Mnemic neglect and past memories in dementia

| Submission date 02/11/2016 | Recruitment status No longer recruiting | Prospectively registered Protocol |
|-------------------------------------|---|--|
| Registration date 16/11/2016 | Overall study status Completed | Statistical analysis plan [X] Results |
| Last Edited 30/12/2022 | Condition category Mental and Behavioural Disorders | Individual participant data |

Plain English summary of protocol

Background and study aims

Dementia is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worse over time. Alzheimer's disease (AD) is the most common cause of dementia. It is a growing problem worldwide, affecting millions of people over the age of 60. In some previous research it was found that the way in which information is given about a diagnosis of dementia affects how well this information is remembered. Another study showed that recalling past memories can improve how people feel about themselves, for example by increasing self-esteem. The aim of this study is to combine these two projects to see whether recalling a past memory beforehand leads to better recall of information about an illness.

Who can participate?

Patients who have recently been diagnosed with dementia.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are asked to remember a nostalgic memory and those in the second group are asked to remember an ordinary event in the past. All participants complete questionnaires asking them about how they feel before taking part in a memory test. This involves a researcher reading out 24 illness-related statements in four blocks of six and participants are asked to remember as many as possible after each block.

What are the possible benefits and risks of participating?

There are no direct benefits for participants taking part. There are no major risks in taking part in this study. Some of the statements to remember might be upsetting to some people but the researcher will support the participant if this happens. The participant will be fully debriefed after the study and the researcher will ensure the participant is feeling ok before finishing the appointment.

Where is the study run from? The RICE Centre (UK)

When is the study starting and how long is it expected to run for? April 2016 to May 2017 Who is funding the study? Alzheimer's Research UK (UK)

Who is the main contact? Professor Richard Cheston richard.cheston@uwe.ac.uk

Contact information

Type(s) Scientific

Contact name Prof Richard Cheston

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 32203

Study information

Scientific Title

A feasibility study to test whether using past memories to increase psychological resources leads to better recall of information about dementia

Study objectives

Hypotheses: 1. Participants in the nostalgia (vs. control) condition will recall a higher proportion of high threatening dementia related statements compared to less threatening statements

2. Participants in the nostalgia (vs. control) condition will have higher self-esteem, social connectedness, and meaning in life

3. Recall of highly threatening statements in the nostalgia condition (vs control) will not be associated with increased levels of anxiety

4. There will be no differences in recognition between participants in the nostalgia and control arms

5. Participants in the nostalgia (vs control) condition will make fewer protective compared to threatening intrusion errors

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of Scotland Research Ethics Service REC 2, 30/08/2016, ref: 16/ES/0097

Study design

Randomised; Interventional; Design type: Process of Care, Psychological & Behavioural

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Specialty: Dementias and neurodegeneration, Primary sub-specialty: Dementia; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions

Participants will be randomly allocated to either the intervention condition (n=15) or the control condition (n=15).

Intervention condition: Participants will be instructed to bring to mind a nostalgic memory

Control condition: Participants will be instructed to bring to mind an ordinary event in the past

Participants in both groups will complete questionnaires to measure psychological resources and complete a nostalgia manipulation check. Next participants will take part in the memory test; the recall of 24 statements related to dementia. From previous research half have been rated as high threat to identity and half rated as low threat to identity. These will be read out in four groups of six statements. Recall will be assessed immediately after each of the four groups and after a two-minute distracter task. Finally a recognition test will follow in which participants are provided with 48 statements and asked to identify the 24 they have previously heard. This research takes place within one session and lasts for approximately 45 minutes.

Intervention Type

Other

Primary outcome measure

Number of highly threatening and low threatening related statements recalled is measured by counting the correct number of statements recalled the single study appointment.

Secondary outcome measures

All outcomes are measured at the single study appointment.

1. Psychological resources are measured using State Functions of Nostalgia Scale

2. Recognition is measured by counting the number of correct statements participants recognise from a list of statements they have and haven't heard previously

3. Intrusion errors (protective of self/threatening to self) are measured by counting the number of errors participants make in recall (protective error = valence reversal of high threat statements, repetition of low threat statements; threatening error = valence reversal of low threat statements, repetition of high threat statements)

Overall study start date

20/04/2016

Completion date 31/05/2017

Eligibility

Key inclusion criteria

1. A diagnosis made within the previous 18 months of either probable Alzheimer's disease or probable Vascular Dementia or a mixed form of these

3. Mild levels of cognitive impairment (e.g. MOCA score over 12 or equivalent score on an alternative assessment tool)

3. The capacity to consent to be part of the research

4. Sufficient communication skills to be able to take part in the research

5. Aged 18 years and over

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex Both Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria

 A significant history of premorbid psychiatric problems
 A diagnosis of dementia with Lewy Bodies (McKeith, 2002) or Frontaltemporal dementia (Snowden, Neary and Mann (2002))
 If deficits in short term memory are not a primary cause of disability

Date of first enrolment

01/10/2016

Date of final enrolment 28/02/2017

Locations

Countries of recruitment England

United Kingdom

Study participating centre The RICE Centre Building 8 Royal United Hospital Combe Park Bath United Kingdom BA1 3NG

Sponsor information

Organisation

University of the West of England

Sponsor details

Frenchay Campus Coldharbour Lane Bristol England United Kingdom BS16 1QY +44 (0)117 965 6261 Leigh.taylor@uwe.ac.uk **Sponsor type** University/education

ROR https://ror.org/02nwg5t34

Funder(s)

Funder type Charity

Funder Name Alzheimer's Research UK

Alternative Name(s) Alzheimer's Research Trust, AlzheimersResearch UK, AlzResearchUK, ARUK

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location United Kingdom

Results and Publications

Publication and dissemination plan

Participants will be offered the option of being sent a summary of the results at the end of the study. Where funds allow, the protocol will be published and the findings from this study will be published in high quality open access journals with good impact factor. Findings will be presented at conferences. The trial management team will liaise with the university's press team to establish an appropriate mechanism to disseminate to the wider public.

Intention to publish date

31/08/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version V02 | 16/08/2016 | 16/11/2016 | No | Yes |
| Results article | results | 01/04/2018 | | Yes | No |
| Other publications | | 10/06/2021 | 30/12/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |