MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

Clinical Research Portfolio

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Chapter 1: SYSTEMATIC REVIEW

The Efficacy of Electronic Memory Devices for People with Dementia: A Systematic Review

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Abstract

Background

Memory problems are the most commonly reported difficulty in people with dementia. While electronic devices as a support for memory have been applied with success in other conditions, including brain injury, their effectiveness among the dementia population is not yet established.

Aims

The aim of this present review was to assess the efficacy of electronic memory devices for improving performance in tasks or activities of daily living in people with dementia and to consider the nature and methodological quality of the available evidence.

Method

Five databases were systematically searched. Intervention studies that examined electronic technology which has been designed to be an on-going aid to memory through reminding, alerting, storing, displaying or micro-prompting were included. Twenty-one papers were identified, which included thirty-three single case experimental design (SCED) studies. The Risk of Bias in N-of-1 Trials (RoBiNT) Scale (Tate et al., 2013) was used to rate the methodological quality of each SCED.

Results

Thirty-three SCEDs (mean of 15.4/30 on RoBiNT scale) were found. Baseline and intervention performance for thirty-eight participants in ten of the SCED studies was re-calculated using non-overlap of all pairs (Parker and Vannest, 2009), giving a mean score of 0.99 on a 0 to 1 scale.

Conclusions

Results from the current review suggest that electronic devices can improve performance on activities of daily living requiring memory, however the need for further, more rigorous, investigations with this population remains.

Introduction

Demographic Shift

It is estimated that there are close to 50 million people worldwide currently living with dementia (Prince et al., 2016). With better standards of living and improved healthcare, people are living longer; hence the number with dementia is likely to double every 20 years, reaching 131.5 million by 2050 (Prince et al., 2016). While the greatest impact of dementia is progressive destruction of quality of life and the likelihood of an earlier death, there is also an economic cost to be considered. Currently, the national direct and indirect costs of caring for an individual with dementia in the UK exceeds £26 billion (Prince et al., 2014). While these costs include health and social care, the greatest cost identified (£12.4 billion) is time given by unpaid carers to people with dementia (Lewis et al., 2014).

Taking both the psychological and economic impact of dementia into account, there has been an increasing emphasis placed on early diagnosis (Salmon and Bondi, 2009). Early diagnosis, theoretically, allows access to interventions and medications that may sustain cognition, mental wellbeing and quality of life. This prolonged independence can delay the need for care home or hospital admission, which ultimately adds savings to the health economy (Knapp et al., 2015).

Dementia

Dementia is an umbrella term used to describe a group of diseases that cause cognitive impairment. Alzheimer's disease is the most common cause of dementia, accounting for around 62% of dementia diagnoses in the UK (Lewis et al., 2014). Other common dementias include vascular dementia, frontotemporal dementia and Lewy Body dementia. While each dementia can result in a multitude of cognitive impairments, memory problems are the most commonly reported difficulty in people with dementia. Memory problems include difficulties recalling past information, as well as remembering to do something in the future (prospective memory)(Smith et al., 2000). This includes remembering to attend appointments, take medication or pay a bill.

Cognitive Rehabilitation

Cognitive rehabilitation (CR) is an individualised approach of helping people with cognitive impairments identify personally relevant goals and devise strategies for addressing them (Wilson, 2002). Unlike cognitive training, (which typically involves guided practice on a set of standardised tasks in a structured environment, aiming to improve or maintain ability in a specific cognitive domain), cognitive rehabilitation approaches tend to be implemented in real-world settings, with emphasis on improving functioning and independence in an everyday context and environment (Clare and Woods, 2004; Bahar-Fuchs et al., 2013).

Compensatory CR approaches focus on teaching people to adapt to, or bypass, their cognitive impairment using internal or external strategies. Through mastery of compensatory strategies, it is assumed that the individual will be able to manage in everyday environments, despite the presence of an underlying impairment (Dewar et al., 2016). Strategies identified include

teaching people to utilise learning techniques such as errorless learning, mnemonics and rehearsal, and external aids, including calendars, diaries and pagers.

Memory Aids

External memory aids are the most effective and widely used intervention for the rehabilitation of memory impairments (Sohlberg, 2005; Sohlberg et al., 2007). According to Sohlberg (2006, p.51), an external memory aid is a tool or device that "either limits the demands on the person's impaired ability or transforms the task or environment such that it matches the client's abilities". Devices currently available include non-electronic (e.g. calendars, post-it notes) and electronic memory aids (e.g. pagers, smart phones). In surveys of people with memory impairments as a result of brain injury, asking someone to remind them, calendars, lists and diaries were among the most frequently used memory aids (Evans et al., 2003; Jamieson et al., 2017a).

The efficacy of non-electronic memory aids for people with dementia has been investigated in several studies (e.g. Bourgeois, 1992; Hanley and Lusty, 1984). These include the use of memory wallets and books to enhance conversation skills (e.g. Bourgeois, 1992) photographs and memory boxes to increase room finding (Nolan *et al.* 2001)(Nolan et al., 2001) and memory notebooks to reduce stress and distress (Johnson, 1998). While non-electronic aids have been widely available for a number of years, advances in technology have led to growing interest in the field of assistive electronic technology for supporting cognitive impairment. Electronic memory aids are potentially superior to their non-electronic equivalents as they can offer time- or event- specific reminders in various modalities, can be programmed to help organise and plan daily activities, and can be interactive .

Electronic Memory Aids

Electronic devices as a support for prospective memory have been applied with success in various conditions, including brain injury. For example, the NeuroPage system (Wilson et al., 1997; Wilson et al., 2001), a pager system which sends reminders for target behaviours at a pre-agreed time, has been shown to be successful at improving target behaviour performance in people with encephalitis (Emslie et al., 2007), traumatic brain injury (Wilson et al., 2005), and cerebrovascular disease (Fish et al., 2008). Other aids demonstrating similar success within the brain-injured population include voice recorders, personal data assistants (PDA), smartphones, calendars operated on a computer, and watches with alarms (see Kapur et al., 2004; Kapur and Wilson, 2009; Jamieson et al., 2017b). In a recent meta-analysis of seven group studies, a strong evidence base for the efficacy of electronic prospective memory-prompting devices for people with an acquired brain injury (ABI) was identified ($d = 1.27$; $n = 147$) (Jamieson et al., 2014).

Electronic Memory Aids and Dementia

In their review of assistive technology for people with dementia, Bharucha et al., (2009) acknowledged the wide range of commercially available and emerging assistive technologies for cognition (ATC), however noted a paucity of clinical trials evaluating their use within the

dementia population. They further raised concerns about the generalizability of these technologies as they were developed principally for younger people with brain injury. In a review of cognitive prosthetic technology for people with memory impairments, studies investigating their use among the dementia population accounted for only 18% (eight studies) of all studies identified (Jamieson et al., 2014). These were identified as single case experimental designs (SCED's). Furthermore, the efficacy of the technology used could only be evaluated in three of these eight studies due to insufficient raw data available for meta-analysis in the other studies. A large effect size (Non Overlap of All Pairs (NAP)> 0.93) was noted for these three studies, providing preliminary evidence of the benefits of ATC among the dementia population.

Present Review

The aim of the current paper was to review the methodological quality and results of studies that have investigated the use of electronic prospective memory aids with people with dementia. Studies testing any prospective memory aid or device designed to support future intentions, plan retention or task organisation were considered. In their review, differentiated between prospective prompting devices (PPDs) and micro-prompting devices (MPDs). PPDs support the ability to retain future intentions in the medium and long term (e.g. Neuropage), while MPDs are designed to support plan retention and task organisation in everyday tasks with multiple steps (e.g. following a recipe) . Since the review of Jamieson et al. (2014) a significant number of new studies have been published and hence a new review was considered appropriate.

A Cochrane review evaluating the efficacy of ATC for memory support in people with dementia has recently been published (Van der Roest et al., 2017). This review limited its search to randomised controlled trials (RCTs) and clustered randomised trials with blinded assessment of outcomes and identified no studies that met the inclusion criteria. Although the present review included similar outcome measures, the inclusion criteria were expanded to include single case experimental designs (SCEDs). While randomised group designs are methodologically strong, because they minimise internal validity threats, SCEDS provide a rigorous, methodologically sound alternative method of evaluation (e.g. Kratochwill and Levin, 2010). The Oxford Centre for Evidence-Bases Medicine currently ranks the n-of-1 trial as Level 1 evidence for treatment decision purposes in individual patients, alongside systematic reviews of multiple RCT's (Tate et al., 2013).

Objectives

- To evaluate the effectiveness of electronic prospective memory aids for people with dementia on performance in tasks or activities of daily living.

- To consider the nature and methodological quality of available evidence on this topic.

- To assist in establishing the appropriateness of technological prospective memory aids as an appropriate memory intervention for people with dementia.

Method

Eligibility Criteria

Participants

Studies were limited to people with a diagnosis of dementia, regardless of clinical course or length of time since diagnosis. Studies with mixed diagnosis samples were included if individual data were reported for the participants with dementia. Memory impairments were not defined in advance and it was assumed that people receiving the technological intervention had memory impairments. Participants were aged 18 years and above.

Intervention

Any papers that examined electronic technology which has been designed to be an aid to memory through reminding, alerting, storing, displaying or micro-prompting were included. This technology could take the form of both short-term reminding (reminding the patient of each step required to complete a task such as coffee preparation) and long-term reminding (e.g. reminding the patient to attend an appointment at a certain time).

Comparators/Context

The review included studies that investigated task performance with technology compared to performance without technology or with performance with a non-technology based control treatment.

Outcome

Only studies that reported quantitiative outcome measures, which reflect memory-based functioning in activities of daily living that require prospective memory, were included. Qualitative feedback in the form of interviews, focus groups, usability outcomes, amount of usage outcomes or well-being outcomes were excluded.

Study Type/Design

Studies evaluating the effectiveness of interventions were considered for review, and included RCT's, controlled clinical trials (CCT's), before and after designs, and SCED's. A study was deemed to be a RCT on the basis that the trial participants were definitely or probably assigned prospectively to one or two (or more) alternative forms of intervention using random allocation (Higgins and Green, 2011). SCED studies were distinguished from descriptive case reports by the inclusion of a control phase, either through multiple baseline measures or a separate control measure that allowed the causal impact of the treatment efficacy to be inferred, as in reversal/withdrawal (ABA) designs (Tate et al., 2008).

Studies not published in the English language were excluded, as were any reviews, dissertations, conference abstracts and book chapters.

Search Strategy

The following electronic bibliographic databases were searched from inception up until 16th of June 2017: Medline, PsychINFO, EMBASE, CINAHL and PsycBITE. All the databases were searched via the Glasgow University online services (http://eleanor.lib.gla.ac.uk/search~S0/y). The search strategy used and modified for all databases can be found in Appendix 1.2.

Titles and abstracts were examined to identify articles featuring prospective memory devices and dementia. Reference lists of included studies were also checked to identify further relevant papers.

Rating of Methodological Quality

Selected papers were categorised into group studies and single case experimental designs, based on the selected criteria. Only SCED studies were identified. The tool used to rate the methodological quality of each SCED was the Risk of Bias in N-of-1 Trials (RoBiNT) Scale (Tate et al., 2013). The scale consists of 15 items in two subscales: the Internal Validity (IV) Subscale (7 items) and the External Validity and Interpretation (EVI) Subscale (8 items). Points range from 0-2 on each item, with a maximum possible score of 30. A copy of the RoBiNT record form, listing scale items and summaries of rating criteria, can be found in Appendix 1.3. This form was used in conjunction with the manual offered by Tate et al. (2013) for rating each paper.

All papers were rated by the author, and a second rater assessed 25% of the papers to establish inter-rater reliability of the checklists. Across all the checklist items in the methodological quality rating tools, there was 88% agreement between raters, suggesting adequate reliabilty.

Efficacy Rating

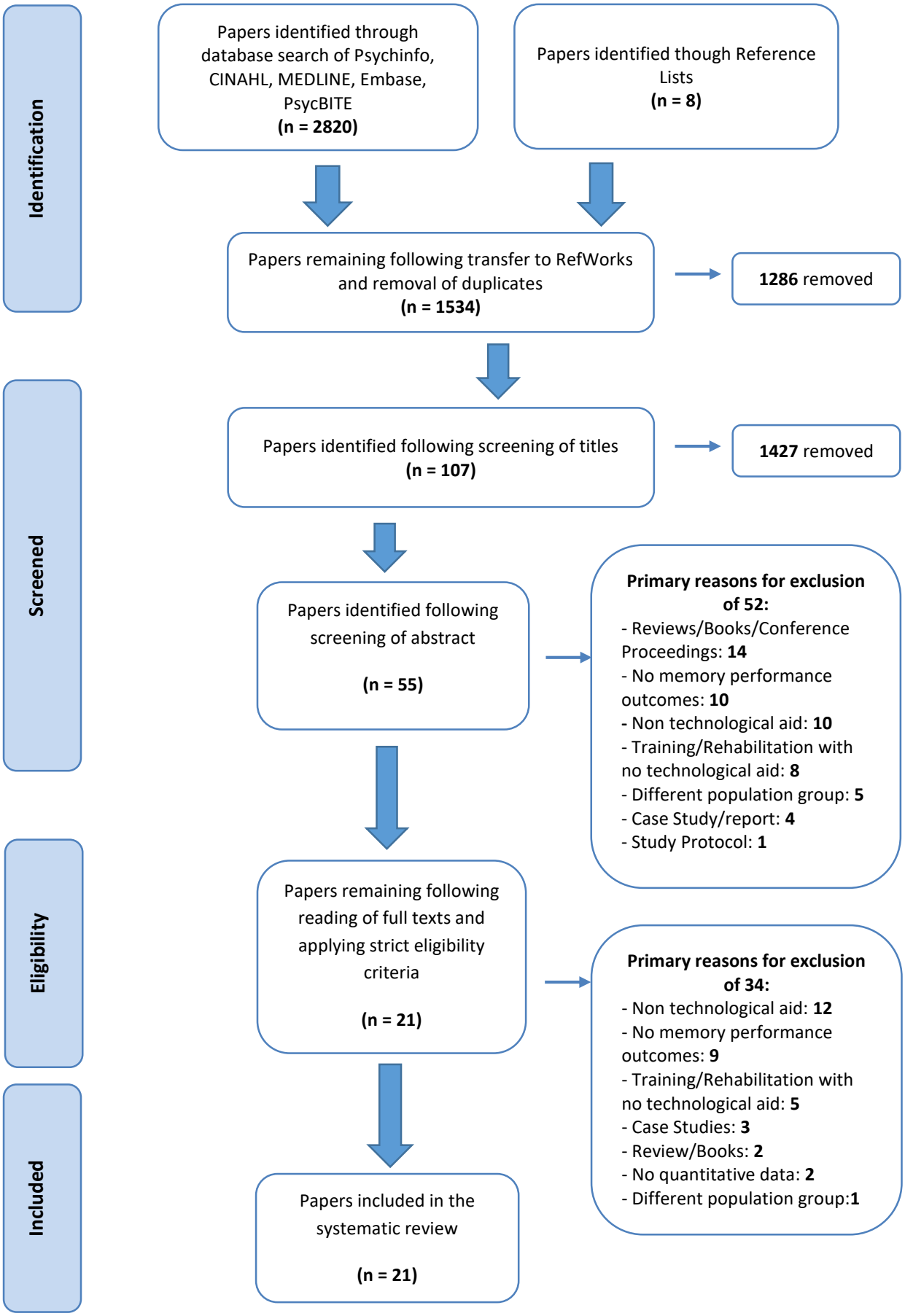
Non-overlap of all pairs (NAP) analysis was performed to evaluate the impact of the intervention phases on performance compared to baseline phases. NAP is a nonparametric technique that calculates a percentage of non-overlapping data by investigating the extent to which each data point in phase A (baseline) overlaps with each data point in phase B (intervention)(Parker and Vannest, 2009). NAP scores range from 0 to 1; scores closer to 0 are considered less effective, as the proportion of overlapping pairs are larger. Interventions closer to 1 are considered more effective, due to the smaller proportion of overlapping pairs. Only SCED papers that reported participant's raw data, and included at least two data points in each phase, could be included in the NAP analysis.

Results

Study Selection

Figure 1.1 is a flowchart showing details of the search process and results.

Figure 1.1. Flow Diagram of Selection of Paper for Inclusion in the Systematic Review



Study Characteristics

Twenty-one papers were identified; a detailed description of the included papers is given in Table 1.1, providing details on: the type of dementia (and severity) of patient groups, setting, design, the type of technology tested, target outcome, methodological rating and technology efficacy of the studies included in this review. Overall, the studies examined 146 participants. All studies were conducted in the developed world. Four studies were conducted in Canada (Labelle and Mihailidis, 2006; Mihailidis et al., 2001; Mihailidis et al., 2004; Mihailidis et al., 2008), two in Taiwan (Chang et al., 2011; Chang et al., 2013) and the rest in Italy. Most studies took place in a day centre (43%), followed by rehabilitation/long term care unit (38%), and residential unit (14%); while one study took place in a pizza store (Chang et al., 2013).

SCED's

All papers included in the systematic review were SCED's. Eight of the papers identified included more than one study in their publication (e.g. Lancioni et al., 2010), and therefore each SCED study was individually assessed using the RoBiNT scale. Thirty-one (94%) investigated the efficacy of micro-prompting devices, and two (6%) investigated prospective prompting devices. A total of thirty-three SCED's were evaluated; the mean RoBiNT scale score for all SCED studies was 15.8/30 (range = 10 – 22). The highest score recorded was for Mihailidis et al.'s (2008) study (SCED score = 22) using the COACH system to improve handwashing. This was followed by Labelle and Mihailidis's (2006) study (SCED score = 20), which also used the COACH system. Chang et al.'s (2013) study, using the Kinept system to prepare a pizza, scored the lowest (SCED score = 10).

