

# Can a personalised memory app improve the quality of life of older people living with dementia and their carer(s)?

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<b>Registration date</b> 02/11/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 28/12/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A personalised game application or 'App' is a type of software that you can install on your electronic device (either a mobile phone or electronic tablet) which allows you to perform specific tasks or play games. When you open an application (App), it runs inside the operating system of your phone or tablet until you close it. The application (App) in this study is developed by Memory Lane Games Ltd and will have 12 different games to play.

The study aims to see if the use of a new, personalised game application (App), when used with people with a diagnosis of dementia, changes the person's and/or their carer's or family member's quality of life, compared to using a non-personalised game application (App).

### Who can participate?

Patients aged over 65 years with a self-reported diagnosis of dementia and a designated carer

### What does the study involve?

The participant and the carer will be involved in the study. The participants will be provided with one of two Apps and will be asked to play games on this App at least once a week for about 6 months. The personalised App allows the carer or family member to create games that are personalised. The non-personalised App already has built-in games. The quality of life of people with dementia and their carers is measured using questionnaires at the start of the study and after 13 and 26 weeks.

### What are the possible benefits and risks of participating?

May improve the quality of life of people with dementia and/or their carer(s).

If a tablet is received at the beginning of the study the participants may keep them if they wish.

There are no physical risks involved in the study although there is a small possibility that participants may get tired using the app.

### Where is the study run from?

Scholl Academic Centre at Hospice Isle of Man

When is the study starting and how long is it expected to run for?  
April 2021 to November 2022

Who is funding the study?  
Memory Lane Games (Isle of Man)

Who is the main contact?  
Mrs Rachel Convery  
research@hospice.org.im

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Rachel Convery

**Contact details**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
202101

## Study information

**Scientific Title**  
Improving quality of life for people over 65 living with dementia - a pilot study

**Study objectives**  
The aim of this study is to determine whether the use of this new, personalised app appears to be associated with changes in quality of life of the person with dementia over 65 and/or their carer (based on DEMQOL /C-DEMQOL scores).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 03/11/2021, Isle of Man Ethics Committee (Douglas, Isle of Man IM1 2PU; +44(0) 1624685685; research.enquiries@gov.im), ref: 0119

## **Study design**

Single-site randomized controlled study

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Dementia

## **Interventions**

Thirty pairs of people with dementia and their identified informal carer will be recruited and randomised to two groups with a 2:1 intervention to control allocation ratio. 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-personalised App will use images of objects such as flowers, fruit and geographic locations which may or not be relevant to the individual. Personalisation means that the participant, carer or family members 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 6 months.

## **Randomisation:**

Participants 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.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Quality of life of people with dementia measured using the Dementia Quality Of Life measure (DEMQOL) scores at baseline, 13 and 26 weeks.
2. Quality of life of carers measured using the Dementia Carer Quality of Life measure (C-DEMQOL) scores at baseline, 13 and 26 weeks.

## **Key secondary outcome(s)**

The feasibility and acceptability of the app will be measured using:

1. Semi structured interview with the carer at baseline, 13 and 26 weeks
2. Frequency (How often the user engages with the app) measured every week
3. Duration (Engaged playing time of user per session) measured every week
4. Total games played by user (The amount of games a user has accessed) measured every week
5. Categories played (List of categories and topics played by a user) measured every week

6. Completion (how many people remained engaged throughout the duration of the game and whether they made it to the end) measured every week
7. Answer to Question ratio (the total number of answer attempts over the total number of questions in a game) measured every week
8. The number of games liked and disliked measured every week
9. Unanticipated effects of using the personalised App, compared to the non-personalised App measured at week 13 and 26 by asking 'Have you any concerns as a result of using the app?'

**Completion date**

24/11/2022

## Eligibility

**Key inclusion criteria**

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-reported diagnosis of any type of dementia
2. Age 65 years 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 13-24)
4. Potential participant does not suffer from 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 has the capacity to provide written, informed consent
9. Potential participant has a regular carer who is willing to participate and provide their own written, informed consent (over 18 years)
10. Potential participant has the ability to understand and communicate in English

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

1. Potential carer has the 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

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

### **Key exclusion criteria**

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

1. No diagnosis of dementia
2. Aged 64 or younger (person with dementia)
3. Normal cognition or severe dementia based on the Standardised MMSE score at baseline (SMMSE score of normal=25-30 or severe=12 or less)
4. Indication of severe depression at baseline (PHQ-9 score: 20-27 severe)
5. Participant has a condition or conditions reducing their physical ability to use the App (e.g. visual, hearing, motor impairments)
6. Participant does not have the ability to complete or respond to the questionnaire and/or interview
7. Participant lives in a residential or nursing home
8. Participant lacks the capacity to provide informed consent
9. Lack of a regular carer over 18 years who is willing to participate and provide written informed consent
10. Potential participant does not have the ability to understand and communicate in English

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

### **Date of first enrolment**

30/11/2021

### **Date of final enrolment**

27/05/2022

## **Locations**

### **Countries of recruitment**

Isle of Man

### **Study participating centre**

**Hospice Isle of Man**

Strang

Douglas

Isle of Man

IM4 4RP

## **Sponsor information**

### **Organisation**

Hospice Isle of Man

# Funder(s)

## Funder type

Industry

## Funder Name

Memory Lane Games

# Results and Publications

## Individual participant data (IPD) sharing plan

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.

Any data, specimens, forms, reports, audio recordings, and any other records will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. The key to this PID and 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 Expert Advisory Group. All organisations involved with this study are GDPR compliant. No personally-identifiable data will be shared with non-Research staff, except in the case of safety or clinical concerns.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other unpublished results</a>	version 3.2	23/12/2022	28/12/2022	No	No
<a href="#">Protocol file</a>	version 3.2	09/02/2022	15/11/2022	No	No