Improving Quality of Life for people over 65 living with dementia

Pilot Study

IMPROVING QUALITY OF LIFE FOR PEOPLE OVER 65 LIVING WITH DEMENTIA

A randomized controlled pilot study of using a personalized memory game app to improve the quality of life of people over 65 living with dementia and their carer(s)

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Memory Lane Games

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2 STUDY OBJECTIVES

2.1 Primary objective

The aim of this study is to determine whether use of this new, personalised app appears to be associated with changes in quality of life of the person (over 65) with dementia and/or their carer.

2.2 Secondary objectives

The secondary objectives are:

- To monitor unanticipated effects of using the personalised app, compared to the non-personalised app.
- To test the feasibility and acceptability of study instruments.
- To gather pilot data to inform the design of a hypothesis-testing study.

3 BACKGROUND AND RATIONALE

3.1 Background on condition

Alzheimer's Disease (AD), together with other forms of dementia, represents a major challenge for health care systems with aging populations. AD is associated with neurodegenerative changes, which compromise not only cognitive functioning, but also lead to a decline in functional abilities and induce a spectrum of psychological or behavioural symptoms (1, 2).

Today, over 46 million people live with dementia worldwide, more than the population of Spain. This number is estimated to increase to 131.5 million by 2050 (3). Diagnosis can help people with dementia and their carers to receive the treatment, care and support (pharmacological, psychosocial, social and emotional) to enable them to manage this condition. However, there is a growing need for an evidence-based approach to home support for people with dementia and their carers following diagnosis (4).

3.2 Study rationale

In many parts of the world, there is a growing awareness of dementia, but across the globe it remains the case that a diagnosis of dementia can bring with it stigma and social isolation (3). This pilot study aims to assess the impact of using a memory games application (App), personalised by informal carers and/or relatives, on the quality of life of persons with dementia and their carer(s). This study aims to show that, by increasing positive engagement between the person with dementia and their carer/relative via face-to-face and remote engagements, there is a positive benefit to patients, carers or both. Engagement with the personalised content in the form of a game might lead to improvement in the quality of life of the person with dementia and/or their carer by facilitating and improving communication. It might also encourage interaction helping to reduce social isolation or provide carers with short periods of respite.

4 STUDY DESIGN

4.1 Design of trial

This is a single site, randomised controlled study. The primary outcome measures are the DEMQOL (5) and C-DEMQOL (6), measured at baseline, 13 and 26 weeks (primary endpoint) after baseline. Thirty pairs of people with dementia and their identified carer, will be recruited and randomised to two groups with a 2:1 intervention to control allocation ratio. The intervention group will receive the App with 12 generic memory games plus the option to construct 12 games with personalised content. The comparator group will receive an App with 12 generic memory games and no access to personalised games.

4.2 Outcome measures

4.2.1 Primary outcome:

- The primary outcome of the study is the quality of life of people with dementia (over 65) for and their carers based on DEMQOL /C-DEMQOL scores compared to people using the non-personalised game.

4.2.2 Secondary outcomes

- Unanticipated effects of using the personalised App, compared to the non-personalised App.
- The feasibility and acceptability of study instruments (i.e. in the areas of quality of life, communication, and cognitive function), judged by the answers to specific questions, interview findings and adherence to the use of the App.

4.3 Study population

The intervention group will include 20 participant-carer pairs and 10 pairs in the control group, i.e. 30 pairs in total. All participants will be volunteers, recruited via study promotion posters, local community organisations and participant information sheets. Local memory services, 3rd sector providers and clinicians will be informed of the study in case they attend anyone who is included in the study.

For the purpose of this study 'carer' will be defined as anyone over the age of 18 who provides support for a family member, partner, or friend with dementia. The carer must provide at least a couple of hours of care each week and does not have to live with the person with dementia. The care can be physical or emotional and must be unpaid (this does not include carers allowance). The carer, who provided informed consent, must be present at all study visits.

4.4 Study location

The study will run at a single site, with the screening, consent, baseline data collection, App installation and training, week 13, week 26 and completion visits taking place in the participants' own home. Hospice, Isle of Man, is the single site and will be responsible for delivering the activities described in this protocol, and will employ appropriately trained persons.

4.5 Study duration

The duration of the intervention is approximately 6 months for the participant and their carer. The study will take place in a period of 12 months to allow for staggered recruitment, analysis and reporting.