Table 1.1. Details of Studies Included

Author (Year), Country	Type of Dementia of Participants [severity if specified] (number)	Setting	SCED Design	Technology Type (name)	Target Behaviour	Method Quality Rating Score on RoBiNT scale	Effect size (NAP) [reason for exclusion from analysis]
1. Chang *et al.* (2011) Taiwan	Dementia (1)	Rehabilitation Centre	ABAB	MPD – (Kinempt)	Food preparation	12	1
2. Chang *et al.* (2013) Taiwan	Dementia, paranoid schizophrenia (1)	Community – pizza store	ABC	MPD – (Kinempt)	Food preparation	10	1
3. Labelle and Mihailidis (2006) Canada	Alzheimer's Disease (2), Mixed (3), Lewy Body Dementia (1), Not identified (2)	Hospital – long term care unit	Alternating Treatments	MPD - Automated prompting system (updated version of COACH; Mihailidis et al., 2000)	Handwashing	20	0.91 and n/a [*individual results reported for one subject only*]
4. Lancioni et al. (2009b) Italy	*Study 1* Alzheimer's disease *[moderate]* (2) *Study 2* Alzheimer's disease [*moderate]* (2) *Study 3* Alzheimer's disease *[moderate]* (3)	Rehabilitation Centre	*Study 1 &2*: Non-concurrent Multiple Baseline Design (MBD) *Study 3*: Multiple Baseline Design across Activities	MPD – *Study 1*: battery-powered, radio-frequency photocells, light-reflecting paper, a Walkman, microprocessor-based electronic control unit *Study 2 & 3*: Amplified MP3 player with USB pen drive connection replaced Walkman	*Study 1*: Coffee preparation *Study 2*: Applying make-up *Study 3*: Tea preparation and applying make-up	Study 1: 17 Study 2: 17 Study 3: 18	Study 1: 1, 1 Study 2: 0.99, 1 Study 3: 1, 1, 1

5. **Lancioni et al. (2009)** **Italy**	*Study 1* Alzheimer's disease *[mild-moderate]* (4) *Study 2* Alzheimer's disease *[moderate]* (2) *Study 3* Alzheimer's disease [*moderate]* (3)	Rehabilitation Centre	*Study 1, 2, 3, 4*: Non-concurrent MBD	MPD – battery-powered, radio-frequency photocells, light-reflecting paper, a Walkman, microprocessor-based electronic control unit	*Study 1*: Completing morning bathroom routine *Study 2*: Table setting *Study 3*: Coffee preparation	Study 1: 17 Study 2: 16 Study 3: 16 Study 4: 10	Study 1: 1, 1, 1, 1 Study 2: 1, 1 Study 3: 1, 1, 1
6. **Lancioni et al. (2009a)** **Italy**	*Study 1* Alzheimer's disease *[mild – moderate]* (3) Study 2 Alzheimer's disease [*moderate]* (3) Study 3 Alzheimer's disease *[moderate]* (3)	Rehabilitation Centre	*Study 1, 2, 3*: Non-concurrent MBD	MPD – battery-powered, radio-frequency photocells, light-reflecting paper, a Walkman, microprocessor-based electronic control unit	*Study 1*: Bathroom routine *Study 2*: Dressing *Study 3*: Table-setting	Study 1: 16 Study 2: 17 Study 3: 16	Study 1: 1, 1, 1 Study 2: 1, 1, 0.99, 1 Study 3: 0.99, 0.91, 1
7. **Lancioni *et al.* (2010)** **Italy**	*Study 1* Alzheimer's disease *[moderate]* (7*)* *Study 2* Alzheimer's disease *[moderate]* (3)	Day Centre	*Study 1:* Non-concurrent MBD *Study 2*: Multiple probe across activities	MPD – battery-powered, radio-frequency photocells, light-reflecting paper, an amplified MP3 player with USB pen drive connection, a pen containing the recording of the verbal instructions related to the activity, microprocessor-based electronic control unit	*Study 1*: Coffee preparation; Table preparation *Study 2*: Food preparation	Study 1: 15 Study 2: 15	n/a [*not enough data reported*]

8. Lancioni *et al.* (2011) **Italy**	Alzheimer's disease [mild – moderate] (3)	Residential Centre	Non-concurrent MBD	PPD - Electronic alarm system	Self-initiated toileting	13	1, 0.94, 1
9. Lancioni *et al.* (2012) **Italy**	Alzheimer's disease *[moderate]* (3)	Day Centre	Alternating Treatments	MPD – Microprocessor-based electronic control unit, amplified MP3 player with USB pen drive connection, a pen containing the recording of the verbal instructions, optic sensors	Food preparation	17	n/a [*not enough data reported*]
10. Lancioni *et al.* (2014) **Italy**	*Study 1:* Alzheimer's disease *[moderate]* (4) *Study 2:* Alzheimer's disease *[moderate]* (4)	Day Centre	*Study 1*: Multiple probe across activities *Study 2*: Multiple probe across patients	MPD – *Study 1*: laptop fitted with Pinnacle Studio software (version 14) *Study 2:* laptop computer with amplifier, microswitch with related interface, and basic software	*Study 1:* Coffee/Snack preparation *Study 2*: Selecting and playing music	Study 1: 14 Study 2: 14	n/a [*not enough data reported*]
11. Lancioni *et al.* (2015) **Italy**	*Study 1:* Alzheimer's disease *[moderate]* (3) *Study 2:* Alzheimer's disease *[moderate/severe*] (3) *Study 3*: Alzheimer's disease [*moderate/severe]* (3)	Residential Centre	*Study 1 & 2:* Non-concurrent MBD	MPD – laptop computer with amplifier, microswitch with related interface, and basic software	*Study 1*: Selecting and playing music *Study 2*: Arm-raising exercise *Study 3:* leg-foot exercise	Study 1: 13 Study 2: 15 Study 3: 15	n/a [*not enough data reported*]
12. Lancioni et al. (2016a) Italy	Alzheimer's disease *[moderate – severe]* (10)	Day Centre	Non-concurrent MBD	MPD – computer with amplifier, microswitch and basic software	Arm-raising exercise	18	n/a [*not enough data reported]*

13. Lancioni et al. (2016b) **Italy**	Alzheimer's disease *[low moderate – severe]* (9)	Day Centre (for people with AD and other dementias)	Non-concurrent MBD	MPD – computer with amplifier, microswitch, and basic software	Leg exercise	18	1
14. Lancioni *et al.* (2017) **Italy**	*Study 1:* Alzheimer's disease [*moderate – severe]* (11) *Study 2:* Alzheimer's disease *[moderate]* (10)	Day Centre	*Study 1 & 2:* Non-concurrent MBD	MPD – *Study 1*: computer with amplifier, microswitch, and basic software *Study 2*: optic microswitches, computer with amplifier and basic software	*Study 1*: Leg-raising exercise *Study 2*: Sorting objects	Study 1: 16 Study 2: 17	n/a [*not enough data reported*]
15. Mihailidis et al. (2000) **Canada**	Alcoholic dementia *(moderate)* (1)	Residential Unit	ABAB	MPD – Computerised cueing device (prototype of COACH)	Handwashing	11	n/a [*not enough data reported*]
16. Mihailidis et al. (2004) **Canada**	Dementia *[moderate – severe]* (10)	Long Term Care and Cognitive Support Unit	ABAB	MPD – (COACH)	Handwashing	19	0.97 and n/a [*individual results reported for only one participant]*
17. Mihailidis et al. (2008) **Canada**	Dementia *[moderate – severe]* (6)	Long Term Care Facility	ABAB	MPD – (updated version of COACH)	Handwashing	22	n/a [*individual results not reported*]
18. Oriani *et al.* (2003) **Italy**	Alzheimer's Disease *[mild – moderate]* (5)	Alzheimer's Dementia Research and Care Unit	ABC	PPD – portable voice recorder (EMA)	Performance on various tasks including:	16	n/a *[not enough data reported]*

					- Take a felt pen - Write on the sheet of paper a certain word - Go out of the room		
19. Perilli *et al.* (2012) **Italy**	Alzheimer's Disease *[moderate]* (3)	Day Centre	Non-concurrent MBD	MPD – Netbook computer, global system for mobile communication modem (GSM), microswitch, interface, software program (written with Borland Delphi Developer Studio, from Inprise Corporation, 2005)	Make a phone call	16	1, 1, 1, 1
20. Perilli *et al.* (2013b) **Italy**	Alzheimer' disease [mild – moderate] (5)	Day Centre	Non-concurrent MBD	MPD - Netbook computer, global system for mobile communication modem (GSM), microswitch, interface, software program (written with Borland Delphi Developer Studio, from Inprise Corporation, 2005)	Make a phone call	15	n/a [*not enough data reported]*
21. Perilli *et al.* (2013a) **Italy**	Study 1: Alzheimer's Disease [mild – moderate] (4) Study 2: Alzheimer's Disease [mild – moderate] (4)	Nursing home; Day Centre	*Study 1 & 2:* Alternating Treatments	MPD – computer with specific software	*Study 1:* Coffee preparation *Study 2:* Food preparation	Study 1: 19 Study 2: 19	n/a [*not enough data reported]*

Key: MPD = micro-prompting device; PPD = prospective prompting device; COACH = *C*ognitive *O*rthosis for *A*ssisting Activities in the *h*ome; EMA = electronic memory aid

Figures 1.2a (internal validity (IV) subscale) and 1.2b (external validity and interpretation (EVI) subscale) show base rate data (the percentage of studies meeting criteria on each item of the scale). Each item was given a score of 0, 1 or 2 based on manualised criteria defined by Tate et al. (2015). The maximum possible score on the IV and EVI subscales were 14 and 16, respectively, with higher scores representing greater validity in that domain. The mean score for all studies on the IV subscale was 6.6 (range = 2 – 10), and the mean score on the EVI subscale was 9.4 (range = 6 – 12). On the IV subscale, more than half of the studies scored low, receiving a score of 0, for items 1, 2 and 3 (design; randomisation; and sampling of behaviour). Only one study (Labelle and Mihailidis, 2006) received a point for randomisation. Most studies (92%) scored 2 on the item relating to treatment adherence. By contrast on the EVI subscale, only 1 item (generalisation) scored 0 in more than half of the studies. On this scale item, all studies received a score of 0. Over fifty per cent of the studies scored high, receiving a score of 2 on the items relating to baseline characteristics of participants; target behaviour (dependent variable); and replication.

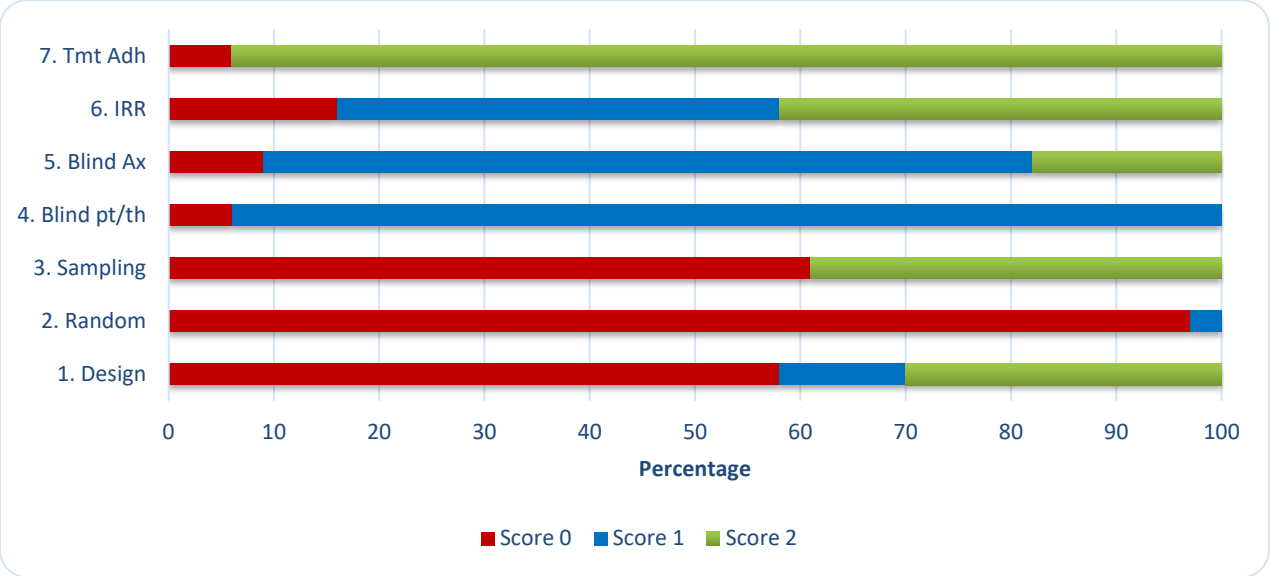


Figure 1.2a. Percentage of SCED's meeting criteria on RoBiNT Internal Validity items. Random = randomisation; Blind = blinding; Ax = assessor; pt/th = participant/therapist; IRR = inter-rater reliability; Tmt Adh = treatment adherence

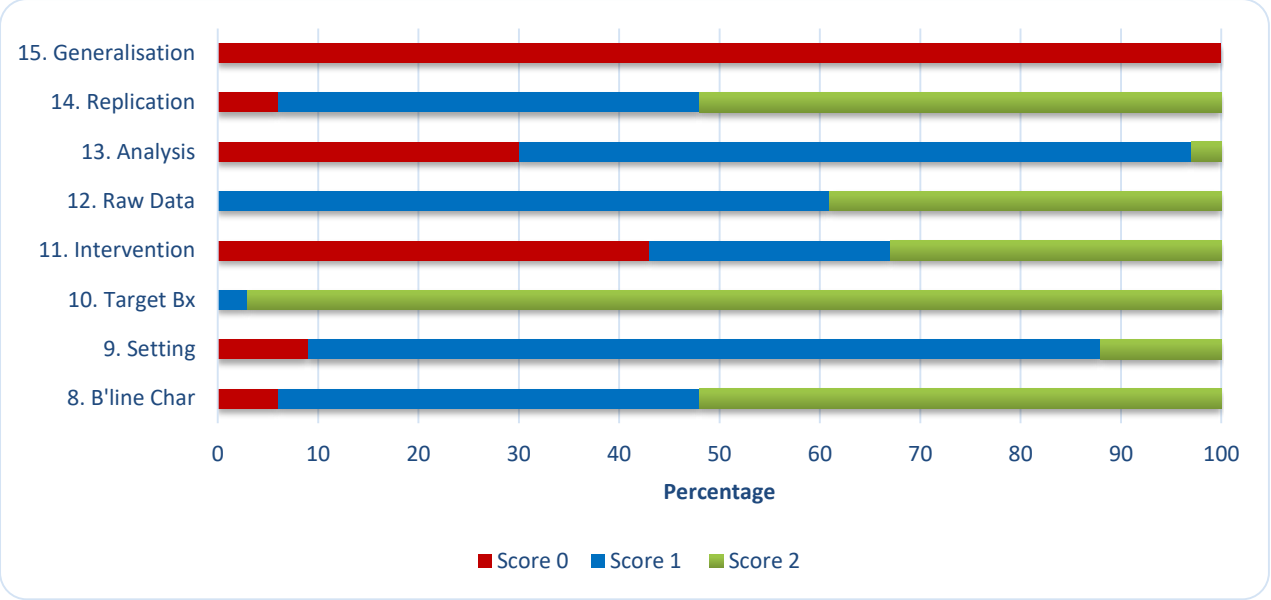


Figure 1.2b. Percentage of SCED's meeting criteria on RoBiNT External Validity items. B'line Char: baseline characteristics for participants; Target Bx = target behaviour

NAP analysis was performed on 38 participants in 10 of the SCED studies. The studies received a mean NAP statistic of 0.99 (minimum = 0, maximum = 1). According to Parker and Vannest (2009) this represents a large effect size as it is greater than 0.93. Individual scores ranged from 0.91 to 1. When studies were divided into those evaluating prospective prompting devices and those evaluating micro-prompting devices the effect size remained large for both (0.98 and 0.99, respectively).

Discussion

The aims of this review were to evaluate the efficacy of electronic memory aids for people with dementia; to report on the methodological quality of the research currently available; and to assist in establishing the appropriateness of technological prospective memory aids as an appropriate memory intervention for people with dementia.

Efficacy

A total of twenty-one studies were identified, which totalled thirty-three single-case experimental designs. This is an increase of twenty-five SCED's from the similar review by Jamieson et al. (2014). NAP analysis found, overall, a large effect size for the impact of both prospective prompting devices and micro-prompting devices on performance of future intentions and ability to multitask. This suggests that both types of devices are effective for people with dementia.

Due to an ageing population, with expected increases in prevalence rates, dementia is a pressing public health challenge. It is possible that the increasing number of studies evaluating interventions for people with dementia is a direct response to this growing concern. While increasing emphasis has been placed on intervening in the early stages, it is important to note that benefits were also observed in six studies that included participants with a

diagnosis of dementia considered to be in the severe stages (e.g. Lancioni et al., 2015; Mihailidis et al., 2008). As more research is completed, it is recommended that group differences are evaluated.

Despite this increase in studies, compared to the ABI literature, the number of studies identified remains considerably small. All micro-prompting devices included in this review were types of computers, including micro-processor units and laptops, that had specialised sensor devices and software for the target tasks (e.g. Kinept: Chang et al., 2013; COACH; Mihailidis et al., 2001;2004;2008). Some studies included the use of a walkman or MP3 player alongside the computer (e.g. Lancioni et al., 2009), and instructions for tasks were presented visually, or through audio. Only two studies evaluating prospective prompting devices (a voice recorder and a wearable electronic alarm device), were identified in the current review (Oriani et al., 2003: Lancioni et al., 2011). Unfortunately, none of the aids evaluated in this review are readily available to purchase for individual or clinician use, however, technological advances have led to the development of several devices (e.g. smartphones, smartwatches), used daily by the general population, that have the potential to assist prospective memory in people with dementia. They include various tools and applications that can send time-based reminders. While studies have evaluated the effectiveness of various types of everyday technologies in people with ABI (e.g. reminders delivered through Google Calendar on a smart phone (Baldwin & Powell, 2015); reminders delivered through smart watches (Jamieson et al., 2017)), only case studies were identified in this review that evaluated target memory performances utilising ubiquitous technological devices, and were therefore excluded from this review's analyses.

For example, El Haj, Gallouj and Antoine (2017) evaluated the effectiveness of reminders delivered through the Google Calendar application on a smartphone, in a person diagnosed with mild Alzheimer's disease, and found a decrease in forgetting of targeted events. Utilising devices already in the individual's possession may be beneficial as the individual is already familiar with the device, and it can also eliminate potential costs and stigma experienced (Baldwin et al., 2011).

No randomised controlled trials were identified in this review. Van der Roest et al., (2017) highlighted the difficulties completing large scale studies involving assistive technology and the dementia population. These include the need for: personalisation of devices; training on how to use the devices; and intensive data collection.

First, due to the heterogeneity of impairment associated with the dementia population, personalisation of devices is often required to meet the needs of the user (e.g. Lancioni et al., 2009). Cicerone et al. (2000; 2011) offered guidelines regarding the use of memory aids for memory impaired individuals as a result of ABI or stroke; they note how the evidence suggests that memory interventions to promote the use of external compensatory strategies should be directly applied to functional activities of the individual. Similarly, Baldwin et al., (2011) found that "life style fit" was an important factor in the use of memory compensations. The

target behaviours identified in the present review appeared to have a good "life style fit"; they focused on meaningful functional tasks related to activities of daily living, including handwashing, preparing food and morning bathroom routine.

