. Finish with thanks, and information on what will happen next

Materials needed:

- *Consent forms + information sheets (both person with dementia and carer)*
- *One iPad with application*
- *Internet access*
- *Pen and paper*
- *Possibly an iCST manual*

Appendix 31: Introduction to Good Clinical Practice certificate

NHS
National Institute for Health Research

CERTIFICATE of ACHIEVEMENT

This is to certify that

Harleen Rai

has completed the course

Introduction to Good Clinical Practice eLearning (Secondary Care)

May 9, 2018

A practical guide to ethical and scientific quality standards in clinical research

Including EU Directives, Medicines for Human Use (Clinical Trials) Regulations & the Department of Health Research Governance Framework for Health & Social Care, as applied to the conduct of Clinical Trials & other studies conducted in the NHS

Modules completed:

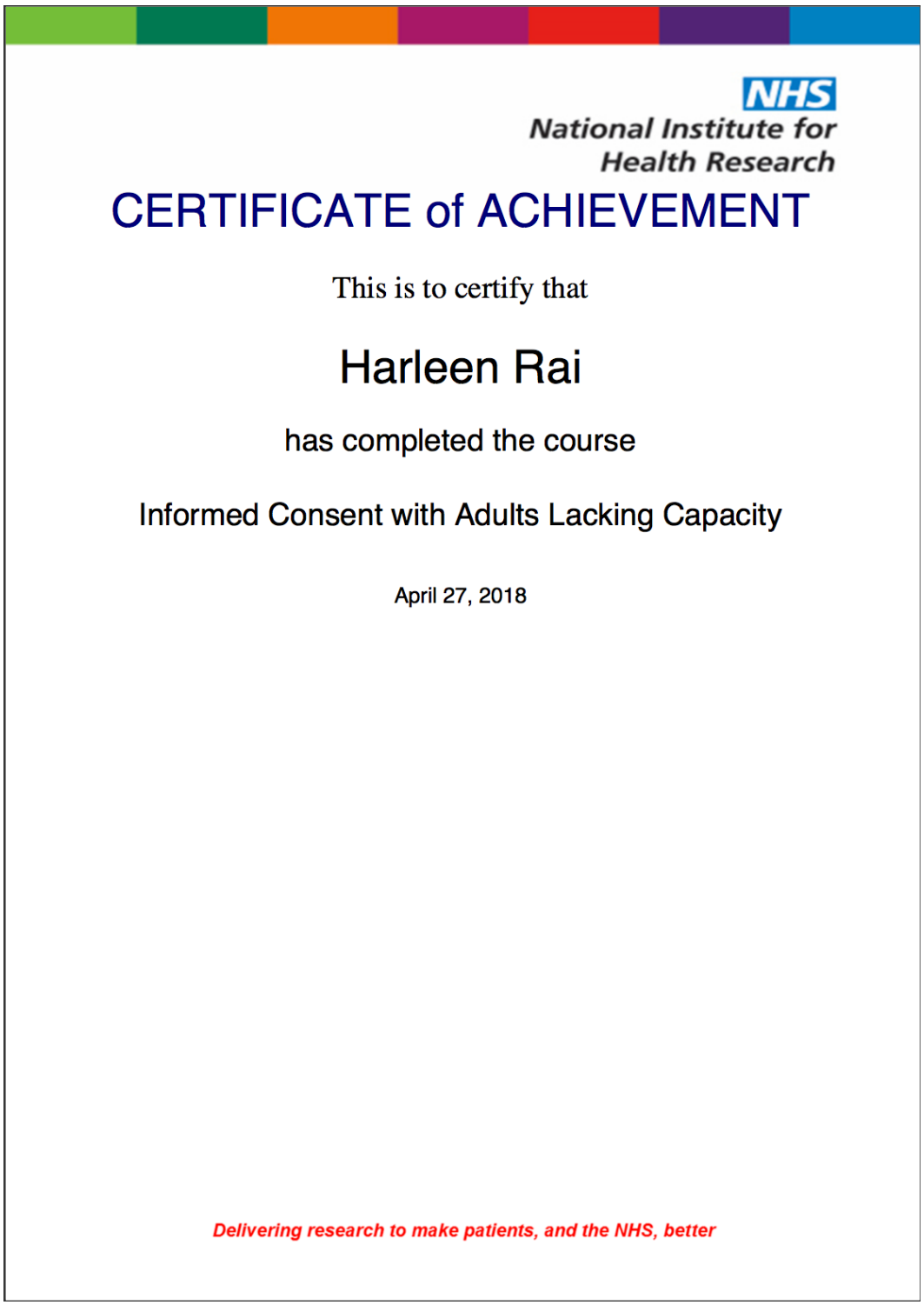
Introduction to Research and the GCP standards
Preparing to deliver your study
Identifying and recruiting participants: eligibility and informed consent
Ongoing study delivery and data collection
Safety Reporting
Study closure