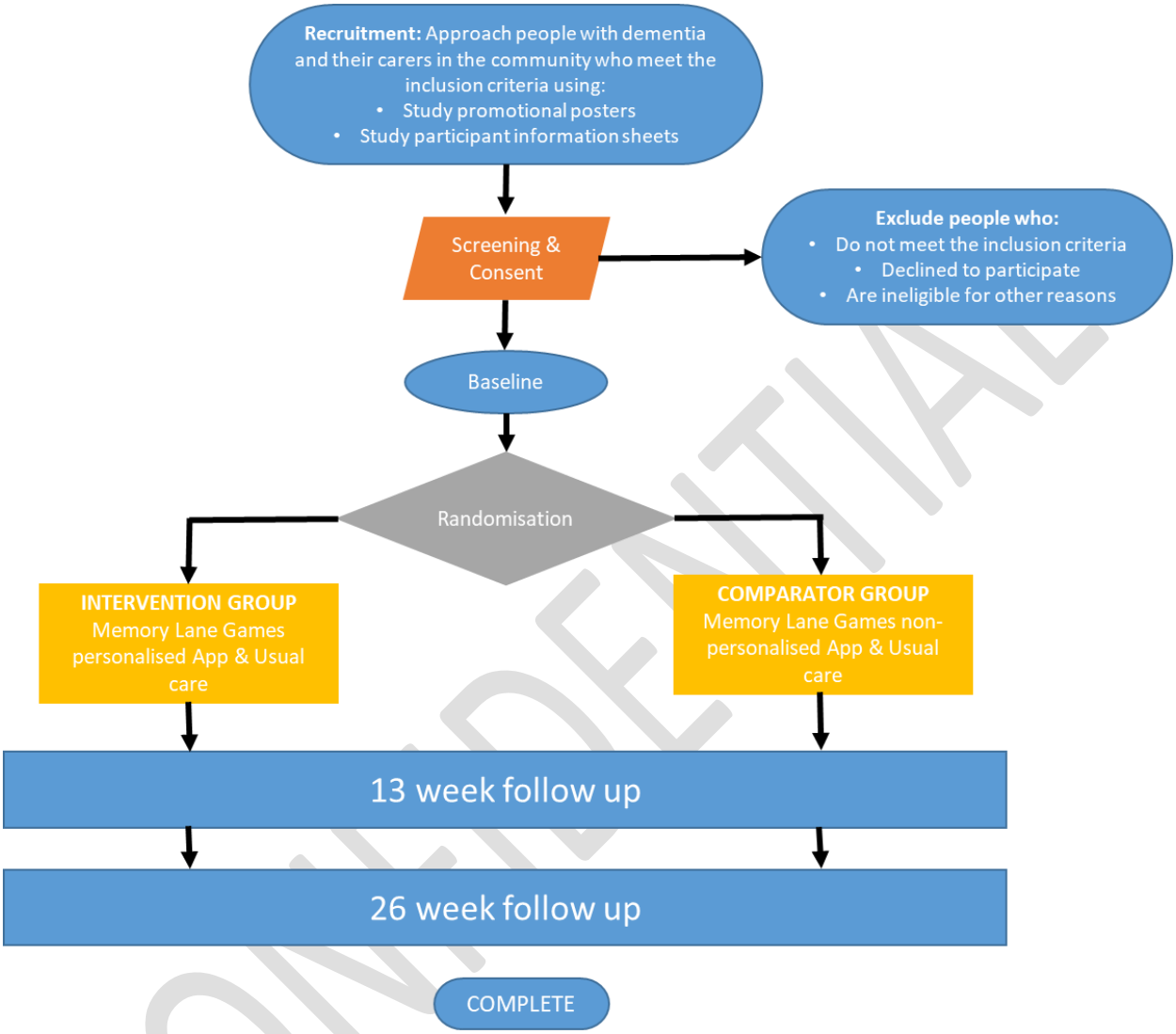
4.6 Intervention

Participants will be randomly allocated to receive one of two apps. The intervention group will receive the personalised App and the control group a non-personalised App. Apps will present images with associated questions in the form of a quiz. The non-personalized App will use images of objects such as flowers, fruit and geographic locations which may or may not be relevant to the individual. Personalisation means that the participant and or carer will also have the ability to upload their own pictures so that the images will be more meaningful to the person playing the game, for example, photographs of family or images of places they have visited. All study participants will be asked to use their App at least once a week for a period of six months. An overview of the study flow can be seen in Figure 1.

4.6.1 Access to electronic tablet & I.T. support

An electronic tablet will be provided for the duration of the study and participants will have continued free access to the App and a tablet, after the study.
The app is designed for people with dementia, therefore is simple functioning and frustration free. Video based training and instructions will be pre-loaded onto the device, this can be accessed at any point. The research team will also be available to contact and provide support, should additional support be needed. The research team will liaise directly with Memory Lane Games Limited (MLG) so no communication between the participants and MLG will occur, maintaining confidentiality.