Second, there are a number of cognitive processes involved in the use of memory aids; therefore, training is often required. Indeed, this occurred in most studies of the present review. Due to the likely presence of significant executive dysfunction in people with dementia, giving the patient an aid without further instructions is likely to be insufficient. Kapur et al. (2004) described how training facilitates the development of the "metamemory" skill, whereby patients learn what situations they might need an aid; are motivated to use the aid; and they remember how to operate and use the aid effectively.

Finally, intensive data collection over a long period of time was noted in several studies of this current review. For example, in Mihailidis et al.'s (2008) study, data collection took place over 60 days, and in Perilli et al.'s (2013b) study, there were between 20-50 sessions in the intervention phase alone. These three challenges highlight the difficulties of conducting RCT's, making SCED's a more preferable option among researchers.

Methodology

Rizvi and Nock (2008) maintain that SCEDs provide the same level of rigour as the RCT due to their underlying scientifically robust principles. If implemented properly they will have a high level of internal validity. The results of the current review demonstrate that the internal validity of the studies identified, according to RoBiNT scale standards, was quite *low* (poor). Over 50% of studies obtained a zero score on three of the seven items within the subscale. However, taking each of these three scale items into account, it is important to look at the feasibility and appropriateness of each item within the context of the studies included in the present review.

Only one study received a point for randomisation in their study (Labelle and Mihailidis, 2006). However, Wolery (2013) highlighted instances where randomisation could actually produce bias. For example, in an alternating treatments design, "if the intervention is used in several consecutive sessions (which is possible with randomisation), the dimension of rapid alternation is lost" (Wolery, 2013, p.40). Wolery (2013) warned against weighting the role of randomisation until experimental analysis, that uses blind judging to evaluate the internal validity of studies with and without randomisation, is completed to resolve the issue.

50% of the studies incorporated a non-concurrent multiple baseline design. This resulted in a score of 0 on the scale item for design. However, Watson and Workman (1981) highlight the challenge of completing research in applied settings, such as day centres, hospitals and residential units. For example, appropriate participants, fulfilling the inclusion criteria for the study, may not enter the setting at the same time. Multiple baseline designs avoid the ethical and practical constraints of reversal designs (Kazdin, 1980); and non-concurrent multiple baseline designs provide a level of flexibility necessary for conducting research with this population. Indeed, due to the degenerative nature of dementia, it seems unethical to require

patients to wait until there are a sufficient number of participants to conduct a concurrent multiple baseline design. Unfortunately, the RoBiNT scale does not allow for this flexibility in its scoring. Furthermore, one of the concerns with conducting non-concurrent multiple baseline designs, is the challenge faced precluding the role of historical events on the intervention (Kazdin, 1982). However, due to the progressive and degenerative nature of memory impairment in an individual with dementia, this is unlikely to have impacted the internal validity of the studies in the present review.

With regards to the sampling of behaviour, Tate et al. (2013) recommend a minimum of five data points in every phase. While all the studies in the present review succeeded in recording this minimum requirement in the intervention phase, studies scored 0 as a result of insufficient sampling of behaviours in the baseline phase. Baseline phases in the studies included in the present review, usually involved observing the participant complete an activity of daily living unaided. It is possible that multiple baselines could create distress in the memory-impaired participant, and researchers may have chosen to reduce the number of baseline trials as a result. Furthermore, in certain studies, more than five baseline trials were completed, however data was combined/aggregated when presented graphically (e.g. Lancioni et al., 2013).

The external validity and interpretation items of the studies scored higher than the internal validity items on the scale. Indeed 50% or more of the studies received a score of 2 for replication, baseline characteristics and dependent variable (target behaviours). While none of the studies included measures for generalisation, it is unlikely that generalisation was expected in any of the studies. Most prompting devices were designed to aid specific tasks. The studies aimed to evaluate whether the compensatory strategy was successful in supporting the participant to bypass/adapt to their impairment to complete the specific task identified.

There is currently no agreed upon criteria for statistical analysis of single-case data (Kratochwill et al., 2013). Traditionally, researchers have relied upon the use of visual analysis and strong internal validity of designs to report intervention effectiveness (Olive and Smith, 2005). Visual analysis of data can determine whether a relationship between an independent variable and an outcome variable exists and also the magnitude of that relation (e.g. Gast, 2010). Guidelines for conducting visual analysis describe how various outcome-measure features must be examined within- and between-phase data; level; trend; variability; immediacy of the effect; and overlap; and consistency of data patterns across similar phases (e.g. Fisher, Kelley, and Lomas, 2003; Hersen and Barlow, 1976; Kazdin, 1982). However, for the majority of the studies in the present review only “level” and/or “overlap” were reported. Of the studies that included a statistical technique, the rationale for use was not presented.

Limitations

NAP analysis could only be completed in 10 (29%) of the studies included in the current review. The challenges of ensuring strong internal validity of SCEDs in applied health settings has

already been highlighted in this review. Effect size calculations, such as NAP analysis, offer an alternate means of documenting intervention effectiveness, especially when challenges to strong internal validity are present. It is important that future similar studies with this population include a method for effect size calculation when faced with challenges to strong internal validity. This is in line with the recommended guidelines for conducting and reporting SCED research (SCRIBE; Tate et al., 2016).

The RoBiNT scale used to evaluate the studies in the present review was published in 2013. Most of the current papers (seventeen) were published before or during 2013. The tool was an update to the original SCED scale (Tate et al., 2008), and followed publication of various reporting standards and guidelines for single case experimental research (Kratochwill et al., 2013; Wolery, Dunlap, and Ledford, 2011, SCRIBE: Tate et al., (2016) – in preparation at the time). It will be important to repeat the review in the future to evaluate the impact of these guidelines on subsequent SCED studies completed.

Additionally, there was a lack of inter-rater reliability in the process of screening the abstracts for inclusion, as not all abstracts were second-screened by an independent evaluator. This may mean a small number of studies, which met inclusion criteria, were missed.

Finally, the majority of the studies included in the present review were conducted within the same research group (e.g. Lancioni et al., 2009; Lancioni et al., 2013). Kratochwill et al., (2013) recommend a threshold of at least three research teams, with no overlapping authorship, at three different institutions, for systematic reviews of SCED's. To this extent, the current review achieves that.

Conclusion

Despite the proliferation of electronic devices available and in use by the general population today, research exploring their potential as a memory aid for individuals presenting with memory impairments, associated with a dementia, remains limited. A large increase in studies evaluating electronic memory aids since Jamieson et al.'s (2014) study was found; these were primarily micro prompting devices on computers. The reviewed studies reported improved performance on activities of daily living, suggesting that electronic devices are an effective intervention for memory impaired individuals with dementia. This is an important finding, in terms of shaping future clinical guidelines that influence clinical practice. While the methodological quality was rated as quite low on several items of the RoBiNT scale, the reality of complying with many of these items in this type of intervention and this population group needs to be considered.

In summary, research evaluating electronic memory aids in the dementia population remains in the early stages. As an ageing population, prevalence rates of dementia are expected to increase, therefore, identifying appropriate and effective interventions to support these individuals is imperative. While this requires more rigorous and robust research, and future RCT's are recommended, the challenges and flexibility required conducting research with this population needs to be considered in both the design and research evaluation stages.

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Chapter 2: MAJOR RESEARCH PROJECT

MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

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Plain English Summary

Title

MindMate: A Single Case Experimental Design Study in People with Mild Dementia

Background

Prospective memory (PM) refers to the ability to remember to do something in the future, and is often impaired in people with dementia. PM tasks include remembering to attend an appointment, take medication, and turn off the oven after cooking. While there is no cure for dementia, there is an increasing emphasis on early diagnosis to enable access to interventions that focus on improving independence and quality of life. Electronic PM aids (e.g. pagers, personal digital assistants (PDA's)) have been shown to be effective for assisting different populations with various memory impairments; however, little research has explored their use among the dementia population.

Mindmate (2015) is a relatively new dementia specific mobile application (app) that has been developed for smart devices, including tablets and smart phones. The application includes a reminder tool that can deliver timed-reminders to the person's smart device.

Aims

This study explored the use of the MindMate app as a memory aid for people who have received a diagnosis of dementia, considered to be in the early stages. The aim of the study was to see if their performance on certain memory tasks improved following the introduction of the MindMate app on their smart phone or tablet. The study was also interested in whether people liked the app and would consider using it in the future.

Method

Three participants from Older People Community Mental Health Teams within Greater Glasgow and Clyde, who had received a diagnosis of mild dementia from their psychiatrist, were recruited to the study. They owned a smart phone or tablet and their partner also participated in the study.

The researcher and the participant identified certain tasks that needed to be remembered each week and these were recorded on a weekly monitoring form that was given to their partner. During the baseline period (5-7 weeks), the carer put a tick next to the task if the participant remembered, and a cross if they needed reminding or forgot about it. During the intervention (5 weeks), the participant received a reminder on their phone or tablet from MindMate about each event, and the carer continued completing the weekly monitoring form. Participants completed a pre- and post- intervention questionnaire that evaluated the participant's views of the app and whether they would use it again in the future.

Results

Two participants successfully used the app throughout the intervention weeks and gave positive usability ratings. There was a significant increase in memory performance between baseline and intervention phase. A third participant withdrew from the intervention phase following difficulties turning off the reminders and frustrations with the alert sound.

Conclusions

Results from this study provide evidence supporting the effectiveness of MindMate as a memory aid for people with dementia. While participant's

comments were mostly positive, some concerns were raised when the reminder did not function properly.

This research highlights the benefits of supporting people with memory difficulties as a result of their diagnosis of dementia, using an electronic device, and further research is encouraged.

(508 words)

Abstract

Background

Prospective memory difficulties are commonly reported in people with dementia. The evidence supporting the use of prospective memory devices among the dementia population remains limited. MindMate is a recently developed smart device application that aims to support individuals with a diagnosis of dementia, improving self-management skills and quality of life.

Aims

This study investigated the effectiveness and usability of the reminder tool on the MindMate application as a memory aid.

Method

Three participants with a diagnosis of mild Alzheimer's disease were recruited to this multiple baseline single case experimental design study. Partners of the participants recorded their performance on everyday tasks on weekly monitoring forms during a baseline phase (for between five and seven weeks) and during the intervention phase (five weeks) whilst using MindMate.

Results

Two participants successfully used the app throughout the intervention weeks and gave positive usability ratings. Tau-U analysis showed a significant increase in memory performance between baseline and intervention phase (Tau-U = 1, 0.94, $p<0.01$). A third participant withdrew from the intervention phase following difficulties turning off the reminders and frustrations with the reminder alert sound.

Conclusions

The use of the MindMate app was feasible for people with dementia in the community. It was effective compared to practice as usual, with participants reporting intentions to use in the future. Limitations and implications for future research are discussed.

Introduction

Background

Prospective memory (PM) refers to the ability to remember to do something in the future (McDaniel and Einstein 2011) and is often impaired in people with dementia. PM tasks include remembering to attend an appointment, take medication, and turn off the oven after cooking. PM relies upon various cognitive functions, including executive functioning, working memory, attention and long-term memory (Einstein and McDaniel 1990); therefore, it is unsurprising that individuals with dementia experience difficulties with PM tasks. PM is highly important for maintaining functional independence (Chasteen *et al.* 2001). Failure to complete an intended action can negatively impact activities of daily living and have serious health consequences (Spíndola and Brucki 2011). Furthermore, carers of individuals with dementia report failures in PM as more burdensome than retrospective memory failures (i.e. the ability to recall past events or information) (Smith *et al.* 2000).

Taking into consideration the impact of prospective memory difficulties on people with dementia, it is important to identify appropriate interventions to address these difficulties. While there is currently no cure available for dementia, there is an increasing emphasis on early diagnosis to enable access to interventions that focus on improving independence and quality of life (BPS, 2016). Appropriate support can have a significant impact on the degree to which someone is able to manage their condition over time and live independently, delaying the need for care home or hospital admission, which adds savings to the health economy (Knapp *et al.* 2013). It also reduces both individual and caregiver distress (Jamieson *et al.* 2017a).

Memory Aids

External memory aids are a widely used and effective intervention for assisting people with memory impairment (Sohlberg et al., 2007). As a compensatory approach, they aim to bypass the deficit area and teach the individual strategies to solve functional problems (Kapur and Wilson, 2009). Mastering these strategies will, it is assumed, help the individual manage in their everyday environment despite the presence of the impairment (Dewar et al., 2016). While paper-based aids, including calendars, to-do lists and diaries, are omnipresent in populations with and without memory impairment, they are limited by being passive reminders - they require individuals themselves to initiate using or checking them which, in itself, is a memory task (Wilson *et al.* 1999). Electronic memory aids offer a means of overcoming this difficulty, as they often include a cueing device that attracts the individual's attention to the task and can include a facility for storing information (Kapur, Glisky, and Wilson, 2004).

Assistive Technology

Various electronic technology aids compensating for prospective memory difficulties have been shown to be effective in the acquired brain injury (ABI) population. For example, several studies have explored the use of NeuroPage, a portable pager that sends audio/vibration

alerts to remind the person to do something, and have reported a significant improvement in target behaviours relative to baseline (e.g. Evans, Emslie, and Wilson, 1998; Wilson et al., 2001). Similar success has been demonstrated in personal digital assistants (PDAs) (e.g. Gillette and DePompei, 2008; Wright et al., 2001); smart watches (Jamieson *et al.* 2017b); and smartphones (Savage and Svoboda, 2013; Svoboda and Richards, 2009). In their systematic review, Jamieson *et al.* (2014) found good evidence for the efficacy of prospective memory reminding systems; a meta-analysis of seven group studies, of participants with ABI, gave a large overall effect size (d = 1.27) (n = 147).

Assistive Technology & Dementia

While numerous studies have evaluated the use of technological memory aids among the ABI population, research into their effectiveness among the dementia population remains scarce. Indeed, most research has been confined to micro-prompting devices, which guide people through a single task with several sub-steps. These studies have demonstrated success completing tasks including; hand-washing (COACH; Mihailidis, Carmichael, and Boger, 2004); food preparation (e.g. Kinempt: Chang et., 2013); and table-setting (Giulio E. Lancioni *et al.* 2009).

Smart Phones and Applications

As previously mentioned, studies investigating the use of mobile and smartphones, in particular delivering alerts, have proven effective in people with memory problems. Various applications (apps) can be used with smartphones, such as Google Calendar and Microsoft Office Calendar. In a study of people with an ABI, McDonald *et al.* (2011) conducted a small randomised controlled trial using the Google Calendar application, in which participants recorded completion of prospective memory tasks. After event details are recorded, Google calendar sends timed reminders to the person's mobile phone. In their study, McDonald et al., (2011) found Google Calendar to be significantly more effective than a paper-based diary. Similar positive outcomes were reported with an individual with ABI, who had severe verbal and visual memory difficulties and no prior use of a memory aid (Baldwin and Powell 2015). However, only one case report was identified investigating the effectiveness of an app (Google Calendar) with a participant with mild Alzheimer's disease (El Haj *et al.* 2017). This study showed a reduction in forgetting of chosen target behaviours.

More recently, a dementia specific application called MindMate (2015) was developed, with the aim of supporting users in their everyday lives, improving self-management skills, and therefore maintaining the independence of users for as long as possible. This application includes a reminding tool similar to the one on Google Calendar.

Current Study

The present study aimed to examine the use of MindMate as a memory aid for people who have received a diagnosis of dementia, who are considered to be in the early stages, and who are specifically experiencing memory and executive functioning difficulties. A secondary aim

of the study was to help understand whether an application synced to a tablet or smartphone is a usable and acceptable off-the-shelf assistive technology.

The main hypotheses were:

- Performance on target memory tasks will improve significantly with the introduction of the MindMate reminding tool.
- The app will be a usable and acceptable form of assistive technology for people with dementia

Reporting follows the guidelines detailed in the Single-Case Reporting Guideline in Behavioural Interventions (SCRIBE) 2016 Checklist (Tate *et al.* 2016) (Appendix 2.1).

Method

Participants

Participants were identified and recruited from their community mental health team to the study. Adults aged 18 or over who had received a diagnosis of mild dementia, by a psychiatrist using ICD-10 criteria, and reported memory difficulties which had been confirmed by a professional or family member, were considered for participation. Participants owned a smart phone or tablet computer with internet, and had a partner willing to support and monitor memory aid use.

Exclusion criteria were participants who:

- Had a pre-existing neurological or severe psychiatric problem (e.g. bipolar disorder, psychosis).
- Had a diagnosis of dementia considered to be in the moderate to severe stages.
- Had visual or auditory difficulties (which cannot be corrected with the use of glasses or hearing aids) that would prevent use of a smartphone.
- Had a diagnosed or suspected developmental learning disability.
- Those whose first language was not English.
- Those who were currently using online or electronic memory aids. Previous memory aid use was documented but did not exclude individuals from participation.

Four participants were initially recruited. One participant and their partner withdrew prior to commencing baseline, as the partner believed the participant was too far advanced to participate. A second participant, CE, withdrew during the first week of the intervention phase. Initially, difficulties with turning off the reminder alarm were found, due to a bug on the app, and required fixing by the app developers. Following this, CE said she found the alarm sound frustrating and with reduced motivation, decided not to continue using the app. However, both CE and her partner agreed to continue with the baseline phase for another five weeks. The cognitive profile of this participant, as well as the remaining two participants, FD and SI, are reported in Table 2.1. Participants were assessed using the following neuropsychological tests and questionnaires:

- Test of Pre-Morbid Functioning (TOPF, Wechsler, 2011);

- Rivermead Behavioural Memory Test -3rd version (RBMT-3; Wilson et al., 2008);
- Wechsler Abbreviated Scale of Intelligence – 2nd edition (WASI-II; Wechsler, 1999);
- Trails subtest of the Delis–Kaplan Executive Function System (D-KEFS; Delis, Kaplan, and Kramer, 2001);
- Controlled Oral Word Association Test using letters F-A-S (Spreen and Benton, 1977);
- Prospective and Retrospective Memory Questionnaire (Smith *et al.* 2000).

Many of these tests had already been completed by participants FD and CE prior to participation in the study (within the previous six months), as part of their diagnostic assessment by their neuropsychological team. During the study, only tests, not completed within the previous six months, were administered by the experimenters, to give an overall impression of participants' intellectual functioning, memory and executive functioning.