This course is worth 4 CPD credits

CPD
The CPD Certification Service

Delivering research to make patients, and the NHS, better

Appendix 32: Informed Consent with Adults Lacking Capacity certificate



NHS
National Institute for Health Research

CERTIFICATE of ACHIEVEMENT

This is to certify that

Harleen Rai

has completed the course

Informed Consent with Adults Lacking Capacity

April 27, 2018

Delivering research to make patients, and the NHS, better

Appendix 33: Overview of all research and training activities during the course of the PhD

Trainings and basic studies with dates	**Masterclasses & Workshops** • Rapid Reading Workshop; University of Nottingham, UK (23/09/2016). • INTERDEM Academy Masterclass - Masterclass 'Involving people with dementia as advisors to your research' - 26th Annual Conference of Alzheimer Europe, October 2016. • Digital Research Strategy Workshop; University of Nottingham, UK, (27/04/2018). • Technology and Mental Health Masterclass; University of Nottingham, UK (04/12/2018). • Making Applications for Post-Doctoral Research Jobs; University of Nottingham, UK (28/01/2019). • Making Applications for R&D Jobs in Industry for Mid to Final Stage PhDs; University of Nottingham, UK (14/02/2019). • Dementia and BME; University of Leicester, UK (07/06/2019). • Research Funding Opportunities; University of Nottingham, UK (24/02/2020). • RA1 – Beginning a Systematic Review Protocol; Cochrane UK, Oxford, UK (04/02/2020). • RA2 – The Methods Section of the Protocol; Cochrane UK; Oxford, UK (05/02/2020). **Online Courses** • MOOC - POSADEM - Living with dementia: Personal perspectives (INDUCT) (11/16–12/16) • Informed Consent for Adults Lacking Capacity; NIHR, (27/04/2018) • Introduction to Good Clinical Practice; NIHR, May 2018 • Thinking Ahead – Exploring Career Options for PhD Students; University of Nottingham, February 2019. **Attended Academic Events** • TAnDem Arts and Dementia Conference; University of Nottingham, UK, September 2016. • 26th Annual Conference of Alzheimer Europe; Copenhagen, DK, October 2016. • Seminar on Fixing your Problems in Research; University of Nottingham, UK (21/02/2017). • Centre for Dementia seminar sessions (monthly), Institute of Mental Health, University of Nottingham, 2016-2018. • Digital Technology in Practice. NIHR MindTech National Symposium; London, UK, December 2017. • Seminar on GDPR; University of Nottingham, UK (27/04/2018). • ARUK Midlands Network Early Careers Day; Aston University, UK, April 2018. • Implementation Science: from principles to practice; University of Nottingham, UK (03/05/2018). • Dementia: Discover the Power of Research (ARUK); Nottingham, UK, (24/05/2018).

	• Health economics and some key challenges and solutions to economic evaluation in dementia; University of Nottingham, UK (19/02/2019); • Webinar COVID-19 and people with dementia and their carers; London School of Economics, UK (08/06/2020). **Courses offered by the University of Nottingham** • Introduction to Endnote (11/10/2016 & 01/03/2018); • Creating and Managing Long Documents in Word (25/10/2016); • Research ethics and the ethics review process for doctoral research (09/11/2016); • Planning your research (23/11/2016); • Systematic review (Medicine and Health Sciences Faculty) (01/12/2016); • Planning to Teach in Higher Education (05/12/2016); • Researcher Information Skills for Medicine & Health Sciences (07/12/2016); • Introduction to Qualitative Research (06/02/2017); • Getting into the Habit of Writing (23/02/2017); • What Do I Want to Get out of a Conference – and How Do I Get it? (10/04/2017); • Individual and Group Interviews (15 & 16/05/2017); • Presentation Skills for Researchers (14/11/2017); • Doing Focus Group Research (16/01/2018); • Various "Shut up and Write" sessions (2016-2018); • Introduction to quantitative methods (24/04 & 01/05/2018); • Identifying and managing intellectual property issues in research (14/05/2018); • Introduction to Research Data Management (23/05/2018); • Microsoft Powerpoint: Creating a Research Poster (05/06/2018); • Structuring your Thesis (14/01/2019); • Creating a strong argument for your thesis (22/01/2019); • Problems with academic writing (25/01/2019); • Introduction to database design (20/02/2019); • Microsoft Word: working smarter (03/07/2019); • MHSGC Doctoral Thesis write up support series - The Viva: The examiners side (22/10/2019); • MHSGC Doctoral Thesis write up support series – The Viva: the doctoral candidates perspective (29/10/2019); • MHS PhD Write Up support: Not falling at the last hurdle: dealing with the stress and isolation of writing (12/11/2019).
Secondments performed and foreseen with dates	• INTRAS/IDES, Spain: 06/2017-08/2017 • Alzheimer Disease International (ADI), Indonesia: 03/2019-05/2019
Networking and transfer of knowledge	• 1st INDUCT School, Maastricht, Netherlands, January 2017. • 2nd INDUCT School, Salamanca, Spain, September 2017. • 3rd INDUCT School, Witten, Germany, January 2018. • 4th INDUCT School, Prague, Czech Republic, September 2018. • 5th INDUCT School, London, United Kingdom, May 2019. • Visits to care homes in Nottingham, UK, 2016-2019. • Visit to a care home in Yokohama, Japan, April 2017.