Figure 1. Study flow diagram



5 SELECTION AND ENROLLMENT OF PARTICIPANTS

Participants must meet all inclusion criteria to participate in this study. Any candidates who meet any exclusion criteria at baseline will be excluded from participation in this study.

5.1 Inclusion criteria for the person with dementia (PWD)

The person with dementia will be referred to as the main "participant". Potential participants must meet all of the following inclusion criteria in order to take part in this study:

1) Self-report diagnosis of any type of dementia.
2) Age 65 or older (person with dementia).
3) Mild to moderate dementia as determined by results from the Standardised Mini Mental State Examination at baseline (Score between 10-24).
4) Potential participant does not suffer with possible severe depression as determined by the PHQ-2 at baseline (Depression severity score: 0-2).
5) Potential participant has no specific condition reducing their physical ability to use the App (e.g. visual, hearing, motor impairments).
6) Potential participant has the ability to complete or respond to questionnaires and interviews.
7) Potential participant lives in a private home or sheltered accommodation.
8) Potential participant demonstrates capacity (Two stage test) and provides written, informed consent.
9) Potential participant has a regular carer who is willing to participate and provide their own written, informed consent (over 18yrs).
10) Potential participant has the ability to understand and communicate in English.

5.2 Exclusion criteria for the person with dementia (PWD)

All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation.

1) No self-reported diagnosis of dementia.
2) Aged 64 or younger (person with dementia).
3) Normal cognition or severe dementia based on SMMSE score at baseline (SMMSE score of normal=25-30 or severe=9 or less).
4) Indication of possible severe depressive disorder at baseline (PHQ-2 score: 3 or above).
5) Potential participant has a condition or conditions reducing their physical ability to use the App (e.g. visual, hearing, motor impairments).
6) Potential participant does not have the ability to complete or respond to the questionnaire and/or interview.

7) Potential participant lives in a residential or nursing home.

8) Potential participant lacks capacity to provide informed consent.

9) Potential participant has no regular carer who is willing to participate (or carer under 18yrs).

10) Potential participant does not have the ability to understand and communicate in English.

5.3 Inclusion criteria for the person with dementia's carer

The participant who is the carer of the person with dementia will be referred to as 'Carer'. Potential carers must meet all of the following inclusion criteria in order to take part in this study:

1) Potential carer has capacity to provide written, informed consent.

2) Potential carer has the ability to understand and communicate in English.

3) Potential carer is over 18 years of age.

4) Potential carer provides unpaid care for a least a couple of hours each week.

5.4 Exclusion criteria for the person with dementia's carer

Any carer meeting any of the exclusion criteria at baseline will be excluded from study participation

1) Potential carer lacks capacity to provide written, informed consent.

2) Potential carer does not have the ability to understand and communicate in English.

3) Potential carer is not over 18 years of age.

4) Potential carer provides paid care.

5.5 Study enrolment procedures

Volunteers will be invited to take part in the study through study promotional posters and public announcements in local media (print and radio), other Third Sector organisations, community organisations and participant information sheets. Materials will provide basic information on the study and study design and eligibility criteria. Interested people will be asked to contact the Scholl Academic Centre (SAC) research team for further details on the study and the process. The Clinical Research Nurse (CRN) will confirm the person meets the basic eligibility criteria using the *Pre-Screening Tool* (Appendix 1). Personal information collected during the screening process will be destroyed if the person is ineligible to participate or if the person does not wish to participate after obtaining more information about the study. Age, sex, and the reason(s) for not meeting the eligibility criteria, or for choosing not to participate will be recorded in the *Screening and Enrolment Log* (Appendix 2). Interested potential

participants will be sent a *Participant Information Sheet* (Appendix 3) and *an Informed Consent Form* (Appendix 4) by mail or email, depending on the person's preference.

5.6 Consent process

Guided by the Mental Capacity Act 2005 (7), it is judged that people with mild to moderate dementia approached in this way have capacity to provide informed consent, given sufficient time to decide. However an '*informal 2 stage test' capacity assessment* (Appendix 5) will be performed by the CRN prior to obtaining informed consent. Candidates will be given a minimum of 24 hours to decide to participate. Potential participants will have the option to contact the CRN with any questions they may have after receiving the *Participant Information Sheet* and *Informed Consent Form.*

Interested and pre-eligible individuals will be scheduled for a *screening assessment* where the CRN will arrange to visit the person with dementia and their carer at home. The CRN will telephone the prospective participant prior to the screening assessment visit to confirm their interest in participating. If a prospective participant decides not to participate after reading the *Participant Information Sheet*, the person will be asked to contact the CRN and their decision will be recorded. No further contact will be made and personal information will be destroyed.