Table 2.1. *Characteristics and Cognitive Profile for Participants FD, SI & CE*

	FD	SI	CE
Age (gender)	74 (male)	71 (male)	59 (female)
Diagnosis (severity)	Alzheimer's disease (mild)	Alzheimer's disease (mild)	Alzheimer's disease (mild)
Test			
WASI-II perceptual reasoning score	*	Average	Average
WASI-II verbal comprehension score	Low Average	Low Average	Low Average
WASI-II Full-Scale - 4	Low Average	Low Average	Low Average
TOPF estimated full-scale pre-morbid IQ	Average	High Average	Average
RBMT score (percentile rank)	Impaired (0.1)	Impaired (0.2)	Impaired (0.4)
Trails A score (percentile rank)	Average (*)	Low Average (20th)	High Average (90th)
Trails B score (percentile rank)	Average (*)	Impaired (<10th)	Average (40th)
Verbal Fluency score (percentile rank)	Impaired (*)	Average (30th)	Average (40th)
PRMQ – self-rating (t-score)	Impaired (7)	Borderline Impaired (34)	Average (56)
PRMQ – carer (t-score)	Impaired (27)	Average (49)	Borderline Impaired (33)

Key: WASI-II = Wechsler Abbreviated Scale of Intelligence – Second Edition; TOPF – Test of Pre-morbid Functioning; RBMT = Rivermead Behavioural Memory Test; PRMQ – Prospective and Retrospective Memory Questionnaire; * = not reported in the neuropsychological assessment report for participant

Recruitment Procedures

Potential participants were given written information (Appendix 2.2) about the study via a member of the Older People Community Mental Health Team (OPCMHT) or post diagnostic service they were known to, within NHS Greater Glasgow and Clyde. Following expression of interest, they were provided with further written information (Appendix 2.3) and they completed an opt-in slip, consenting to be contacted, which was sent to the researcher. The researcher contacted the potential participants who were provided with the opportunity to discuss the study further and ask questions. Once participants and their partners agreed to participate, they were asked to sign a consent form (Appendix 2.4).

Materials

MindMate is a free to download and use dementia application for tablets, iPhone and android devices (http://www.mindmate-app.com/). It includes a "Reminder" tool which allows events to be entered for a specific time and date, then sends reminder alerts about the event, thus acting as a memory prompt. Each participant used their own phone/tablet as it was assumed they would already be familiar with its use.

A weekly monitoring form (Appendix 2.5) listing individual prospective memory targets and the times they need to be completed by was provided to the partner. Baldwin and Powell (2014) highlighted the importance of picking memory targets that were personally meaningful for the individual, therefore memory targets were constructed in conjunction with the participant and the partner. This approach was also used in the NeuroPage studies (Wilson *et al.* 2001). On days where no targets could be identified, the researcher set a reminder for the participant to send a text message or make a phone call to the researcher. The weekly monitoring form was used daily by an identified partner to record whether or not activities were remembered and completed at an appropriate time, during both the baseline and intervention phases. They were asked to tick targets achieved without prompting from other people, and cross targets that were either forgotten, remembered but not completed, completed at the wrong time, or only completed following prompting from partner.

Design

A randomised single case experimental design (SCED) multiple baseline across participants study was used, staggering the onset of the intervention. The Medical Research Council (MRC) Framework for Complex Interventions (MRC, 2008) supports the use of SCED studies in the feasibility and piloting and evaluation stages of complex interventions (Craig et al., 2008). While best practice is to develop interventions systematically (i.e. development; feasibility/piloting; evaluation; implementation) the present study focused on both the usability and the effectiveness of the intervention. This was in part, due to the widespread availability of the app (the app was free to download from app stores) and also due to the small number of participants recruited to the project.

Withdrawing intervention might raise ethical issues, therefore a multiple baseline, as opposed to a withdrawal (e.g. ABA) design was deemed more appropriate. The three participants were randomly allocated to a five, six or seven-week baseline using the Research Randomizer programme provided by the Social Psychology Network (http://www.randomizer.org). MindMate was then introduced for participants for a five-week period.

The study was developed with reference to the methodological quality criteria for single case experimental design studies (Risk of Bias in N of 1 trials – RoBiN-T, Tate et al., 2013) (Appendix 1.4).

Ethics

Ethical approval was obtained from the West of Scotland Research Ethics Committee 3 (16/WS/0219) and Specific Site Approval (16/WS/0219) (see Appendix 2.6) granted from NHS Greater Glasgow and Clyde. Informed consent was obtained from all three participants and their partners.

Setting, Sessions, and Data Recording

An initial interview with the participant and their partner identified target behaviours as well as previous memory aid use (see Table 2.2 for example target events). Baseline data was gathered over 5-7 weeks, during which time, all target events that were forgotten and instances of reminding were recorded. Prior to the start of the intervention phase, each participant completed training in using the MindMate app. This involved a demonstration of the reminder tool on their smart phone or tablet; participants were sent reminders asking them to undertake a number of tasks (e.g. call the researcher) to ensure they could read the message and respond appropriately (i.e. press the correct button). Then, the intervention phase lasted five weeks.

Table 2.2 *Sample Target Events for Participants*

Initials	Sample Target Events
FD	- Call a family member - Attend an appointment - Gardening - Go to the shop
SI	- Go to choir - Attend a meeting - Bring/collect granddaughter from ballet - Make soup

At the beginning of each week of the intervention, the researcher met with the partner and participant in their local OPCMHT office or in their home. They were asked about upcoming events for the week which were entered into MindMate by the researcher (see Table 2.2 for sample target events). The participant was asked how far in advance they would like to receive the reminder. Reminders were delivered at various times across the day, and so participants were encouraged to have their tablet or smartphone on them at all times. Similar to baseline, the partner recorded all target events that were forgotten as well as instances of reminding. The partner also recorded instances where the MindMate reminder failed to come through on the correct day or time, or any other technical difficulties noted with the application.

Towards the end of the intervention phase, participants received 2-3 further training sessions on how to use MindMate. This included the provision of a step-by-step guide, alongside illustrated instructions on how to locate, enter, and navigate the app and its Reminder tool (Appendix 2.7). This included inputting and deleting reminder events. The acquisition of this

skill did not form part of the aims of this study; however qualitative information was gathered upon completion of the training.

Following completion of the intervention block, qualitative information was gathered to evaluate the usefulness of MindMate, to identify its strengths and limitations and to ascertain whether the participant would use the aid in the future. Participants were asked to complete a pre- and post-study questionnaire (Appendix 2.8) on eight domains, adapted from the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire (Venkatesh et al., 2003). These were administered at the initial clinical interview and the follow up clinical interview. The UTAUT includes groups of items concerning: performance expectancy (expectancy that the technology will be useful for its purpose); effort expectancy (perception of effort needed to use it); attitude towards the technology; social influence (the influence of others on the use of the technology); facilitating conditions (the extent to which their environment facilitates use of the technology); self-efficacy (estimations of their own ability to use the technology); anxiety (levels of anxiety felt when using the technology) and behavioural intention (an indication of whether the participant is intending to use the technology in the next 6 months). Scores for each item (on a scale of 1 to 5) within each domain can be pooled to give overall scores for each domain at each time point.

Data Analysis

Frequencies were calculated for percentage of target behaviours remembered each week. It was anticipated that the frequency of events to be remembered would differ on a weekly basis, so percentage of events remembered were calculated each week. As well as visual inspection, statistical analysis was also undertaken.

Visual inspection includes the calculation and transformation of each participant's performance to a graph for the purpose of visually analysing (a) trend (progress over time), (b) level (magnitude of the data), and (c) stability (variability or "bounce" of the data) (Gast, 2005). The procedure for visual inspection follows steps as outlined by Lane and Gast (2014) using the graphic display and divided into (a) within-condition and (b) between-conditions analysis of data.

Tau-U analyses were conducted to investigate whether significant improvements in performance of memory tasks were found between the different phases. Tau-U is a method for measuring data non-overlap between two phases (A and B) (Tau-U; Parker et al., 2011b). Non-overlap methods do not rely on means, medians, or modes but rather consider individual values of all data points in pairwise comparisons across phases (Parker et al., 2011b). Non-overlapping data as an indicator of performance difference between phases is included in standards for evaluating SCED's (Horner et al., 2005). Tau-U is a distribution free non-parametric technique, with an index well-suited for small datasets, and is useful in aggregating data across phases to provide an overall effect size. Depending on the data, it possesses statistical power of 91-115 percent of parametric tests (Vannest, Parker and Gonen,

2011). All calculations were performed via the website: http://singlecaseresearch.org/ (Vannest, Parker, and Gonen, 2011).

The UTAUT scores were reported descriptively.

Power

In their meta-analysis of SCED studies of prompting technology in acquired brain injury Jamieson et al (2014) reported medium effect sizes using non-overlap of all pairs methodology. In the present study we anticipated similar levels of effect. It was therefore anticipated that the Tau-U analysis would have sufficient statistical power to detect the anticipated effect size.

Results

Cognitive Profiles of Participants

Table 1 (p. 31) summarised the cognitive profile of participants

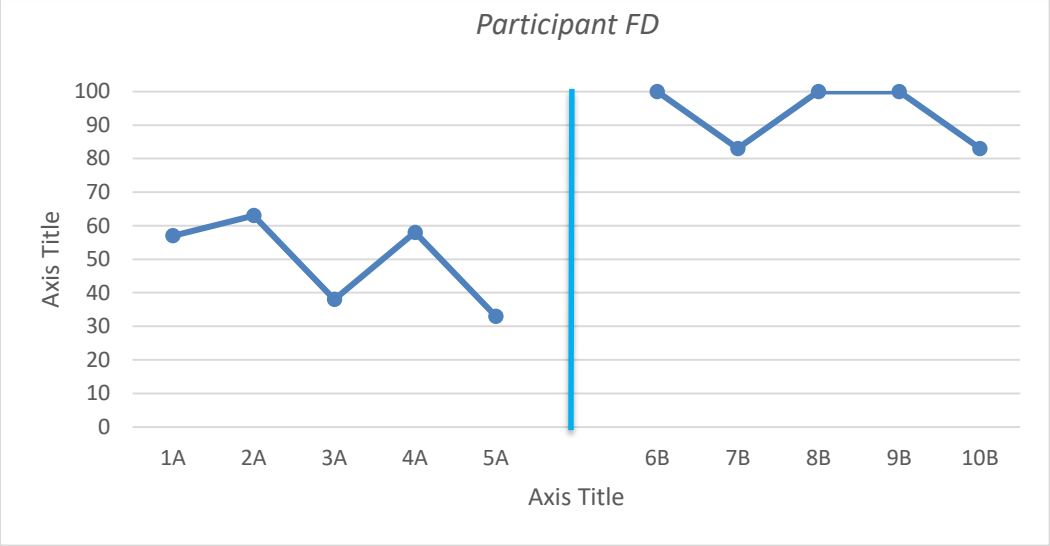
Quantitative Summary of Results

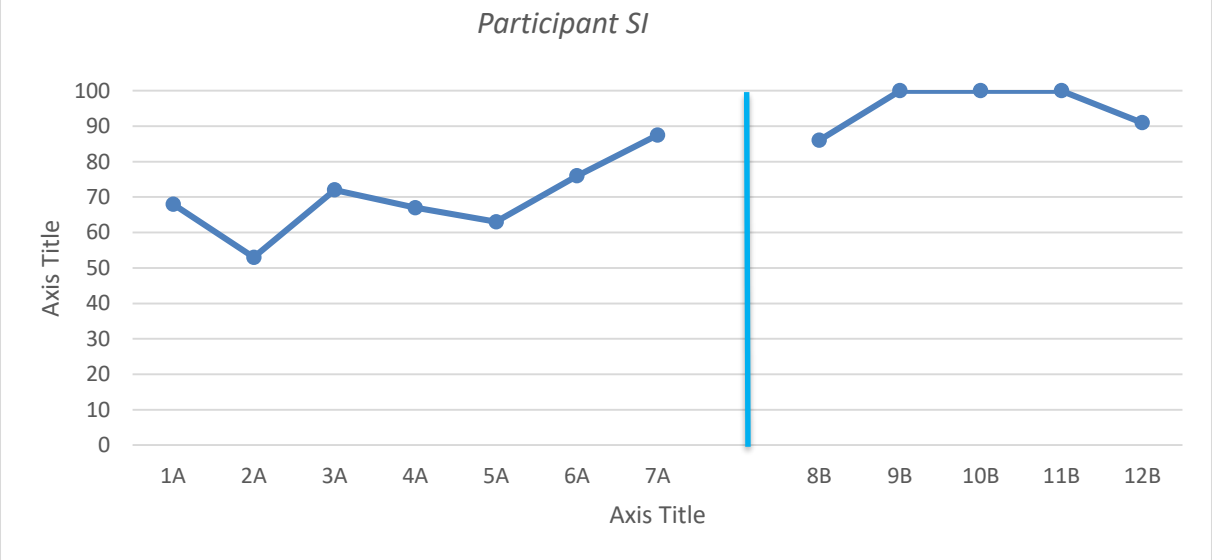
Data were collected between February and June 2017. The three graphs in figure 2.1 summarise the data of the three participants, FD, SI and CE, respectively. The data points represent the percentage of completed target events during baseline and intervention phases. Participant FD completed 49% (41/83) of tasks during baseline phase, and 93% (31/33) of tasks during intervention phase, without partner prompting. Participant SI completed 69% (84/121) of tasks during baseline phase, and 95% (35/37) of tasks during the intervention phase. Participant CE completed 51% (71/137) across eleven weeks of baseline phase.

Participant FD

Visual inspection of each participant's data followed steps outlined by Lane and Gast (2014). Evaluation of phase A and B for participant FD indicated data were variable during baseline and intervention. Split-middle method of trend estimation was conducted and indicated there was a decreasing contra-therapeutic trend during baseline and zero-celerating trend during intervention. Data were considered variable in the baseline phase, and stable in the intervention phase, following application of a stability envelope to trend lines (Appendix 2.9). Mean, median and relative level change measures indicated a positive (improving) change from phase A to B.

Tau-U analysis was used to determine performance change between baseline (phase A) and intervention (phase B), and revealed a significant improvement in performance of tasks between baseline and intervention phases (1, $p<0.01$) for participant FD. According to (Parker *et al.* 2011a) this indicates a large effect size.





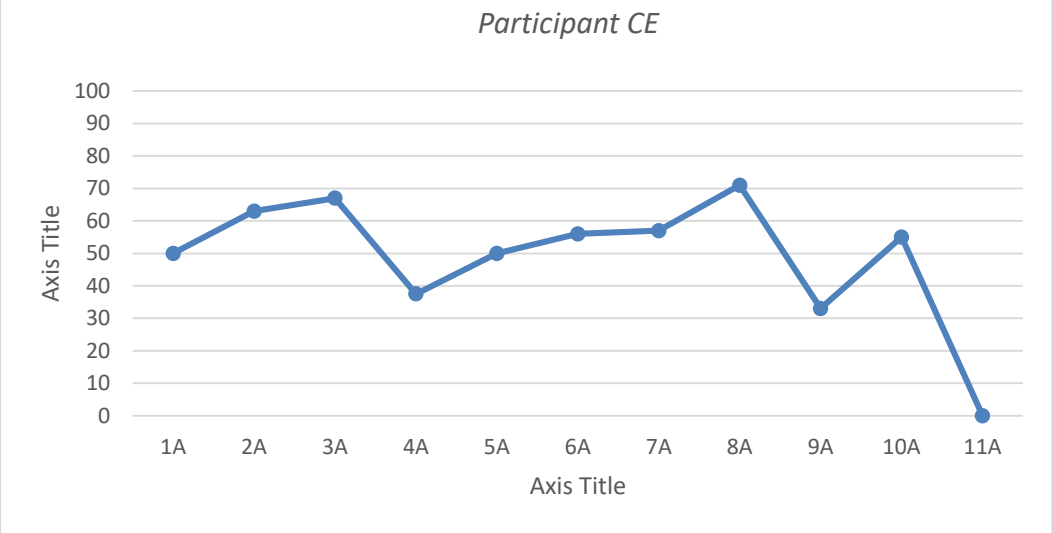


Fig.2.1. The three graphs summarise the data of the three participants, respectively. The data points represent the percentage of target memory tasks completed each week in each study phase (A = baseline, B = intervention). The Y axis shows percent performance and X axis shows study week.

Participant SI

Evaluation of each phase for participant SI indicated data were stable during baseline and intervention. Split-middle method of trend estimation was conducted and indicated there was an increasing trend in a therapeutic direction during both phases. Data were considered stable following application of a stability envelope to trend lines. Mean, median and relative level change measures indicated a positive (improving) change across conditions.

Tau-U analyses revealed a significant improvement in performance of tasks between baseline and intervention phases (0.94, $p<0.01$) for participant SI. According to Parker *et al.* (2011a) this indicates a large effect size.

Participant CE

Evaluation of the baseline phase for participant CE indicated data were variable, and remained variable following application of a stability envelope to trend lines. Split middle method of trend estimation was conducted and indicated there was a marginally increasing trend in a therapeutic direction.

Usability and User Experience

It was also of interest to know whether or not the participants found the app acceptable. FD completed three weeks of training prior to beginning the intervention phase, and SI completed one week of training. Problems with the app were reported for all three participants (Table 3). These included occasions where the reminder did not come through at the specified time/day and when the reminder alarm failed to stop despite the participant clicking into the app. The developers recognised a bug on the app with regards to the latter problem and updated the app to remove it.

Table 3 *Number of App Errors Reported by Each Participant*

Participant	Number of App Errors Reported
FD	3
SI	5
CE	3

App errors included: reminder not coming through at right time/day; recurring alarm sound; reminder not appearing under correct day;

Table 4 shows mean scores for each individual UTAUT category for participants FD and SI. Lower scores represent a more positive user experience. The results indicate that FD had a better experience using the technology than IS, but both scored quite low overall. There was an overall decrease in FD's scores between pre- and post- intervention, however the mean score for the anxiety domain increased from 1 (strongly agree) to 2 (agree). SI's scores increased on performance expectancy, effort expectancy, social influence, and self-efficacy. While SI expressed intention to continue using the app following completion of the study, he expressed uncertainty about the usefulness and helpfulness of the app as he was still learning to enter reminders independently. Further training sessions were offered, and accepted, to ease any anxiety using the app.

Table 4. *UTAUT Mean Scores on Each Category for FD and SI*

	FD		SI	
	Pre	*Post*	*Pre*	*Post*
Performance Expectancy	1.67	1	2	2.67
Effort Expectancy	1.75	1.75	2.25	2.5
Attitude	1.67	1.67	1.67	2.33
Social Influence	1	1	2	4
Facilitating Conditions	3	1	2	2
Self-efficacy	3	1	2	4
Anxiety	1	2	2	2
Behavioural Intervention	1	1	2	1
Total Score	28	25	36	42

Lower scores in the UTAUT indicate a better user experience. UTAUT item responses are out of 5, with responses ranging from Strongly Agree to Strongly Disagree. The total is out of 85.