	• Visit to Jaume I University in Castellon, Spain, September 2017. • Organised placement of visiting researcher from Copenhagen, Denmark, March/April 2018. • Supervision of an MSc student on the project: "Investigating the qualitative impact of individual Cognitive Stimulation Therapy (iCST) delivered via a web-application on the person with dementia and carer relationship". • Various visits to support groups (Kirkby-in-Ashfield), memory cafes (Eastwood), care homes (Radford Care Group) to recruit participants. • Set-up visit (including a journal club presentation and visits to care facilities) with Alzi/ADI, Jakarta, Indonesia, November, 2018.
Dissemination activities	**Presentations at Conferences/Events** • Oral presentation with ESR 6 at the Nottinghamshire EnRICH Forum. "Touch-screen Technology: using creative apps in care settings"; University of Nottingham, UK, February 2017. • Oral Pitch at World Young Leaders in Dementia (WYLD) Symposium. "INDUCT: Interdisciplinary Network for Dementia Using Current Technology." 32nd International Conference of Alzheimer's Disease International (ADI); Kyoto, Japan, April 2017. • Poster Presentation at 32nd International Conference of Alzheimer's Disease International (ADI). "Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application for people with dementia"; Kyoto, Japan, April 2017. • Poster presentation at the Institute of Mental Health Research day. "Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application for people with dementia"; University of Nottingham, UK, May 2017. • Poster presentation at the Symposium on Technologies for Dementia Care New Advances and Perspectives. "Developing a computerised version of individual Cognitive Stimulation Therapy (iCST) for people with dementia"; University of Salamanca, Spain, September 2017. • Poster presentation at 27th Annual Conference of Alzheimer Europe. "Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application for people with dementia"; Berlin, Germany, October 2017. • Oral presentation at 8th International Meeting of Psychogeriatrics. "Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application for people with dementia". Vilamoura, Portugal, November 2017. • Poster presentation and app demonstration at the 2nd International Cognitive Stimulation Therapy (CST) Conference. "Developing a computerised version of individual Cognitive Stimulation Therapy (iCST) for people with dementia"; Hong Kong, December 2017. • Oral presentation at 1st International Congress BestCare4Dem. "Cognitive Stimulation Therapy (CST): current and new perspectives; Amsterdam, the Netherlands, June 2018. • Oral & e-poster impact statement at M&HS Faculty Postgraduate Research Forum. "A Cognitive Stimulation App