At the initial visit, the CRN will explain the study in person, perform a two stage capacity assessment, and obtain written informed consent from the person with dementia and their carer prior to administration of any further screening assessments. Once capacity is confirmed and informed consent is obtained from both the person with dementia and their carer, the CRN will administer the *screening assessments* (Standardised MMSE and PHQ-2) to confirm eligibility to participate. If the full set of eligibility criteria is not met, prospective participants will not be enrolled in the study. No further contact will be made and personal information will be destroyed.

As capacity may fluctuate in a person with dementia, if capacity is not confirmed at the initial visit, a second visit will be scheduled, at the participant's convenience. If capacity is not confirmed at this second visit, informed consent will not be sought and the participant will be excluded from the study.

Ongoing assessment of capacity, and a participant's wiliness of their continued participation in the study will be assessed at each follow up visit. If capacity is not confirmed at any follow up visit, study assessments will not take place and a second visit will be rescheduled. If capacity is not confirmed at this second visit, then the participant will be withdrawn from the study and the *Duty of Care Protocol* will be followed (Appendix 6).

Participants may withdraw from the trial at any time for any reason. If they withdraw, a reason will be recorded unless they choose not to provide one. Reasons for withdrawal will be recorded in the *Screening and Enrolment Log.* Unless participants request otherwise, data collected before withdrawal will be retained for analysis.

1. **The Two Stage Test- informal assessment of capacity**
   The Two Stage Test (8) is recommended by the Mental Capacity Act and sets out a 2-stage test of capacity: 1) Does the person have an impairment of their mind or brain, whether as a result of an illness, or external factors such as alcohol or drug use? 2) Does the impairment mean the person is unable to make a specific decision when they need to?

5.7 Screening assessment

These evaluations occur to determine if the candidate is eligible for the study.

1) **Standardised MMSE- Mini Mental State Examination** (score of 10 -24)

The Standardised MMSE (9) is a brief, widely used, test of cognitive function administered by a trained interviewer and answered by the person with dementia. It has good validity and reliability, which measures the severity of cognitive symptoms of dementia. It will be used as a screening test to ensure all included people have mild to moderate dementia (a score of 10 to 24).

2) **The Patient Health Questionnaire-2-PHQ-2 depression scale** (score of 2 or less)

The PHQ-*2* (2) will be used as a screening test to exclude people with dementia who have a score of *3 or more.* The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the past two weeks. The purpose of the PHQ-2 is not to establish final diagnosis or to monitor depression severity but rather to screen for depression in a 'first step' approach. Scores range from 0 to 6. The recommended cut point is a score of 3 or greater.

There is a protocol for action when anyone scores 10 or less in the Standardised MMSE or 3 or more in the PHQ-2 (Appendix 6 Duty of Care Protocol).

6 STUDY INTERVENTION AND EVALUATION

6.1 Randomisation

Participants who meet the inclusion criteria, pass the screening assessment and agree to take part in the study will be randomly assigned to the intervention or control group by the random selection of a sealed envelope during the initial visit. The sealed, unmarked envelopes will contain a card with the allocation and a single envelope will be selected for each participant pair. After the baseline assessment is complete, the envelope will be opened and the relevant App will be allocated. The participant and carer will be instructed on the use of the App and given information on how to obtain further assistance, if required.

Pairs randomised to the intervention arm will be supplied with the App with 12 generic games plus the option to build 12 games based on personalised content. The control group will be given an App with 12 generic games with no option to include personalised content. Participants will be asked to use the App at least once per week for 26 weeks.

6.2 Evaluation plan

6.2.1 Baseline Assessment

For participants who have successfully been screened for eligibility and are enrolled into the study, baseline assessments are performed against which to measure the study outcome. They also ensure that the groups are balanced with respect to baseline characteristics. The baseline evaluation consists of the following assessments:

- Two Stage Test- informal assessment of capacity- (if preformed on a different day from Informed Consent)
- DEMQOL
- CDR
- C-DEMQOL
- HCS

The CRN will offer the baseline assessments of quality of life (DEMQOL, C-DEMQOL), two stage capacity test, Holden Communication Scale and a specially-designed questionnaire covering basic sociodemographic characteristics, brief medical history and current medications (Appendix 7, page 5-7). These will be repeated by the CRN in weeks 13 and 26.