Follow up questions to the questionnaire provided some qualitative information.

FD said, “Wish I had it earlier” when asked about overall impression of the app. His partner said she enjoyed the “principle of it”. She described how she usually does everything for FD and tells him everything that he needs to do whereas the app “gives him something for himself…a sense of independence”.

SI said the alarm “sound was good for catching my attention” when otherwise engaged. He found it helpful “to some extent”, although reported frustration with ongoing memory difficulties. The partner of SI also reported frustration with the errors associated with the app, reported earlier. Specifically, the times when the reminders did not come through as specified. She described how the reminder app does not capture the other, perhaps unexpected, memory difficulties that SI was experiencing, such as remembering to collect luggage from airport carousel or remembering to check he has all necessary items (e.g. keys, wallet) when leaving the house. SI’s partner also reported increased incidences of confusion in SI, since commencing the study, which she attributed to the app and when the reminders did not come through as intended.

When asked about the main difficulties associated with using the App, prior to withdrawal, the partner of CE said that CE was “either in denial of memory difficulties…or lacked insight into them”. CE reported her memory to be “fine” and described the noise from the alarm as “annoying”. CE’s partner reported that usually CE would be very motivated to participate in research studies, however she was struggling to use other parts of the iPhone and so wondered whether her difficulties operating the app made her want to withdraw from the intervention phase. He noted increased apathy in CE and wondered if this was possibly a result of her dementia diagnosis. He said he wished the study had taken place a year ago, when CE exhibited fewer difficulties with memory and completing tasks.

Discussion

Efficacy

Baseline data confirmed that all participants often forgot to carry out target behaviours or only carried them out if reminded by their retrospective partners. The results of the efficacy analysis show that introduction of the reminder app for FD and SI led to a statistically significant change in memory performance for both participants, with a large effect size reported for both. It is unlikely that improvement was due to spontaneous recovery – CE showed little change over time.

With increasing emphasis on early detection and intervention for people with dementia, this study adds to the limited, but growing, body of literature suggesting the effectiveness of electronic memory aids for people with dementia. While this was the first piece of research evaluating the effectiveness of the MindMate app as a reminder tool, similar positive results have been reported with the Google Calendar app with both the ABI and dementia population (McDonald et al, 2011; Baldwin and Powell, 2014; El Haj et al., 2017).

There is an increasing number of older people using smart phones and tablet devices; they are relatively easy to use, socially acceptable and cost-effective. In a recent survey of memory aid use among the brain injured population, Jamieson et al., (2017a) noted that other technologies, including pagers, dictaphones, and electronic organisers have become obsolete, as many of their functions can now be performed on smartphones. This has facilitated the introduction of more sophisticated, cheaper and user-friendly aids, such as the MindMate app.

Smartphones and tablet devices also offer a solution for overcoming any potential stigma that might be associated with using an aid. Baldwin et al., (2011) found that a key factor leading to avoidance of memory aids among the brain injured population was that they were a threat to the individual's pre-injured identity. The same could be considered for those with a diagnosis of dementia. The importance of offering memory compensatory strategies that reflect an individual's sense of self, lifestyle and values has been highlighted previously (Baldwin et al., 2011). Smartphones and tablet devices address this issue, due to their omnipresence in today's society.

Usability

The secondary aim of this research was to evaluate the usability and acceptability of this app as an assistive technology device for people with dementia. The UTAUT scores were overall positive; both participants expressed a favourable opinion of the app, and expressed intention to use the app following completion of the study. However, frustrations were noted when the app did not function as intended, and this influenced both SI's self-efficacy and his partner's beliefs around the potential benefits of the app.

Apps on smart devices are continually developing and upgrading; this is in response to both, growing consumer demand, and to updates on the devices' operating systems, which can

impact the app's functioning. For example, problems with turning off the alarm for CE were a result of a bug developing on the app, following an upgrade of the smartphone's mobile operating system (iOS for Apple). As a result, an update of the MindMate app was required to remove this bug. These changes are difficult to control for and present a challenge in terms of a person with dementia's ability to adapt to these changes and upgrades. The impact of upgrades and changes to an app on the individual with dementia is an important consideration for the developers of apps that target this population as well as researchers.

For example, future studies evaluating apps should be transparent with potential participants about the possibility of technical difficulties at the point of recruitment. The current researcher was in regular contact with both participants and app developers, therefore the difficulties were addressed in a relatively short space of time. However, if this regular access is not available, contact details for accessing technical support should be made available to participants at the outset.

The results of the UTAUT questionnaire should be interpreted with caution as they only reflect the views of two participants. Indeed, the third participant withdrew from the study following reported frustration with the alarm sound and difficulties turning off the reminder. This would suggest that she found it neither acceptable nor usable. The partner of CE believed that CE's dementia was too far advanced for her to learn to operate a new app; this suggests it may be important to consider the role of insight as inclusion criterion for future research. While CE expressed enthusiasm to participate at the outset of the present study, results of her PRMQ would suggest that she did not believe her memory difficulties were at the level of impairment. Indeed, at follow-up interview, CE described her memory as "fine" and "good". While lack of insight is a common clinical feature of people with dementia, it is possible that this might impact participation in research to support a difficulty that they might not believe they have.

Methodological Limitations

The study followed RoBiNT recommendations for both external and internal validity in SCED studies (Tate et al., 2013). While these were mostly met, certain scale items were more difficult to achieve.

It was not expected that that the reminder strategy would have any long-term effects on memory ability following completion of the study; therefore, no generalisation measures were undertaken. A description of setting was also not provided; as the reminders were delivered across the day, the participants may have been in their home or elsewhere in the community at the time of receiving them.

Tate *et al.* (2013) recommend the demonstration of at least three repetitions of treatment effect. Due to time constraints, the present study could only demonstrate two repetitions, following withdrawal of participant CE. This also impacted the score for design with control, as only four phases were recorded. It was also not possible to blind the participant or therapist to the study conditions because training had to be provided on using the app prior to

commencing intervention phase. The lack of blinding of the experimenter was unlikely to cause bias, as it was the app that was delivering the reminders to the participant.

It was often difficult to identify memory targets for the week ahead for participants during the intervention phase, and therefore proxy experimental memory tasks were created (e.g. send researcher a text message at a certain time). The researcher met with each participant and their partners at the beginning of each week, during the intervention phase, and they often did not have clearly defined schedules for the week ahead. This led to the recording of fewer target events during this phase. The majority of people who receive a diagnosis of dementia are in the older adult population, and are therefore, more likely to be retired. People who are retired are less likely to have fixed events in their week as they do not have job responsibilities. It might be helpful to think about future similar research encouraging participants to routinize events that take place more intermittently (e.g. certain household chores on a specific day of the week).

The partner of SI also noted that less anticipated events (e.g. leaving luggage at airport) were most distressing for SI, and these events were difficult to capture using the MindMate app. This difficulty in predicting, measuring and controlling for unexpected or unusual events that might catch people out was also reported by Jamieson et al., (2017) in their study evaluating smartwatches.

Wolery and Harris (1982) advised on the continuation of the baseline phase condition if behaviours were changing in a therapeutic direction. This did not happen for participant SI, despite an increasing trend being observed, for a couple of reasons. First, the participant was very eager to begin using the MindMate app and, having initially informed him and his partner of the 7-week time frame for baseline data collection, the researcher was concerned about patient engagement should baseline have to continue indefinitely. Second, dementia, unlike ABI, is a degenerative condition, and with focus on early intervention, it would seem unethical to make the participant continue with baseline for an unknown period of time.

Recruitment took place across three community mental health teams over a five-month period. However, only four participants were initially identified, and two completed the study. One possible reason for this could be the lack of people being diagnosed with mild dementia within the teams. Indeed, many health professionals and post-diagnostic support workers from the teams noted the dearth of patients with a diagnosis of mild dementia on their caseload; most, if not all, were in the moderate to severe stages of their illness. Jamieson et al., (2014) suggested that memory aids may support learning of associations (e.g. taking medication and mealtimes). For this reason, they highlight the added advantage of training participants to learn to use an aid while the cognitive impairment is relatively mild; the knowledge is more likely to be retained as a person's memory deteriorates. However, other studies have shown positive effects evaluating electronic memory aids with participants with both moderate and severe dementia (e.g. Oriani et al., 2003; Mihailidis et al., 2004; 2008). For example, (Mihailidis et al., 2004) reported increased performance at handwashing using

their computerised device (COACH) in participants with moderate to severe dementia. It would be interesting to expand inclusion criteria for future similar research to include those with a dementia considered to be in the moderate or severe stages, and evaluate differences.

Staff also reported a low number of patients on their caseload who owned a smart phone or tablet. According to an Ofcom (2016), smartphones are the most widely-owned internet-enabled device. Although 66% of adults own a smartphone, and 54% of households own a tablet, the 65+ population are reported to be the slowest in terms of uptake of smart devices. However, the number of users is projected to increase year on year (Statista, 2017).

Conclusion

The findings from this study provide evidence supporting the effectiveness of the intervention. While user experience was mostly positive, some concerns were raised in relation to the nature of the reminder offered and the frustration experienced when the reminder did not deliver, as intended. It is possible that the lack of research looking at the efficacy of memory aids with this population is a result of the many challenges experienced in this study. Nonetheless, both participants indicated overall favourability with the app, with intention expressed to continue using it to support their memory difficulties. Therefore, the MindMate app could serve as a feasible intervention for prospective memory difficulties in people with dementia in clinical practice.

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APPENDICES

Appendix 1.1 Submission Requirements for *Neuropsychological Rehabilitation*

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- Clinical Trials Registry
- Complying with ethics of experimentation
  - Consent
  - Health and safety
- Submitting your paper
- Publication charges
- Copyright options
- Complying with funding agencies
- Open access
- My Authored Works
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Appendix 1.2 Search Strategy for Systematic Review

Search terms

Dementia or Alzheimer* or (cognitive deterioration) or (cognitive decline) or (intel* deterioration) or (mental deterioration) or (degenerative disease)

AND

memory rehabilitation OR cognitive rehabilitation OR cognitive aid∗ OR memory aid∗ OR cognitive orthos∗ OR cognitive prosth∗ OR assistive technolog ∗ for cognition OR compensat∗ technolog∗ OR memory orthot∗ OR memory prosth∗

AND

Technolog∗ OR computer OR digital OR robot OR pag∗ OR text∗ OR messag∗ OR telephone OR smartphone OR (smart hous∗) OR camera OR television OR system OR device

AND

everyday memory OR prospective memory OR retrospective memory OR attention OR reminding OR micro-prompting OR prompting OR alerting OR organisation OR time keeping OR intention∗ OR goal manag∗

Risk of Bias in N-of-1 Trials (RoBiNT) Scale Record Form

This recording form only contains summaries of the rating criteria and should be used in conjunction with the manual

Rater Name: Author & Title:

Internal Validity (IV) Subscale			Score
1 **Design with control**	2 Points:	At minimum: ABAB with 4 phases; concurrent multiple-baseline design (MBD) with 6 phases, 3 tiers; alternating-treatments design (ATD) with 4 sets of alternating sequences; changing-criterion design (CCD) with 4 steps; for medical N-of-1: 3 x AB pairs	0 1 2 Where:
	1 Point:	ABA or 3 phase variant; concurrent MBD with 4-5 phases, 2 tiers; ATD with 3 sets of alternating sequences; CCD with 3 steps; for medical N-of-1: 2 x AB pairs	
	0 Points:	AB; AB+follow-up; non-concurrent MBD; ATD with <3 sets of alternating sequences; CCD with <3 steps; nonwithdrawable treatment in ABA	
2 **Randomisation**	2 Points:	Randomise: sequence (order) and/or onset (start point) for all phases (see manual for exceptions)	0 1 2 Where:
	1 Point:	Restricted randomisation (e.g., participants to blocks of sequences); counterbalancing	
	0 Points:	No information; randomisation of other aspects of the study (e.g., stimulus materials)	
3 **Sampling of behaviour**	2 Points:	5 or more data points in every phase with data presented	0 1 2 Where:
	1 Point:	at least 3 data points in every phase with data presented	
	0 Points:	<3 data points in any phase	
4 **Blinding of people involved in the intervention**	2 Points:	Both participant and practitioner blind to phase of study. If technological intervention used, consult manual	0 1 2 Where:
	1 Point:	Participant or practitioner blind to phase. If technological intervention used, consult manual	
	0 Points:	Neither participant nor practitioner are blind to phase	
5 **Blinding of assessor(s)**	2 Points:	Assessors blind to all phases; use of computer/machine free from human involvement; outcomes self-report and participant is blind	0 1 2 Where:
	1 Point:	Independent assessor(s), but not blind to phase	
	0 Points:	Practitioner collects/extracts/scores/processes the data; no mention of blinding or independence of assessor(s)	
6 **Interrater agreement**	2 Points:	Machine-generated data or data sampled from ≥20% per condition, analysed and reported per condition, with ≥80% agreement (k≥0.6, etc)	0 1 2 Where:
	1 Point:	A reasonably objective measure (as defined in the manual) used or agreement is ≥70% (k≥0.4) even if (a) data are not calculated and reported per condition and/or (b) <20% of data is sampled per condition	
	0 Points:	Agreement <70% (k<0.4, etc); subjective measure used; consensus ratings alone; inter-rater agreement only reported for a previous study	
7 **Treatment adherence**	2 Points:	Machine-delivered intervention free from human implementation or adherence assessed (i) against a clear rating system, (ii) assessor is independent of practitioner/participant, (iii) ≥20% of is data sampled, (iv) resulting in ≥80% adherence	0 1 2 Where:
	1 Point:	Adherence meets 2/4 criteria above, and includes (a) assessor independent of practitioner and (b) adherence ≥70%	
	0 Points:	Adherence <70%; assessor not independent of practitioner; components only loosely related to adherence	

External Validity and Interpretation (EVI) Subscale			Score
8 **Baseline characteristics**	2 Points:	Analysis of baseline characteristics and age, sex, aetiology, severity of condition	0 1 2
	1 Point:	Analysis of baseline characteristics or age, sex, aetiology, severity of condition	Where:
	0 Points:	No analysis of baseline conditions or incomplete listing of the four participant characteristics	
9 **Setting**	2 Points:	Description of general location and detailed description of the specific environment	0 1 2
	1 Point:	Description of either general location or specific environment but details are sparse	Where:
	0 Points:	Neither general location nor specific environment are described	
10 **Dependent variable (target behaviour)**	2 Points:	Target behaviour is operationally defined in precise terms and the method of measuring it is described	0 1 2
	1 Point:	Target behaviour is operationally defined, but its description and/or method of measurement is not clear and precise	Where:
	0 Points:	Target behaviour is not operationally defined	
11 **Independent variable (therapy/ intervention)**	2 Points:	Detailed description of content of the intervention including any equipment/manuals (for medical N-of-1: content of the agents, both active and placebo) and 3 procedural details: number, duration (dosage for medical N-of-1) and frequency of sessions	0 1 2
	1 Point:	General description of content of intervention (and equipment/manuals) and 2/3 procedural details (number, duration/dosage, frequency)	Where:
	0 Points:	Intervention described in general terms; only identified as a treatment approach (e.g., "cognitive-behaviour therapy"); <2/3 procedural details	
12 **Raw data record**	2 Points:	Raw data record with a data point for every session/observation period. If ≥10 individual trials, complete raw data record for ≥3 cases	0 1 2
	1 Point:	If ≥10 or more individual trials, complete raw data record for 2 cases, or provision of a data record but data aggregated/averaged across sessions/periods, or provision of data record but a priori decision not to record data for every session (e.g., multiple probe studies)	Where:
	0 Points:	No raw data reported; data only reported for selected phases, omitted data	
13 **Data analysis**	2 Points:	Systematic visual analysis with specified protocol, or visual analysis aided by quasi-statistical techniques, or statistical analysis with rationale	0 1 2
	1 Point:	Systematic/aided visual analysis with selection of analytic techniques, or statistical analysis but no rationale, or a priori decision re the level of the target behaviour constituting an empirically derived clinically meaningful change	Where:
	0 Points:	Visual inspection without data analysis; analysis not conducted on target behaviour; arbitrary selection of level of target behaviour	
14 **Replication**	2 Points:	1 original + 3 replications (direct inter-subject or systematic including settings, behaviours, practitioners, intervention)	0 1 2
	1 Point:	1 original + 1 or 2 replications (inter-subject or systematic)	Where:
	0 Points:	No replication	
15 **Generalisation**	2 Points:	Specified generalisation measure is probed in every phase	0 1 2
	1 Point:	Specified generalisation measure is probed in at least pre- and post-treatment phases	Where:
	0 Points:	No generalisation measures	

Internal Validity subscale: _____ / 14 **External Validity and Interpretation subscale:** _____ / 16 **Total score:** _____ / 30

Appendix 2.1 The Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) 2016 Checklist

	Title	Identify the research as a single-case experimental design in the title
	Abstract	Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions
	Scientific background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base
	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses
	DESIGN	
	Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined *a priori* or data-driven) and, if applicable, criteria for phase change
	Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study
	Replication	Describe any planned replication
	Randomisation	State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized
	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked
	PARTICIPANT/S or UNIT/S	
	Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment
	Participant characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured
	CONTEXT	
	Setting	Describe characteristics of the setting and location where the study was conducted
	APPROVALS	
	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained
	MEASURES and MATERIALS	
	Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured
	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions
	INTERVENTIONS	
	Intervention	Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication
	Procedural fidelity	Describe how procedural fidelity was evaluated in each phase
	ANALYSIS	
	Analyses	Describe and justify all methods used to analyse data

	Sequence completed	For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons
	Outcomes and estimation	For each participant, report results, including raw data, for each target behaviour and other outcome/s
	Adverse events	State whether or not any adverse events occurred for any participant and the phase in which they occurred

	Interpretation	Summarise findings and interpret the results in the context of current evidence
	Limitations	Discuss limitations, addressing sources of potential bias and imprecision
	Applicability	Discuss applicability and implications of the study findings

	Protocol	If available, state where a study protocol can be accessed
	Funding	Identify source/s of funding and other support; describe the role of funders

MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

My name is Claire McGoldrick and I am a trainee Clinical Psychologist. I would like to invite you to take part in a research study which is exploring whether a mobile application called MindMate is effective at helping people with a diagnosis of dementia to remember to carry out everyday tasks.

The study aims to explore this application with people who are considered to be in the early stages of dementia, together with their carer. For the first few weeks of the study you and your carer will simply record how often you forget to do things that you have noticed are difficult to remember. This will take between five and seven weeks.