	for People with Dementia and Carers"; University of Nottingham, UK, June 2018. • Oral presentation with ESR 6 at the Centre for Dementia Presentation. "Technology & Dementia: updates from the INDUCT project", University of Nottingham, UK, February 2019. • Oral presentation at the Sue Watson Event: 3rd prize winner. "Keeping up with the Digital Age: the involvement of people with dementia and carers in developing a new Cognitive Stimulation application", University of Nottingham, UK, March 2019. • Poster presentation at Alzheimer's Society Annual Conference. "Developing a Cognitive Stimulation application: the involvement of people with dementia and carers in a qualitative study", London, UK, May 2019. • Webinar at the virtual CST Zoom meeting. "Thinkability: the individual Cognitive Stimulation Therapy (iCST) application", Amsterdam, Netherlands, June 2020. **Written pieces** • Dementia Day-to-Day blog – "Using technology for meaningful activities in dementia care". • Alzheimer Europe Newsletter – "INDUCT is developing a Cognitive Stimulation Therapy (CST) application". • IMH Blog – "First INDUCT School was a success!". • IMH Newsletter – "INDUCT (Interdisciplinary Network for Dementia using Current Technology)". • INDUCT newsletter – "Breadcrumbs, burgers and bugs". • INDUCT newsletter – "Memories from the secondments". • Alzheimer Europe Newsletter – "INDUCT has its 3rd successful School including the Mid-Term Review". • IMH Newsletter - "INDUCT success at Mid-Term Review". • INDUCT Newsletter – "Feasibility trial in the UK open for recruitment!" • Alzheimer Europe Newsletter – "Bench-testing a new Cognitive Stimulation App with people with dementia and carers". • IMH newsletter – "Insightful visit to Indonesia chapter of Alzheimer's Disease International (ADI)". • INDUCT Newsletter – "Our INDUCT experiences".
Outreach activities (wider public, e.g. schools, local communities)	• I volunteer at a Memory Café in the community close to the University of Nottingham. The Memory Café is attended by people with dementia and family carers and during the sessions I have the opportunity to interact with the visitors while using touch screen tablets and teach them how to use various touch screen applications (e.g. games, arts, music). • I regularly attend meetings at the Institute of Mental Health with the general public in which I present about my work to lay people and gather advice about how to tailor the application I am developing to the needs and preferences of people with dementia and their carers. • Invited on a radio show named the 'D'-word to talk about Thinkability and INDUCT (out in April 2020).

Appendix 34: Report following secondment in Spain

Annex E: Secondment Research and Training Report (SRT)

ESR name and project number: Harleen Rai, ESR 5

Host Institution: I+D IDES / INTRAS Foundation

Name(s) of supervisor(s): Prof. Martin Orrell and Prof. Justine Schneider

Date: 11-09-2017

Start date of secondment: 05/06/17

End date of secondment: 18/08/17

Location, duration and local supervisor(s) at secondment location: Zamora, Spain; two and a half months; Prof. Manuel Franco.

Detail of activities and training achieved during secondment (max. 500 words)

Focus groups: Upon arrival a start was made with the development of the focus groups discussion guide for both people with dementia and carers. This was a collaborative effort between the ESR, research buddy, local supervisor and a qualitative research expert at INTRAS. The topic guide covered questions about paper-based iCST and the feasibility/acceptability of computerised iCST for Spanish users. The focus groups are set to take place in September (the ESR will not be present for this). They will be conducted by experts from the University of Salamanca in Spanish, translated results will be sent to the ESR in Nottingham (a copy of original raw data should ideally be provided as well). The ESR attended a course of focus groups and observed two other focus groups (all in Spanish).

Delphi consensus process: In order to consult with dementia experts about paper-based iCST and the feasibility/acceptability of computerised iCST, we employed the Delphi consensus process. Questions for the Delphi study were adapted from the focus group discussion guide for people with dementia and carers. A list of potential participants was provided by the local supervisor. A first round has been sent out at the moment (through Kwik Survey) and responses are awaited.

Jaume I University: Contact was established with the team at Jaume I University through email. The researchers have a great amount of experience with usability issues and technology based interventions. We agreed to meet before the summer school at the University in Castellon (20/09-22/09).

GRADIOR: The ESR tried out a few sessions with GRADIOR in order to obtain a better understanding of how it works and why. In addition, the ESR attended a neuropsychological assessment in Spanish where computerised cognitive tests were applied as well.

Spanish cultural context:

By working in a clinical environment the ESR was able to talk to people who visited the centre and made connections with the staff. This helped to build a better understanding of the Spanish cultural context and will facilitate setting up future work for the web-app.

Detail of any expected activities (from the initial plan) which were not accomplished (if any), with reasons (max. 500 words)

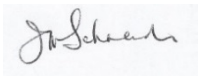
The activities related to the focus groups were not completed within the secondment. The groups had been set up on several occasions but had to be pushed back due to insufficient numbers of participants. Conducting groups during summer time made the process a bit more difficult as well since many people involved in arranging the group were away.

The secondment had to be concluded prematurely due to the first year confirmation of the ESR and the secondment of the research buddy which was due to start in August in Nottingham. It was necessary for the ESR to be present in Nottingham to help start her secondment. However, the ESR will spend a few days in Castellon which will add to her secondment duration.

ESR
Date & Signature

September 11, 2017

Supervisor
Date & Signature



September 9, 2017

Supervisor
Date & Signature

September 11, 2017

Secondment leader
Date & Signature

September 11, 2017