A second and separate visit will be arranged within 8 days of the initial visit for a clinical interviewer to conduct the Clinical Dementia Rating (CDR). The CDR will be repeated by the interviewer in week 26.

Assessments will be conducted in the order specified in Section 6 Schedule of Evaluations (page 15) and may take place on separate visits on the same week, if necessary to accommodate the needs of the participants.

6.2.2 Follow-up Visits

Study visits should be performed within 7 days before or after the weeks indicated in the Schedule of Evaluations. The evaluation time window should be as narrow as technically feasible.

- Week 2 - Telephone call (±3 Days from final Week 1 visit)
  - Participants will be contacted by the Research Team to ensure that the participant and carer are comfortable using the App.
- Week 13 (±1 Week from final Week 1 visit):
  - Two Stage Test- informal assessment of capacity
  - Changes from baseline in study specific data
  - DEMQOL
  - C-DEMQOL
  - HCS
  - Semi-structured interview

6.2.3 Final Evaluation

- Week 26 (±1 Week from final Week 13 visit):
  - Two Stage Test- informal assessment of capacity
  - Changes from baseline in Study Specific Data
  - SMMSE
  - DEMQOL
  - C-DEMQOL
  - HCS
  - Semi-structured interview
  - CDR

6.2.4 Description of the outcome measures

Quality of life measures DEMQOL and C-DEMQOL

The DEMQOL (5) is interviewer-administered to the person with dementia and has 28 items. It is designed to enable the assessment of health-related quality of life of people with dementia, to work across dementia subtypes and care arrangements and to be used at all stages of dementia. It will be used at baseline and both follow-up assessments.

The C-DEMQOL (6) is self-administered and is designed to capture quality of life of family carers of people with dementia. It consists of 30 individual questions under 5 categories, which assess factors shown to influence quality of life.

Cognitive function

1) Standardised Mini Mental State Examination (SMMSE)

The SMMSE (9) is a brief, widely used, test of cognitive function administered by trained interviewer and answered by the person with dementia. It has good validity and reliability. Administration will be at baseline and in Week 26 and will follow the procedures specified in *A Guide to the Standardized Mini-Mental State Examination* (10).

2) Clinical Dementia Rating (CDR)

CDR (11) is a 5 point scale used to characterise 6 domains of cognition and functional performance applicable to AD and related dementias: Memory, Orientation, Judgement & Problem Solving, Community Affairs, Home & Hobbies and Personal Care. The necessary information to make each rating is obtained through semi-structured interview of the patient and a reliable informant or collateral source. It will be used at baseline and at the 26 week assessment. The CDR will be carried out by a Research Psychologist (RP) with CDR certification. Training for administration and scoring of the CDR is provided by Washington University in St. Louis Knight ADRC (knightadrc.wustl.edu/cdr/Application/Step1.htm).

Communication* measure *the Holden Communication Scale (HCS)

The HCS (12) is a validated 12-item questionnaire completed by the carer as proxy for the person with dementia. It was initially developed to assess reminiscence programmes. The items assess conversation, awareness and knowledge and communication. It will be used at baseline and both follow-up assessments at 13 and 26 weeks.

Low mood

Any changes in mood will be monitored using the relevant items in the DEMQOL or C-DEMQOL, responses to specific and open-ended questions and clinical judgement of the CRN. It is difficult to distinguish changes in low mood from changes in dementia symptoms but we would not want to miss any tendencies to change in mood so will look at it in a variety of ways.

6.2.5 Other data to be collected

Semi-structured interview with the person with dementia's carer

At each follow-up assessment, the carer will be interviewed using a semi-structured interview to determine whether there have been any unanticipated positive or negative impacts of using the App. Specific questions on use of the tablet or App and any associated change in their life or interactions will be asked and the individual will be encouraged to raise any other issues. This will provide richer contextual and conversational data about participants' experiences and assessments of the role of the Apps in impacting quality of life and communication. These data will also inform the assessment of feasibility and acceptability of use of the Apps. The interviews will be recorded and transcribed with the consent of the participant but, if the participant does not provide consent for recording, the interviewer will take notes. Questions can be found in Appendix 8.

Sociodemographic data

The CRN will collect sociodemographic baseline data on both the patient and their carer (Appendix 7, page 5).

Study specific data

The CRN will collect information on co-morbidities, medications, supplements and other memory aides and Apps used by the person with dementia (Appendix 7, page 5-7).

Adherence assessment and App usage data

Adherence, or the extent to which participants comply with the study requirements, is defined as use of the App at least once a week for 85% of the total number of study weeks (e.g. 22 out of 26 weeks).