Then MindMate will be downloaded to your phone or tablet and it will provide reminders about things to do. These reminders will be chosen by you and your carer at the beginning of each week, for a period of five weeks. You will also be invited to your nearest clinic or, with your permission, the researcher can visit you at home to complete a small number of cognitive assessments. However, if you have already completed these tests with your Community Mental Health Team psychologist you will not need to do them again. You will be asked to attend the clinic or receive a home visit (according to your preference) once a week for the duration of the study. These should last approximately twenty minutes, and will provide us with an

opportunity to see how you are getting on, and answer any questions you might have.

It is hoped that this study will provide evidence as to whether this memory aid could be useful for individuals with a diagnosis of dementia who report memory difficulties.

If you would like further information about this study, please complete the slip below and hand it to your health care worker. The researcher will then be in touch to provide more information to help you decide if you would like to participate.

MindMate: A Study of a Reminder System for People with Dementia

I would like to find out more about this study and I can be contacted on the details below by the researcher:

Name: _____

Address:

_____

_____

Telephone number: _____

MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

Participant Information Sheet

I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. If anything is unclear or you would like more information please contact me. All relevant contact details are at the bottom of this leaflet.

Who is conducting the research?

The research is being carried out by Claire McGoldrick (Trainee Clinical Psychologist), from the Institute of Health & Wellbeing at the University of Glasgow. I am studying for my Clinical Psychology Doctorate and I am conducting this research to fulfil the requirements of the course. I also have a keen interest in dementia and interventions that aim to support people with the diagnosis.

What is the purpose of the study?

People with a diagnosis of dementia often report difficulties with their memory. This study aims to assess whether a mobile application (app) called MindMate is effective at helping people with the diagnosis to remember to carry out everyday tasks.

Why have I been invited?

You have been invited to take part in this study because you have recently received a diagnosis of dementia, which is considered to be in the early stages.

Do I have to take part?
NO. It is entirely up to you to decide. You will be asked to sign a consent form to show you have agreed to take part. However, you are free to withdraw at any time, without giving reason. If you decide to withdraw from the study, this would not affect any care you or your carer are currently receiving.

What does taking part involve?
You will be invited to attend the clinic or receive a home visit for a couple of hours to complete some cognitive assessments. However, if you have already completed these tests with your Community Mental Health Team psychologist you will not need to do them again, we will record the results of these tests from your medical records instead. The researcher will look at this will help us to develop a clearer picture of your current difficulties.

Following this, a 'baseline' period will take place. This will be randomised for each participant and will occur for 5-7 weeks. Randomisation involves using a computer program to randomly assign you to a baseline period of 5, 6 or 7 weeks. Together with your carer you will first identify the tasks that you are having difficulty remembering in your everyday life. Your carer will then be sent a weekly monitoring form, which they will use each day to note whether or not you have remembered to complete the task. A text reminder will be sent to your carer's phone reminding them to complete this form.

Following this initial baseline period, you will be invited back into the clinic or receive a home visit for approximately one hour. During this visit, you will receive an introduction to MindMate, which has been specifically designed for use by people with dementia, and a demonstration of the reminder tool on the MindMate app. This will involve sending reminder alerts to your smart phone or tablet. A week of practice using the application on your smart phone or tablet will take place before the next stage of the study.

The next phase will then take place for 5 weeks and during this time you will receive a reminder prompt from MindMate for each task that you need to remember. Your carer will monitor which tasks you completed following the reminder prompt, and those you did not, on the weekly monitoring form. This will allow us to see whether using MindMate makes it more likely that tasks will be completed.

At the end of the study, you will be invited back to participate in a final clinical interview, lasting approximately one hour. This will provide you with the opportunity to feedback how you got on with the app and to complete the post intervention questionnaire. Some of this interview will be recorded. Any direct quotes used in the write up of this research will be anonymised.

Both you and your carer will be asked to complete a consent form prior to commencing the study. You will receive a copy of your signed consent to keep.

What happens to the information?
Your identity and personal information will be completely confidential and known only to the researcher and her supervisors (Dr Stephanie Crawford and Professor Jonathan Evans). A representative of the study sponsor, NHS Greater Glasgow and Clyde may also look at this information, to make sure the study is being conducted correctly. All confidential information will be stored within a locked filing cabinet. The data will be held in accordance with the Data Protection Act, which means they are kept safely. Personal information will not be revealed to other people without your permission.

In rare circumstances, confidentiality may have to be breached. This is in cases where the researcher becomes concerned for the safety of the participant or others. The participant will be informed prior to doing so.

What are the possible benefits of taking part?
It is hoped that by taking part in this research, you will be providing valuable information regarding how useful mobile apps are in supporting people with a dementia, who report memory difficulties. Should the intervention prove effective for you, you can continue to use the app following completion of the study. Training on using the app and using other tools within the app will also be offered by the co-founders of the MindMate app in the phase of the study when you are using MindMate.

What are the possible disadvantages and risks of taking part?
Your test results could indicate that your difficulties such as memory have become worse over time. In this instance, additional support can be provided by contacting your healthcare provider who may arrange a review or additional support measures for you. The researcher will be happy to help you with this if required. It will be helpful for your GP to be aware of the results of the tests and therefore if you give your permission we will inform your GP that you have participated and pass on the test results. This study will require your commitment for 11-13 consecutive weeks.

Who has reviewed the study?
This study has been reviewed by the NHS West of Scotland Research Ethics Committee and the University of Glasgow.

If you have any further questions?
You will have a copy of the information sheet and signed consent form to keep. If you would like further information about this research project please contact Claire McGoldrick or her clinical supervisor Dr Stephanie Crawford. If you wish to seek general advice about participating in this study from someone **not** closely linked to the study, please contact Professor Tom McMillan. Please find all contact details overleaf.

Contacts:

Ms Claire McGoldrick
Trainee Clinical Psychologist
Institute of Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
G12 0XH
Tel: 0141 211 0607
Email: c.mcgoldrick.1@research.gla.ac.uk

Dr Stephanie Crawford
Consultant Clinical Psychologist
Inverclyde Older People CMHT
Crown House
30 King Street
Greenock
PA15 1NL
Tel: 01475 558045
Email: Stephanie.Crawford@ggc.scot.nhs.uk

Professor Jonathan Evans
Professor of Applied Neuropsychology
Mental Health and Wellbeing
University of Glasgow
The Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 0694
Email: jonathan.evans@glasgow.ac.uk

Professor Tom McMillan
Professor of Clinical Neuropsychology
Mental Health and Wellbeing
University of Glasgow

The Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 0354
Email: Thomas.McMillan@glasgow.ac.uk

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance. The normal NHS complaint mechanisms are also available to you.

Thank-you for your time

MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

Partner Information Sheet

I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. If anything is unclear or you would like more information please contact me. All relevant contact details are at the bottom of this leaflet.

Who is conducting the research?

The research is being carried out by Claire McGoldrick (Trainee Clinical Psychologist), from the Institute of Health & Wellbeing at the University of Glasgow. I am studying for my Clinical Psychology Doctorate and I am conducting this research to fulfil the requirements of the course. I also have a keen interest in dementia and interventions that aim to support people with a diagnosis of dementia.

What is the purpose of the study?

People with a diagnosis of dementia often report difficulties with their memory. This study aims to assess whether a mobile application (app) called MindMate is effective at helping people with a diagnosis of dementia to remember to carry out everyday tasks.

Why have I been invited?

You have been invited to take part in this study because you are the partner/family member of someone who has received this diagnosis.

Do I have to take part?
NO. It is entirely up to you to decide. You will be asked to sign a consent form to show you have agreed to take part. However, you are free to withdraw at any time, without giving reason. If you decide to withdraw from the study, this would not affect any care you or your partner are currently receiving.

What does taking part involve?
As a carer, you will initially be invited to participate in an interview, along side your partner/family member, with the main researcher. This will last approximately an hour and take place in the clinic or at your home, and will involve answering questions about the difficulties your partner/family member currently faces. This will help us to develop a clearer picture of their current difficulties.

Following this, a 'baseline' period will take place. The length of this period will be randomised across all participants, lasting for 5, 6, or 7 weeks. Together with your partner or family member you will first identify the tasks that they are having difficulty remembering and completing in their everyday life (e.g. missed appointments). You will then be sent a weekly monitoring form, which you will use each day to note whether or not your partner/family member remembered to complete the task. A daily text reminder will be sent to your phone reminding you to complete this form.

Following this initial baseline period, your partner/family member will be invited back into the clinic or receive a home visit for approximately one hour. During this visit, they will receive an introduction to MindMate, which has been specifically designed for use by people with dementia, and a demonstration of the reminder tool on the MindMate app. This will involve sending reminder alerts to their smart phone or tablet. A week of practice using the application on their smart phone or tablet will take place before the next stage of the study.

The next phase will then take place for 5 weeks and during this time they will receive a reminder prompt from MindMate for each task that they need to remember. You will monitor which tasks they completed following the reminder prompt, and those they did not, on the weekly monitoring form. This will allow us to see whether using MindMate makes it more likely that tasks will be completed.

Both you and your partner/family member will be asked to complete a consent form prior to commencing the study. You will receive a copy of your signed consent to keep.

What happens to the information?
Your identity and personal information will be completely confidential and known only to the researcher and her supervisors (Dr Stephanie Crawford and Professor Jonathan Evans). A representative of the study sponsor, NHS Greater Glasgow and Clyde may also look at this information, to make sure the study is being conducted correctly. The information obtained will remain confidential and stored within a locked filing cabinet within the University of Glasgow. The data will be held in accordance with the Data Protection Act, which means they are kept safely. Personal information will not be revealed to other people without your permission.

What are the possible benefits of taking part?
It is hoped that by taking part in this research, you will be providing valuable information regarding how useful mobile apps are in supporting people with a dementia, who report memory difficulties. Should the intervention prove effective for your partner/family member, they can continue to use the app following completion of the study. Training on using the app and using other tools within the app will also be offered by the co-founders of the MindMate app in the phase of the study when your partner/family member is using MindMate.

What are the possible disadvantages and risks of taking part?
Your partner/family member's test results could indicate that their difficulties such as memory have become worse over time. In this instance, additional support can be provided by contacting your healthcare provider who may arrange a review or additional support measures. The researcher will be happy to help you with this if required. It will be helpful for your partner/family member's GP and Community Mental Health Team to be aware of the results of their tests and therefore if they give their permission we will inform them that they have participated and pass on the test results. This study will require your commitment for 11-13 consecutive weeks.

Who has reviewed the study?
This study has been reviewed by the NHS West of Scotland Research Ethics Committee and the University of Glasgow.

If you have any further questions?
You will have a copy of the information sheet and signed consent form to keep. If you would like further information about this research project please contact Claire McGoldrick or her clinical supervisor Dr Stephanie Crawford. If you wish to seek general advice about participating in this study from someone **not** closely linked to the study, please contact Professor Tom McMillan. Please find all contact details overleaf.

Contacts:
Ms Claire McGoldrick
Trainee Clinical Psychologist
Institute of Health and Wellbeing
Gartnavel Royal Hospital
1055 Great Western Road
G12 0XH
Tel: 0141 211 0607
Email: c.mcgoldrick.1@research.gla.ac.uk

Dr Stephanie Crawford
Consultant Clinical Psychologist
Inverclyde Older People CMHT
Crown House
30 King Street
Greenock
PA15 1NL
Tel: 01475 558045
Email: Stephanie.Crawford@ggc.scot.nhs.uk

Professor Jonathan Evans
Professor of Applied Neuropsychology
Mental Health and Wellbeing
University of Glasgow
The Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 0694
Email: jonathan.evans@glasgow.ac.uk

Professor Tom McMillan
Professor of Clinical Neuropsychology
Mental Health and Wellbeing
University of Glasgow
The Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Tel: 0141 211 0354
Email: Thomas.McMillan@glasgow.ac.uk

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance. The normal NHS complaint mechanisms are also available to you.

Thank-you for your time

CONSENT FORM

Title of Project: MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

Name of researcher: Claire McGoldrick

Participant Identification number for this Trial:

Please Initial Box

1. I confirm that I have read and understand the information sheet (version 2 08/09/2016) for the above study. ☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without given any reason. ☐
4. I understand that information from the questionnaires I complete will be kept strictly confidential, and any information about me will have my personal details removed so that I cannot be recognised. ☐
5. I consent to my G.P being informed of my participation in this study. ☐
6. I consent to the use of quotations from interviews. Any quotes used from clinical interviews will be anonymised. ☐
7. I consent to the researcher retrieving the data on my neuropsychological assessment from my medical file. ☐
8. I understand that relevant sections of my care record and data collected during the study may be looked at by responsible individuals from the sponsor or host organisation or from regulatory authorities where it is relevant to taking part in this research. ☐
9. I agree to take part in this study. ☐

Name of Participant	Date:
	Signature:
Name of Person Taking Consent	Date:
	Signature:

CONSENT FORM – PARTNER/FAMILY MEMBER

Title of Project: MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

Name of researcher: Claire McGoldrick

Participant Identification number for this Trial:

Please **Initial** Box

1. I confirm that I have read and understand the information sheet (version 2 08/09/2016) for the above study. ☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without given any reason. ☐
4. I understand that information from the interviews I complete will be kept strictly confidential, and any information about me will have my personal details removed so that I cannot be recognised. ☐
5. I understand that a representative from the study sponsor, NHS GG&C, may look at information from the study for audit purposes. I understand that this information will be kept strictly confidential. ☐
6. I agree to take part in this study. ☐

Name of Participant Date:
Signature:

Name of Person Taking Consent Date:
Signature:

Appendix 2.5 Weekly Monitoring Form

Monitoring Form **Week Beginning: _____**

Day of the Week	Target to be Remembered	Time due to be completed by:	Completed without prompting? Please ✓/X*
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

***✓ if completed independently or X if forgotten/ prompting require**

Appendix 2.6 NHS Ethics & SSA Letters

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Jon Evans
Professor of Neuropsychology
University of Glasgow
R212 Level 2
Mental Health and Wellbeing, Gartnavel Royal Hospital
Glasgow
g12 0XH

West of Scotland REC 3
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SW

Date 07 November 2016

Direct line 0141 232 1804
E-mail WoSREC3@ggc.scot.nhs.uk

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Professor Evans

Study title: **MindMate: A Single Case Experimental Design study of a Reminder System for People with Mild Dementia**
REC reference: **16/WS/0219**
IRAS project ID: **204924**

Thank you for your response of 4 November 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 03 November 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant consent form [V3 4.11.2016]	3	04 November 2016
Participant information sheet (PIS) [Participant V5 16.09.2016]	5	04 November 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters [V4 8.09.2016]	4	08 September 2016

Document	*Version*	*Date*
Interview schedules or topic guides for participants [Interview Schedule 8.09.2016]	1	08 September 2016
Letters of invitation to participant [V3 08/07/2016]	3	08 July 2016
Non-validated questionnaire [Pre UTAUT]	4	16 September 2016
Non-validated questionnaire [Post UTAUT]	3	16 September 2016
Other [Weekly Monitoring Form V2 16.09.2016]	2	16 September 2016
Participant consent form [Carer V3 16.09.2016]	3	16 September 2016
Participant consent form [V3 4.11.2016]	3	04 November 2016
Participant information sheet (PIS) [Carer V2 8.09.2016]	2	08 September 2016
Participant information sheet (PIS) [Participant V5 16.09.2016]	5	04 November 2016
REC Application Form [REC_Form_07102016]		07 October 2016
Research protocol or project proposal [Research Proposal V2 7.09.16]	2	07 September 2016
Response to Additional Conditions Met [No letter was received]		
Summary CV for Chief Investigator (CI) [CV 8.07.2016]		18 March 2016
Summary CV for student [CV 23.09.2016]		
Summary CV for supervisor (student research) [CV 15.9.2016]	2	15 September 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Method Flow Diagram V1 04.10.2016]	1	04 October 2016
Validated questionnaire [Rivermead BMT]		
Validated questionnaire [Trails]		
Validated questionnaire [Test of Pre Morbid Functioning]		
Validated questionnaire [Prospective and Restrospective Memory Questionnaire]		
Validated questionnaire [Fluency Tests]		
Validated questionnaire [PRMQ-Carer]		
Validated questionnaire [WASI II]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/WS/0219 **Please quote this number on all correspondence**

Yours sincerely

Rose Gallacher
Assistant Administrator

Copy to: *Ms Emma-Jane Gault*
Ms Joanne McGarry, NHS Greater Glasgow and Clyde

Coordinator/administrator: Joanne McGarry/JD
Telephone Number: 0141 232 1818
E-Mail: Joanne.McGarry@ggc.scot.nhs.uk
website www.nhsggc.org.uk/r&d

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

12/12/2016

NHS GG&C Board Approval

Dear Ms McGoldrick

Study Title:	MindMate: A Single Case Experimental Design study of a Reminder System for People with Mild Dementia
Principal Investigator:	Claire McGoldrick
GG&C HB site	NHS Greater Glasgow & Clyde
Sponsor	University of Glasgow/NHS Greater Glasgow & Clyde
R&D reference:	GN16NE538
REC reference:	16/WS/0219
Protocol no:	V2 07/09/2016

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **overall governance and management approval** for the above study.