All App data will be collated and stored securely within MongoDB (A source-available cross-platform document-oriented database program; see Appendix 9-MLG Data Policy for further details and privacy policy). The App data which is collected is:

- Frequency (How often the user engages with the App).
- Duration (Engaged playing time of user per session).
- Total games played by user (The amount of games a user has accessed).
- Categories played (List of categories and topics played by a user).
- Completion (how many people remained engaged throughout the duration of the game and whether they made it to the end).
- ATQR (answer-to-question-ratio or *the total number of answer attempts over the total number of questions in a game).*
- The number of games liked, the number of games disliked (likes to dislikes ratio).

Further detail on each of these variables is in Appendix 9.

Data collected through the app will be provided week by week, in a csv (comma separated values) exported from Mongo, from Memory Lane Games to Scholl Academic Centre. A unique identifier will be used for this data transfer so that the Researcher in Scholl Academic Centre can make a link, using a secure key, to the individual with that App ID. Memory Lane Games will be unable to identify an individual through their App ID; they will only use that App ID to transfer individual App data to the Scholl Academic Centre researchers for the analyses. Neither Memory Lane Games nor Scholl Academic Centre will have access to any personalized content uploaded to the App.

Schedule of Evaluations

Assessment	*Eligibility*	*Week 1*	*Week 2 (+/- 3 days)*	*Week 13 (+/- 7 days)*	*Week 26 (+/- 7 days)*
Person with dementia (PWD) and carer					
Two Stage Test (informal capacity assessment)	***CRN¥***			***CRN¥***	***CRN¥***
Informed Consent Form	***CRN***				
Eligibility	***CRN***				
Sociodemographic		***CRN (PWD,1; C, 1)***			
Study specific data		***CRN (PWD,2; C, 2)***		***CRN (PWD,1; C, 1)***	***CRN (PWD,1; C, 1)***
Person with dementia					
SMMSE	***CRN (PWD, 1)***				***CRN (PWD, 2)***
PHQ-2	***CRN (PWD, 2)***				
DEMQOL		***CRN (PWD, 3)***		***CRN (PWD, 2)***	***CRN (PWD, 3)***
CDR		***RP (PWD,4; C, 5)***			***RP (PWD,4; C, 5)***
Carer					
C-DEMQOL (Carer)		***Carer (C,3)***		***Carer (C, 2)***	***Carer (C, 2)***
HCS (Carer as proxy)		***Carer (C, 4)***		***Carer (C, 3)***	***Carer (C, 3)***
Semi-structured interview				***CRN (C, 4)***	***CRN (C, 4)***
Follow-up telephone call			***CRN (C, 1)***		

¥- PWD-prior to informed consent or any study interventions/assessments (if needed, this may also be performed by the RP).

Note: Person responsible for administration is denoted as CRN for Clinical Research Nurse, RP for Research Psychologist, and Carer where the questionnaire is self-administered. The numbers in parentheses refer to the order of assessments for the Person with Dementia (PWD) and Carer (C).

6.3 Handling of Study Interventions

6.3.1 Blinding and bias

Participants and research staff will not be blinded since full masking of allocation status is not possible, or desirable, for the participants and principal researchers. To minimise the risk of bias, several precautions will be taken:

1. Allocation status will be kept in a password-protected Excel sheet using the participant ID. The allocation status will also be recorded in the source data forms used by the CRN.
2. The CRN and RP will follow a specific order of assessments as specified in Section 6.1 Schedule of Evaluations. To minimise the risk of interviewer bias, methods of administration are detailed in Section 6.2 Description of Evaluations.

7 DATA COLLECTION AND MANAGEMENT

7.1 Data collection methods

Data will be collected using paper-based questionnaires and forms to facilitate self-completion by the participant and carer wherever possible. Data will also be collected by the CRN (Study specific data) or the RP who will conduct the CDR assessment. These data will be entered into a spreadsheet by a Research Assistant, identified only by participant's Study ID.

7.2 Data Management

All personal information will be held securely in accordance with local data protection legislation on the Isle of Man and according to Hospice and SAC guidelines, which are GDPR compliant. The SAC will store paper copies of questionnaires and consent forms in a locked cabinet for the period of time required by the Hospice Research Policy.

Participants will be allocated unique study ID numbers and these will be used in all data processing and analyses to ensure participants remain anonymous to all but those research staff who need to make contact with them. A link between study ID, personal identifiable information and the App ID will be kept in a separate, password protected file. Only the SAC research staff will have access to the link file and only for necessary purposes. No personally-identifiable data will be shared with non-research staff, unless safety or clinical concerns warrant this, and then only to those who need to have it. A *Trial Masterfile* will hold all completed anonymised source data in a locked cabinet and electronic data will be stored in password-protected Excel file with access limited to specific named persons. A full audit trail will be maintained by recording all amendments to data with the reason and the time of amendment.

The funder (Memory Lane Games) may inspect or audit study data but will not be given access to any personal information. App usage data will be collected automatically by the App and transferred from Memory Lane Games to SAC research staff in a secure, password protected spreadsheet, using the App ID.

8 DATA PROCESSING AND ANALYSIS

8.1 General Design Issues

This pilot study is designed to determine if there is an indication of improvement in quality of life of the person with dementia or their carer associated with using a personalised game App compared to a non-personalised game App. The purpose of the study is to test various assessment instruments and to gather pilot data to inform the design of a hypothesis-testing study.

8.2 Quantitative Data Analyses

Baseline descriptive characteristics of participants by allocation status will be presented. Primary analyses will focus on DEMQOL and C-DEMQOL scores at 26 weeks and any changes in the HCS. Secondary analysis will take account of the content of, and adherence to, the intervention to explore the effect of adherence on the scores.

Further descriptive analyses will be conducted for each assessment at baseline, at Week 13, and at Week 26. Comparison of mean score or proportions (as appropriate) between 1) baseline and Week 13 (interim analysis), 2) baseline and Week 26, and 3) Week 13 and Week 26 will be tested using a two-sided t-test for continuous variables or a Pearson's chi-square test for categorical variables. Statistical significance will be set at α=0.05. We will investigate if effect measure modification is present by stratifying analyses according to adherence status and other App usage variables. Significance (*p*-values) will not be adjusted to account for multiple comparisons as analyses are exploratory.

8.3 Qualitative Data Analysis

Recorded interviews will be transcribed using NVivo software. Thematic and narrative analysis of interview transcripts will be undertaken to elicit the experiences of people with dementia and their carers. At least two researchers will analyse each semi-structured interview and questionnaire. Once all issues have been identified, an iterative process will be used to identify the major themes and processes through conceptual abstraction. Achievement, or not, of data saturation will be determined by discussion among research staff (13).

Feasibility and acceptability of the intervention and the instruments will be assessed at week 13 and at the conclusion of the study, including any unanticipated positive or negative events, in order to inform future studies.

9 SAFETY ASSESSMENTS AND QUALITY ASSURANCE

9.1 Expert Advisory Group (EAG)

We have set up an Expert Advisory Group (EAG) whose role will be to a) regularly review the progress of the study (b) monitor the quality assurance processes and c) respond as required to unanticipated events, with expert advice. They will be asked to advice e.g. should anyone have medication changes during the study period or experience an Adverse Event. At the end of the study, the EAG will perform a clinical review of all collected data to confirm diagnoses and ensure that reported findings are clinically accurate and appropriate.

The membership of the EAG includes experts in dementia and in digital health

- Dr Rhoda Macrae, Senior Lecturer, School of Health and Life Sciences, Later Life and Dementia, Institute of Healthcare Policy and Practice and the affiliated Alzheimer Scotland Centre for Policy and Practice
- Jeanette Hogg, Lead Admiral Nurse, Hospice Isle of Man
- Dr Sarah Russell, Lead Nurse for Palliative and End of Life Care at Portsmouth University Hospitals NHS Trust
- Dr Leo Lewis, Director of Research and Development, International Foundation for Integrated Care (IFIC)

9.2 Adverse Events

An adverse event, in the context of this study is defined as an undesirable experience for the participant or their carer, associated with the use of the App or any study assessment.

Serious adverse events are not anticipated from using either App or from any study procedures. As well as the CRN, we will have access to further clinicians (EAG) who can respond specifically to any concerns raised by participants, carers, interviewers or researchers. A *Distress Protocol* (Appendix 11) and *Duty of Care Protocol* (Appendix 6) provide guidance in the event a participant or their carer exhibit distress or an adverse event deemed to require clinical care. Participant information sheets will advise participants of the possibility that some photographs or simply the inability to remember may cause distress. They will also remind carers that the aim of the App is to remind the participant of positive experiences, as far as possible and recommend careful consideration of content used for the personalised App.