At the point of this management approval, R&D has received confirmation of Head of Department approval for Glenkirk OPCMHT and Belmont OPCMHT. It is the responsibility of the investigator to approach individual heads of any additional study sites to negotiate access for patient recruitment. Any additional sites participation is entirely at the discretion of the unit/department head and R&D should be updated when additional HOD approvals are sought.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

    a. During the life span of the study GGHB requires the following information relating to this site
        i. Notification of any potential serious breaches.
        ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
    a. Recruitment Numbers on a quarterly basis
    b. Any change of staff named on the original SSI form
    c. Any amendments – Substantial or Non Substantial
    d. Notification of Trial/study end including final recruitment figures
    e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

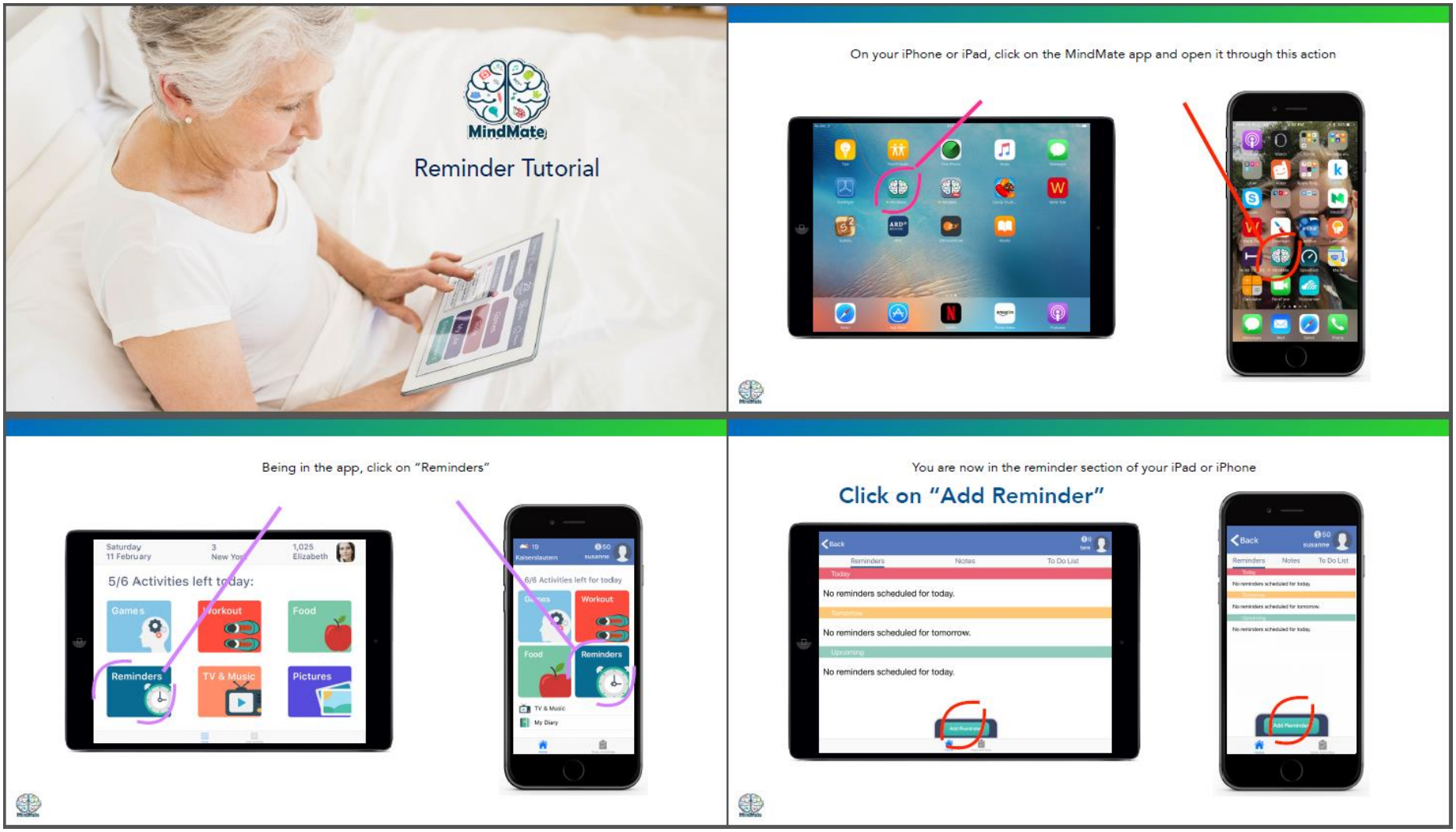
Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Joanne McGarry
Research Co-ordinator

Appendix 2.7 MindMate Tutorial Presentation



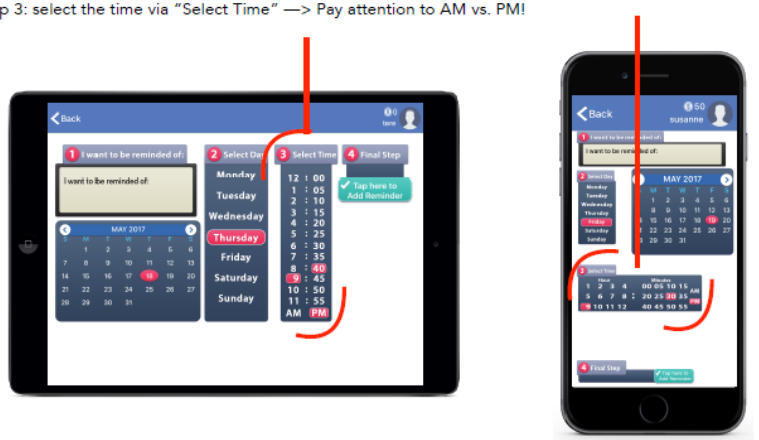
You are now in the reminder section of your iPad or iPhone

Adding a reminder is just 4 steps away

Step 1: click on the field "I want to be reminded of" and type in the purpose of your reminder. E.g. "Call Claire"

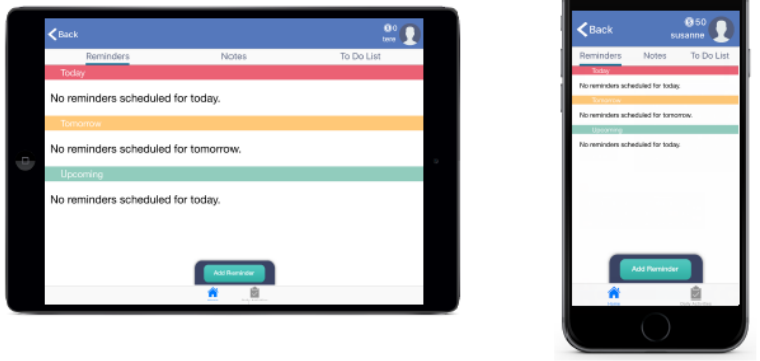
Step 2: select the day via "select day" OR the calendar function under "I want to be reminded of"

Step 3: select the time via "Select Time" —> Pay attention to AM vs. PM!



Step 4: tap on "Tap here to Add Reminder" via Final Step —> the reminder will be added to the first screen.

This is where your reminder will show up



MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

***Pre*-Intervention Questionnaire**

The following questionnaire is adapted from the Unified Theory of Acceptance and Use of Technology (UTAUT) and attempts to develop an understanding of your intentions to use assistive technology and subsequent usage behaviour.

Please answer each question by circling the number which best reflects how you feel about the statement provided. Answers range from 1 (Strongly Agree) to 5 (Strongly Disagree).

I think the MindMate Reminder will be useful for remembering everyday tasks

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using the MindMate Reminder will enable me to accomplish tasks at the right time

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using MindMate Reminder will help me get more things done than usual

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

MindMate Reminder will be clear and understandable

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

It will be easy for me to become skilful at using MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I will find MindMate Reminder easy to use

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Learning to operate MindMate Reminder will be achievable for me

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using MindMate Reminder is a great idea

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Working with MindMate Reminder will be fun

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I will like working with MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

People who are important to me think that I should use MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I have the knowledge necessary to use MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I will be able to complete a job/task using MindMate reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I feel apprehensive about using MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

It worries me to think that I could lose a lot of information using MindMate Reminder by hitting the wrong key

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I hesitate to use MindMate Reminder for fear of making mistakes I cannot correct

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I intend to use MindMate Reminder following completion of the current study

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Thank you for completing this questionnaire

MindMate: A Single Case Experimental Design Study of a Reminder System for People with Dementia

***Post*-Intervention Questionnaire**

The following questionnaire is adapted from the Unified Theory of Acceptance and Use of Technology (UTAUT) and attempts to develop an understanding of your intentions to use assistive technology and subsequent usage behaviour.

Please answer each question by circling the number which best reflects how you feel about the statement provided. Answers range from 1 (Strongly Agree) to 5 (Strongly Disagree).

I find the MindMate Reminder useful for daily tasks.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using the MindMate Reminder enables me to accomplish tasks at the right time

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using MindMate Reminder helps me get more things done than usual

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

MindMate Reminder is clear and understandable.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

It will be easy for me to become skilful at using MindMate Reminder.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I find MindMate Reminder easy to use.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Learning to operate MindMate Reminder is achievable for me.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Using MindMate Reminder is a great idea.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Working with MindMate Reminder is fun.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I like working with MindMate Reminder.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

People who are important to me think that I should use MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I have the knowledge necessary to use MindMate Reminder.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I could complete a job/task using MindMate Reminder

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I feel apprehensive about using MindMate Reminder.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Its worries me to think I could lose a lot of information using MindMate Reminder by hitting the wrong key.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I hesitate to use MindMate Reminder for fear of making mistakes I cannot correct.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

I intend to use MindMate Reminder in the next 3 months.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1	2	3	4	5

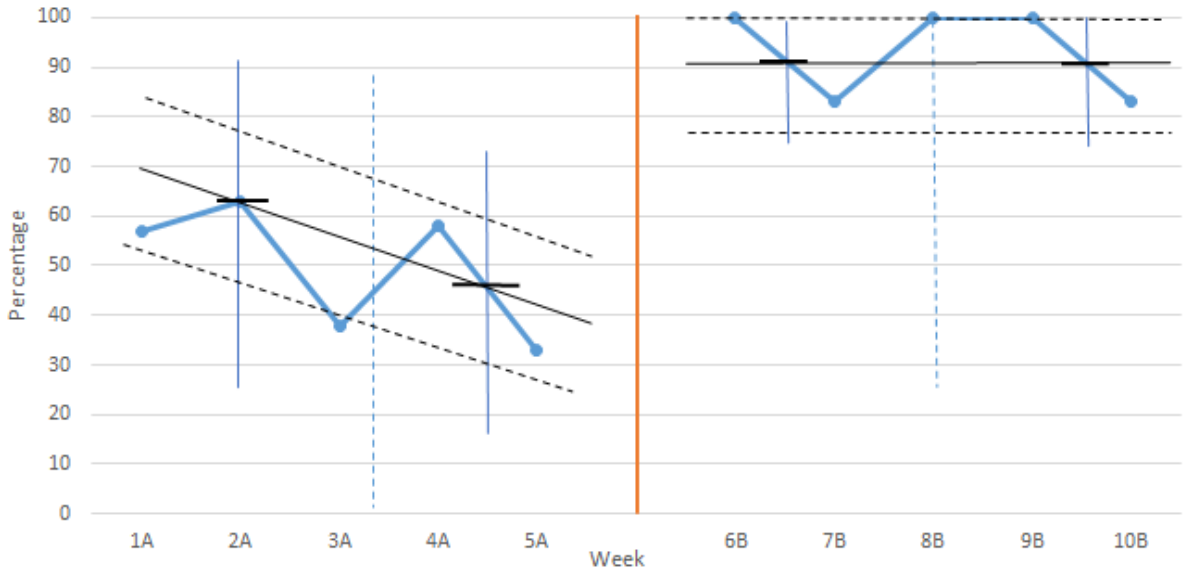
Thank you for completing this questionnaire

Appendix 2.9 Visual Analysis of Participants

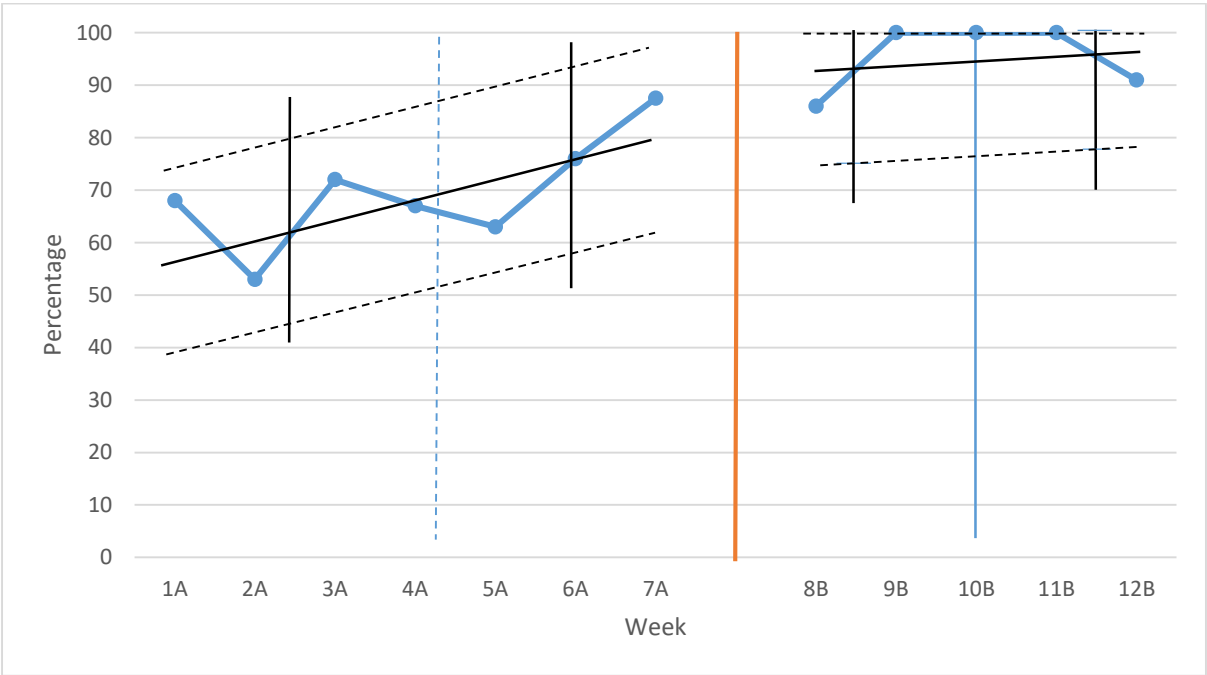
Within-condition and between-condition analysis of graphed data. The three graphs summarise the data of the three participants, respectively. The data points represent the percentage of target memory tasks completed each week in each study phase (A = baseline, B = intervention). The Y axis shows percent performance and X axis shows study week.

All data points located between the dashed black line are considered within the stability envelope.

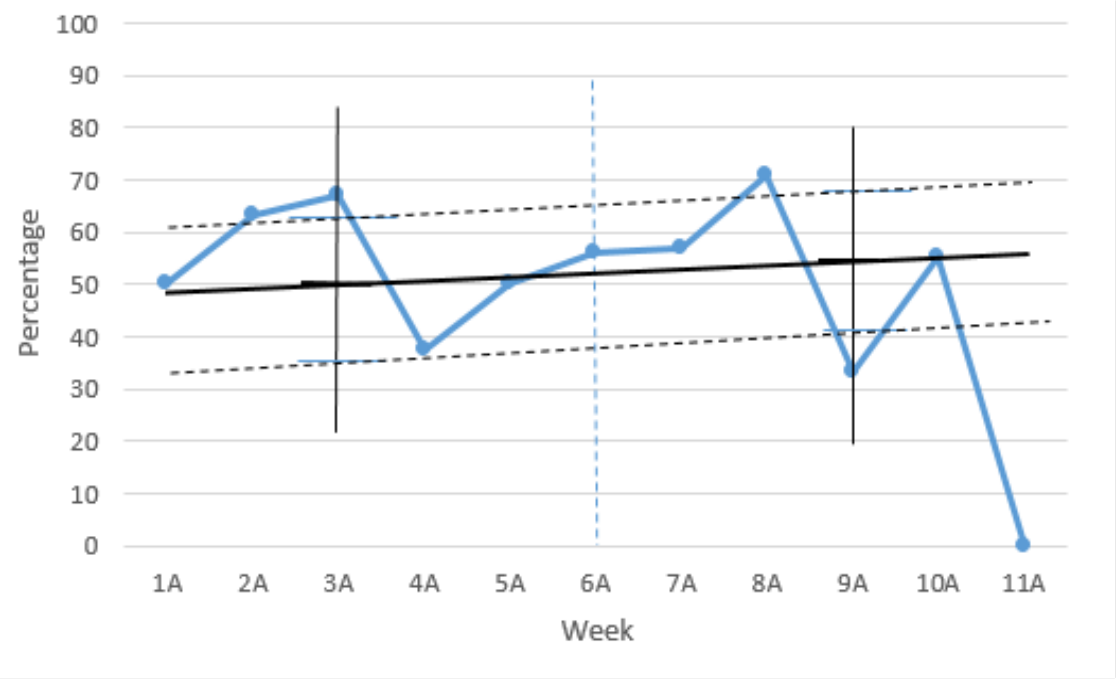
Participant FD



Participant SI



Participant CE



University of Glasgow

MindMate: A Single Case Experimental Design Study in People with Mild Dementia

Name of Assessment:	Course 8 Major Research Project
Matriculation Number:	2166409m
University Supervisor:	Professor Jonathon Evans
Field Supervisor:	Dr. Stephanie Crawford
Version:	2
Date of Submission:	7th of September 2016
Word Count:	4,099

Abstract

Research into the effectiveness of electronic devices such as memory aids remains limited in individuals with a diagnosis of dementia. Mindmate is a recently developed mobile application that aims to support individuals with a diagnosis of dementia, improving self-management skills and quality of life. A single case experimental design multiple baseline across participants study will be used to explore the effectiveness of MindMate reminder alerts delivered to a smartphone or tablet computer as a memory aid.

Three participants with a diagnosis of dementia, who are considered to be in the early stages and who report everyday prospective memory difficulties, will be recruited. A multiple baseline across participants design will be incorporated, and will include a baseline phase that will last between five to seven weeks, followed by a five-week intervention phase where MindMate is used. Target memory behaviours will be identified prior to the intervention phase, and family members or carers will monitor their success.

Results will be analysed using visual inspection and Tau-U analysis.

Introduction

Background

According to Alzheimer's Scotland there are approximately 90,000 people living with dementia in Scotland (Alzheimer's Scotland Action on Dementia, 2015). With improved healthcare and better standards of living people are living longer, which for Scotland means that the number of people with dementia is expected to double between 2011 and 2031 (Patch, 2015). Dementia remains one of the foremost public health challenges within the country, with current costs estimated at £1.7 billion per annum and dementia caregivers reported to be more burdened and more vulnerable to health problems than other caregiver groups (Schulz & Martire, 2004, Sussman & Regehr, 2009).

While there is currently no cure available for dementia, interventions have focused on improving independence and quality of life. As a result, increasing emphasis has been placed on the early diagnosis of dementia to enable those affected to access early interventions and treatments, as well as for accessing practical information, advice and support (Alzheimer's Society, 2013). Appropriate support can have a significant impact on the degree to which someone is able to manage their condition over time and live independently, delaying the need for care home or hospital admission, which ultimately adds savings to the health economy (Department of Health, 2009).

Assistive Technology

Memory difficulties reported among those with a diagnosis of dementia not only include the ability to recall past information, but also the ability to remember to do something at a specific time and place in the future (Prospective memory) (Dewar, Kopelman, Kapur & Wilson, 2015). A range of memory aids currently exist, with the potential to be highly effective in the compensation of memory problems. In their systematic review and meta-analysis, Jamieson, Cullen, McGee-Lennon, Brewster & Evans (2013) noted that evidence supports use of Assistive Technology (AT) for reminding, however noted the dearth of investigations into their use amongst people with degenerative diseases.

Compensatory approaches to memory impairment aim to bypass the deficit area and teach the individual strategies to solve functional problems (Kapur and Wilson, 2009). Mastering

these strategies will, it is assumed, help the individual manage in their everyday environment despite the presence of the impairment (O'Neill & Gillespie, 2015).

External memory aids are the most widely used and effective intervention for assisting memory difficulties and include various devices such as personal hand-held computers, e.g., mini notebooks and tablets, such as the iPad, mobile phones and smartphones. Various electronic aids have been shown to aid prospective memory, including the NeuroPage and Personal Digital Assistant (PDA) (e.g. Wilson, Emslie, Quirk & Evans, 2001; Gentry, Wallace, Kvarfordt, & Lynch, 2008). Jamieson et al., (2013) suggest that memory aids may support learning of associations (e.g. taking medication and mealtimes). This highlights the importance of learning to use an aid while the cognitive impairment is relatively mild; this knowledge is more likely to be retained as a person deteriorates.

Mobile applications (Apps), computer programs that run on mobile devices such as smartphones and tablet computers, offer an alternative solution to overcoming the cost associated with the use of technological memory aids, if the individual already owns a smartphone/tablet. In a study of people with an acquired brain injury, McDonald, Haslam, Yates, Gurr, Leeder, & Sayers et al., (2011) conducted a small randomised controlled trial using the Google Calendar application, in which participants recorded completion of prospective memory tasks. After event details are recorded, Google calendar sends timed reminders to the person's mobile phone. In their study, McDonald et al., (2011) found Google Calendar to be significantly more effective than a paper-based diary. While all participants in this study had prior experience in the use of memory aids, a more recent single case experimental design study tested its use on an individual who had severe verbal and visual memory difficulties and no prior use of a memory aid (Baldwin and Powell, 2015). Their study showed a reduction in forgetting in chosen target behaviours, with the participant also reporting improvements in memory.

More recently, a dementia specific application called MindMate (2015) was developed, with the aim of supporting users in their everyday lives, improving self-management skills, and therefore maintaining the independence of users for as long as possible. This application includes a reminding tool similar to the one on Google Calendar. Mindmate also offer two other versions of the app, Mindmate Pro and Mindmate Plus. The Mindmate Pro version is intended for care homes and allows more than one individual profile to be created on the

one app. Mindmate Plus allows remote access for carers who may wish to enter information (e.g. Reminders) for the individual with dementia from their own phone/tablet.

Aims and hypotheses

The present study aims to examine the use of MindMate as a memory aid for adults who have received a diagnosis dementia, who are considered to be in the early stages, and who are specifically experiencing memory and executive functioning difficulties.

The main hypothesis is:

> Performance on target memory tasks will improve significantly with the introduction of MindMate reminding tool.

Plan of Investigation

Participants

Three participants, aged 18 years or above and who have received a diagnosis of mild dementia, will be recruited from Community Mental Health teams within the Greater Glasgow and Clyde Health board. All three participants will have been given a diagnosis by a psychiatrist using ICD-10 criteria. They will be reporting memory difficulties which have been confirmed by a professional or family member. They will also own a smart phone or tablet computer with internet, and have a family member/carer willing to support and monitor memory aid use.

Exclusion criteria will be participants who:

- have a pre-existing neurological or severe psychiatric problem (e.g. bipolar disorder, psychosis)
- have a diagnosis of dementia, considered to be in the moderate to severe stages
- have visual or auditory difficulties (which cannot be corrected with the use of glasses or hearing aids) that would prevent use of a smartphone;
- those whose first language is not English;
- have a diagnosed or suspected developmental learning disability;
- are currently using online or electronic memory aids. Previous memory aid use will be documented but will not exclude individuals from participation.

Neuropsychological data will be used to confirm that participants are presenting with some degree of cognitive impairment. This will be gathered using the:

- Test of Pre-Morbid Functioning (TOPF, Wechsler, 2011);
- Rivermead Behavioural Memory Test -3rd version (RBMT-3; Wilson, Greenfield, Clare, Baddeley, Cockburn, Watson, et al., 2008);
- Wechsler Abbreviated Scale of Intelligence – 2nd edition (WASI-II; Wechsler, 1999);
- Trails subtest of the Delis–Kaplan Executive Function System (D-KEFS; Delis, Kaplan, & Kramer, 2001);
- Controlled Oral Word Association Test using letters F-A-S (Spreen & Benton, 1977);
- Prospective and Retrospective Memory Questionnaire (Smith, Della Sala, Logie, & Maylor, 2000).

Neuropsychological assesssment is often, although not always, used in the diagnostic process of dementia. Therefore, some of the participants may have already completed these assessments. In cases where they have not completed the tests, or they have not completed all of the tests, the main researcher will admininister the tests prior to beginning the baseline phase of the study.

Recruitment Procedures

Potential participants will be given written information about the study via a member of the Older People Community Mental Health Team or post diagnostic service they are known to, within Greater Glasgow and Clyde. If interested, they will be provided with further written information and they will complete an opt-in slip, consenting to be contacted, which will be sent to the researcher. The researcher will contact the potential participants who will be provided with the opportunity to discuss the study further and ask questions. If potential participants agree to participate, they will be asked to sign a consent form. All information provided will be in size 16 font to ensure ease of reading for those with visual impairments. If more than three participants declare interest, those who have indicated interest first will be recruited with a reserve list for any surplus. Should one or more of the three participants drop out of the study, those on the reserve list will replace them.

Materials

Mindmate, Mindmate Pro and Mindmate Plus are free to download and use dementia applications. Mindmate includes a "Reminder" tool which allows events to be entered for a specific time and date, then sends reminder alerts about the event, thus acting as a memory prompt. Each participant will use their own phone/tablet as they will already be familiar with its use.

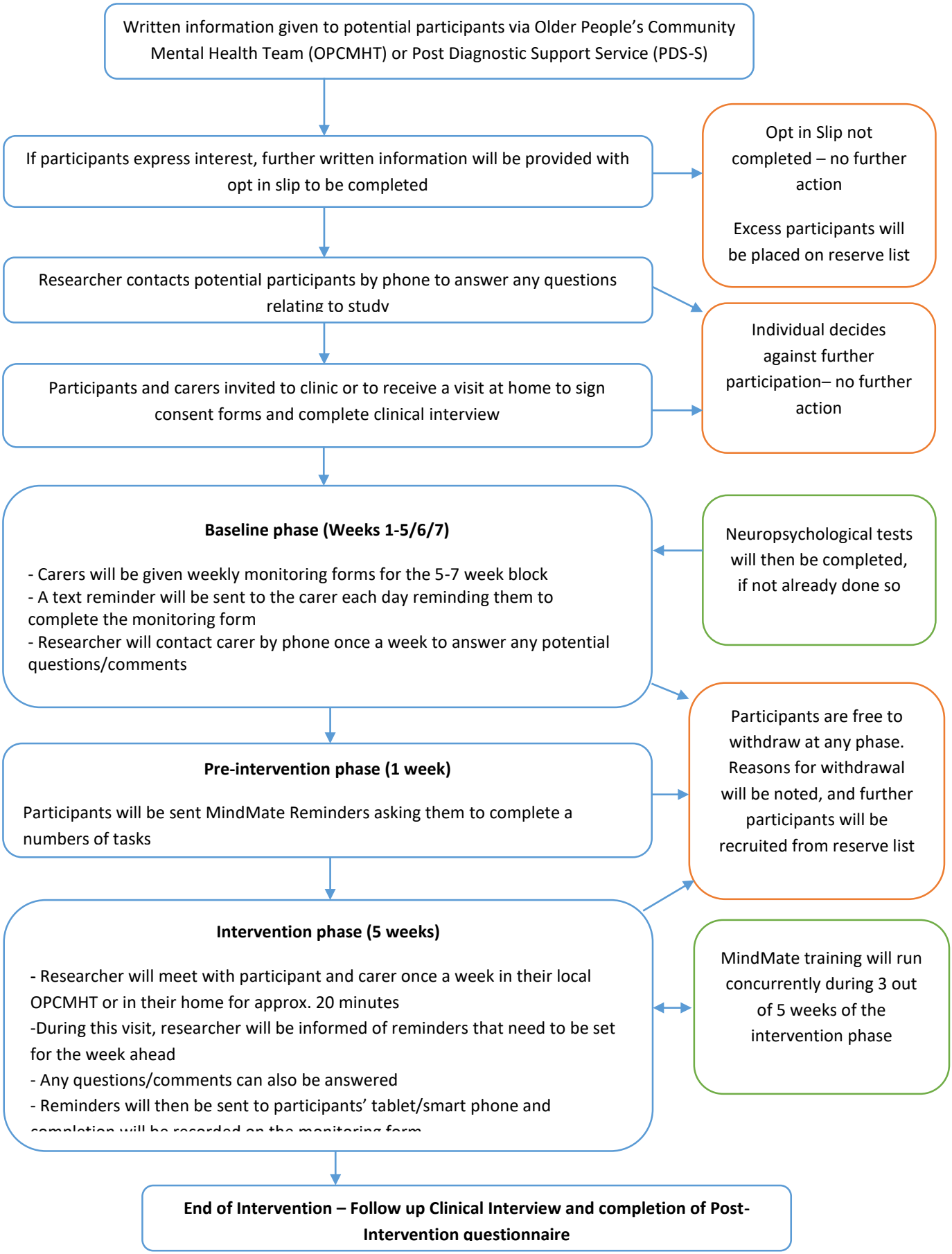
A weekly monitoring form listing individual prospective memory targets and the times they need to be completed will be provided to the carer/family member. Baldwin and Powell (2014) highlighted the importance of picking memory targets that were personally meaningful for the individual therefore memory targets will be constructed in conjunction with the participant and the carer. These will be causing the most disruption in the participants' daily lives. This form can be used daily by an identified family member/carer to record whether or not activities were remembered and completed at an appropriate time. They will be asked to tick targets achieved without prompting from other people, and cross targets that were either forgotten, remembered but not completed, completed at the wrong time, or only completed following prompting from carer.

Design

A randomised single case experimental design (SCED) multiple baseline across participants study will be used, staggering the onset of the intervention. The three participants will be randomly allocated to a 5, 6 or 7-week baseline using the Research Randomizer programme provided by the Social Psychology Network (http://www.randomizer.org). MindMate will then be introduced for all three participants for a 6-week period. Withdrawing intervention might raise ethical issues, therefore a multiple baseline, as opposed to a withdrawal (e.g. ABA) design is more appropriate.

The study was developed with reference to the methodological quality criteria for single case experimental design studies (Risk of Bias in N of 1 trials – RoBiN-T, Tate, Perdices, Rosenketter, Wakim, Godbee, Togher & McDonald, 2013).

Procedure


Written information given to potential participants via Older People's Community Mental Health Team (OPCMHT) or Post Diagnostic Support Service (PDS-S)
If participants express interest, further written information will be provided with opt in slip to be completed
Opt in Slip not completed – no further action
Excess participants will be placed on reserve list
Researcher contacts potential participants by phone to answer any questions relating to study
Individual decides against further participation– no further action
Participants and carers invited to clinic or to receive a visit at home to sign consent forms and complete clinical interview
Baseline phase (Weeks 1-5/6/7)
- Carers will be given weekly monitoring forms for the 5-7 week block
- A text reminder will be sent to the carer each day reminding them to complete the monitoring form
- Researcher will contact carer by phone once a week to answer any potential questions/comments
Neuropsychological tests will then be completed, if not already done so
Participants are free to withdraw at any phase. Reasons for withdrawal will be noted, and further participants will be recruited from reserve list
Pre-intervention phase (1 week)
Participants will be sent MindMate Reminders asking them to complete a numbers of tasks
Intervention phase (5 weeks)
- Researcher will meet with participant and carer once a week in their local OPCMHT or in their home for approx. 20 minutes
-During this visit, researcher will be informed of reminders that need to be set for the week ahead
- Any questions/comments can also be answered
- Reminders will then be sent to participants' tablet/smart phone and
MindMate training will run concurrently during 3 out of 5 weeks of the intervention phase
End of Intervention – Follow up Clinical Interview and completion of Post-Intervention questionnaire

Ethical approval will be obtained from NHS Greater Glasgow and Clyde Ethics Committee. Informed consent will also be obtained from all three participants and their carers.

An initial interview with the participant and a family member/carer will identify target behaviours as well as previous memory aid use. This will be followed by approximately two hours of neuropsychological assessment in order to obtain quantitative data related to their cognitive difficulties. If data from these tests is available from routine assessment within the previous six months, these data will be used instead.

Baseline data will then be gathered over a period of time of 5-7 weeks, during which all target events that were forgotten as well as instances of reminding will be recorded. As in the Baldwin and Powell (2015) study a text message reminder will be sent to the carer every day (time of day to be pre-determined) to remind them to make the recording.

Immediately following baseline data collection, there will be week before intervention recording begins to familiarise each participant with the process involved. Part of this training process will include sending each participant reminders asking them to undertake a number of tasks (e.g. making a phone call to arrange an appointment). Intervention will then take place for 5 weeks.

At the beginning of each week of the intervention, the researcher will meet with the carer and participant in their local OPCMHT or in their home. They will be asked about upcoming events for the week which will be entered into MindMate by the researcher. The participant will be asked about how many reminders they would like to receive about each event and how far in advance they would like to receive the reminder (decided before commencing the study). The carer will record all target events that were forgotten as well as instances of reminding. A text message reminder will also be sent each evening to remind the carer to make the recording.

It will also be important to establish early on whether each participant will be able to enter events themselves onto their smart phone. Following the initial training session familiarising the participant with the process for the intervention, there will be a 3 week block of training sessions on how to use MindMate. This will run concurrently to the intervention phase and will include the provision of a step-by-step guide, alongside illustrated instructions on how to locate, enter, and navigate the app and its Reminder tool. This will include inputting,

editing, or deleting reminder events. The acquisition of this skill does not form part of the aims of this study; however qualitative information will be gathered upon completion of the training.

Following completion of the intervention block, qualitative information will be gathered to evaluate the usefulness of MindMate, to identify its strengths and limitations and to ascertain whether the participant would use the aid in the future. Participants will also be asked to complete a pre and post study questionnaire on eight domains, adapted from the unified theory of acceptance and use of technology (UTAUT) (Venkatesh, Morris, Davis & Davis 2003). These will be administereted at the initial clinical interview and the follow up clinical interview.The UTAUT includes groups of items concerning; performance expectancy (expectancy that the technology will be useful for its purpose); effort expectancy (perception of effort needed to use it); attitude towards the technology; social influence (the influence of others on the use of the technology); facilitating conditions (the extent to which their environment facilitates use of the technology); self-efficacy (estimations of their own ability to use the technology); anxiety (levels of anxiety felt when using the technology) and behavioural intention (an indication of whether the participant is intending to use the technology in the next 6 months). Scores for each item (on a scale of 1 to 6) within each domain can be pooled to give overall scores for each domain at each time point.

Data Analysis

Frequencies will be calculated for percentage of target behaviours remembered/missed within a week. It is anticipated that the frequency of events to be remembered will differ on a weekly basis, so percentage of events forgotten will be calculated each week. As well as visual inspection, statistical analysis will also be undertaken.

Visual inspection includes the calculation and transformation of each participant's performance to a graph for the purpose of visually analysing (a) trend (progress over time), (b) level (magnitude of the data), and (c) stability (variability or "bounce" of the data) (Gast, 2005). The procedure for visual inspection will follow steps as outlined by Land & Gast (2014) using the graphic display and divided into (a) within-condition and (b) between-conditions analysis of data.

Tau-U is a method for measuring data non-overlap between two phases (A and B) (Tau-U; Parker, Vannest, David, & Sauber, 2011). Non-overlap methods do not rely on means, medians, or modes but rather consider individual values of all data points in pairwise comparisons across phases (Parker, Vannest & Davis, 2011). Non-overlapping data as an indicator of performance difference between phases is included in standards for evaluating SCED's (Horner, Carr, Halle, McGhee, Odom et al., 2005). Tau-U is a "distribution free" nonparametric technique, with an index well-suited for small datasets, and is useful in aggregating data across phases to come up with on overall effect size. Depending on the data, it possesses statistical power of 91-115 percent of parametric tests (Vannest, Parker & Gonen, 2011).

Power

In their meta-analysis of SCED studies of prompting technology in acquired brain injury Jamieson et al (2013) reported medium effect sizes using non-overlap of all pairs methodology. In the present study we anticipate similar levels of effect. It is therefore anticipated that the Tau-U analysis would have sufficient statistical power to detect the anticipated effect size.

Dissemination

Once the thesis is completed it will be submitted to the University of Glasgow as part fulfillment of the award of Doctorate in Clinical Psychology. The researcher will explore appropriate academic journals with the academic supervisor and submit for publication. Participants will be given the option of receiving a summary sheet of the findings of the study. This will be discussed with them when the researcher completes the consent form.

Ethical Issues

In order to address issues of consent and capacity, psychiatrists responsible for the potential participant's care will be consulted. All participants will be checked for consent on the day of assessment and throughout the study. As this study is only recruiting participants with Mild Dementia, this should minimise difficulties with capacity to consent in participating. However, if doubt remains, the researcher will discuss with the psychiatrist and if their capacity remains in doubt, the participant will not be recruited or results not included.

Due to the nature of the study, there is a possibility that recording and discussing memory problems may increase the participant/carer's awareness of them and this may cause distress. Regular contact will be maintained between the researcher and the participant, offering reassurance and advice, in the hope of overcoming any worry.

All information recorded will be on a university encrypted laptop. The data will be backed up on an encrypted memory stick and on the University of Glasgow secure network Paper copies of completed tests and consent forms will be stored in accordance with local and national Data Protection guidelines, and will be stored in a locked filing cabinet within NHS premises. The researcher and Chief Investigator will have access to the data and upon completion of the study, the Chief Investigator will retain the data. This will be held within the Institute of Mental Health and Wellbeing at the University of Glasgow (Gartnaval Royal Hospital) for ten years. Paper files containing personal information used to contact participants (e.g. name, address) will be destroyed by shredding upon the completion of study. There will be an application to the NHS Research Ethics Committee who will provide feedback on plans to minimise any adverse effects on participants.

Financial Issues

Mindmate is a free app, and only participants who already own a smart phone or tablet will be recruited.

The main costs will come from use of response forms for the various neuropsychological tests. These, as well as all miscellaneous costs, are included in the Expenses form (Appendix 1).

Health and Safety Procedures

See Appendix 2

Timetable

Submission to Ethics	June/July 2016
Information to OPCMHT's	September 2016
Recruitment of Participants	September-November 2016
Data Collection	January-March 2016
Analysis and Write-Up	April-May 2016
Final Write-Up and Preparation for Viva	June-July 2016

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