Participants will be asked to report any distress or negative consequence associated with using the App. If so, or if severe depression is identified through the assessment process, participants will be asked if they wish to continue to participate in the study. In the event that the CRN has a clinical concern at any point in the study, the CRN will recommend the participant (person with dementia or their carer) talk to

their General Practitioner. If clinical judgment indicates, the CRN will seek permission (if possible) from the participant to contact their General Practitioner/Mental Health Practitioner for them. All adverse events will be communicated to the EAG and recorded in an *Adverse Event Log* (Appendix 12).

9.3 Loss of capacity (PWD) during the study

As capacity may fluctuate in a person with dementia, ongoing assessment of capacity and a participant's willingness of their continued participation in the study will be assessed at each follow up visit. If capacity is not confirmed at any of the follow up visits, study assessments will not take place and a second visit will be rescheduled. If capacity is not confirmed at this second visit, then the participant will be withdrawn from the study and the Duty of Care Protocol will be followed (Appendix 6). The PWD's carer will be asked to act in the PWD's best interest and decide what they would like to happen to the PWD's personal data (full use of data, use of data up to the last analysis, withdrawal of any unreported data).

9.4 Protocol Deviations

Deviations from the protocol will be recorded in a spreadsheet with the date, nature of the protocol deviation and any actions taken (Appendix 10). Protocol deviations will be reported to the EAG.

9.5 Monitoring and Quality Assurance

Study records (e.g. consent forms, screening and enrolment log, adverse event log) will be available to the EAG for the purposes of monitoring at any time throughout the study. In addition, we will request three audits be carried out by members of the EAG, where they will review all procedures and sample the collected data to ensure all are of sufficient quality.

A single CRN will conduct all assessments with the exception of the CDR, which will be conducted by a single Assistant Research Psychologist. This will minimise inter-rater differences. Both these research staff will undergo specialist training for assessments with established procedures.

10 PARTICIPANT RIGHTS AND CONFIDENTIALITY

10.1 Ethics Review

This protocol and the *Informed Consent Form* (Appendix 4) and any subsequent modifications will be reviewed and approved by the Isle of Man Research Ethics Committee (IOMREC), who is responsible for the oversight of this study. This study follows the *UK policy framework for health and social care research* v3.3 07/11/2017.

10.2 Patient Information sheets and Informed Consent Forms

Consent forms will be approved by the IOMREC, who is responsible for this study and the participant will be asked to read and review the document. The CRN will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice, and that their usual care will not be affected if they decline to participate in this study.

Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants will be given a copy of the informed consent form so that they may discuss the study with their family or surrogates or think about it prior to agreeing to participate. The informed consent process will be conducted and documented in the *Screening and Enrolment Log* (Appendix 2) and the form signed, before the participant undergoes any study-specific assessments. A copy of the signed informed consent document will be given to the participants for their records. Signed informed consent forms will be stored in a locked cabinet accessible by the Research Team.

Section 3.3 of the protocol defines 'carer' for this study protocol, however, NHS England (14) recognizes that many carers do not see themselves as carers and it may take an average of two years for carers to acknowledge their role as a 'carer', therefore, throughout the participants information sheets carers are referred to as 'loved ones', 'carers' and 'family members' interchangeably, in the hope that a wider audience of people can identify with the caring role that they may provide.

10.3 Participant Confidentiality

Any data, specimens, forms, reports, audio recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by the EAG. All organisations involved with this study are GDPR compliant.

10.4 Publication of results

Publication of the results of this study will be governed by the policies and procedures developed by the SAC and will be reviewed by the EAG. No identifiable data will be published in any form. Any presentation, abstract, or manuscript will be made available for review by the EAG prior to submission.

10.5 End of study information

During the last study visit, the researcher will explain:

- The participant does not need to play on the App, if they do not wish to, however they will still have access to the App and a tablet, should they wish to.
- Should the participant wish to access the App that they were NOT allocated (eg allocated 'non-personalised' therefore 'personalised App' can be set up or vice versa), then the researcher will help the participant to do so, with free subscription.
- Unless there have been any safety concerns identified from the interim analysis, participants will not receive any further visits from the researcher at home. They can, however, contact the research team, as detailed on the PIS, at any time.
- The researcher will establish if the participant would like to be kept up to date about the results of the study and how they would like to be updated (email, post, face to face).
- Any report or publication will not identify the participant(s) personally.

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12 APPENDICES

1. Pre-Screening Tool
2. Screening and Enrolment Log
3. Participant Information Sheet
4. Informed Consent Form
5. Informal 2 stage test- capacity assessment
6. Duty of Care Protocol
7. MLG Study Data Booklet (inc demographics and study specific data)
8. Semi Structured Interview Questions
9. MLG Data Policy
10. Protocol Deviation Log
11. Distress Protocol
12. Adverse Event Log