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Understanding social changes in people with Alzheimer's disease

Submission date
08/06/2023

Recruitment status
Recruiting

Registration date
28/06/2023

Overall study status
Ongoing

Last Edited
20/09/2023

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Impaired social functioning is a core feature of dementia and declines progressively through the disease course, but we do not currently understand the specific causes of this decline and have no effective treatments for social functioning. Social cognitive impairment, particularly impaired theory of mind (meaning inability to understand that other people have other thoughts and conceptualise what those thoughts might be), is a likely major cause of this decline and, if this is established, it could be a target for future interventions which aim to maintain social cognition. Is impairment in theory of mind associated with decline in social functioning in people with mild Alzheimer's disease (AD)?

Who can participate?
207 people with mild Alzheimer's disease and 207 family/friend informants recruited from NHS memory clinics and other sources.

What does the study involve?
At baseline, we will assess social cognition using a detailed neuropsychological battery and will assess social functioning. At 4 and 8 months, participants will remotely rate their social functioning using a questionnaire and the full battery of testing will be repeated at 1 year follow-up. In a remote monitoring sub-study (SOCIAL-RM), up to 50 consenting participants with a mobile phone will have remote digital monitoring using a mobile phone application throughout the study duration. In a further behavioural observation sub-study (SOCIAL-BO), up to 50 consenting participants will have social behaviour assessed during a video-recorded semi-structured social interaction at baseline and 1 year follow-up.

What are the possible benefits and risks of participating?
Participants may not receive direct benefit from being in this study but information learned from this study may help us to improve care for people with Alzheimer's dementia in the future. Each person with Alzheimer's dementia will receive a £20 gift certificate as a token of our thanks for their time. There are no specific risks associated with participation. Participants may feel anxious before or tired after taking part in the tasks, but we will do everything we can to minimise or prevent this and participants will be given the opportunity to have either a short break or for the testing to be stopped if necessary.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
July 2022 to June 2026

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313873

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56436, WT 222932/Z/21/Z, IRAS 313873

Study information

Scientific Title

Social cognition and functioning in Alzheimer's dementia

Study objectives
Research Question
Is impairment in theory of mind associated with decline in social functioning in people with mild Alzheimer's disease (AD)?

Objectives
1. To test whether theory of mind deficits, or those in other social cognitive domains, are associated with current and subsequent level of social behaviour and functioning in Alzheimer's disease.
2. To establish the reliability and validity of novel approaches to the measurement of social behaviour and function in Alzheimer's disease

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2023, Wales REC 6 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941090; Wales.REC6@wales.nhs.uk), ref: 23/WA/0157

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Care home, GP practice, Home, Hospital, University/medical school/dental school

Study type(s)
Other

Participant information sheet
See additional files. The main information sheet is here – please use the contact details below to request the information sheets for family informants or for the sub-studies.

Health condition(s) or problem(s) studied
Dementia

Interventions
Procedures:
Main Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) Study

The volunteer will meet with us on two occasions – the first study visit, and then a final visit after 1 year when the tests of social cognition and behaviour will be repeated. Between these face-to-face visits, after 4 and 8 months, we will make telephone contact with the volunteer or their

relative to complete a questionnaire and repeat the mobile phone monitoring for those taking part in that part of the study.

As above, these visits can take place at the university building or other appropriate research site, and we will reimburse travel via taxis if needed. Or if volunteers prefer, we will visit them at their homes.

Baseline: Once the consent form is signed, participants will complete a form asking about basic characteristics such as age, sex, ethnicity etc. The person with Alzheimer's dementia will then complete a series of tasks on a computer which test their ability to understand what another person might be thinking, recognise other peoples' emotions, and empathise with their perspectives. These tasks involve either watching a short video or listening to a brief and then choosing from a list of options which test the volunteer's understanding of what happened in the scenario. They will also complete other standard questionnaires assessing social functioning and other symptoms of dementia. These tasks will take around 60-75 minutes. Participants can have a break during this or can continue testing on a separate occasion if required.

The consenting family member or friend of the person with dementia will also provide basic information about themselves and then complete with a researcher several questionnaires about the social functioning and other symptoms of the person with Alzheimer's dementia, lasting 35-45 minutes.

4 and 8 months: We will contact the family member of friend of the person with dementia by phone or email and ask them to complete a single questionnaire about social functioning lasting around 5 minutes.

1 year follow-up: We will meet again at the university or NHS site or participants home to repeat all tests conducted at baseline.

SOCIAL-Behavioural Observation sub-study

We will ask up to 50 of the SOCIAL study participants to also take part in this sub-study (these will be participants recruited from Camden and Islington NHS Foundation Trust or University College London for practical reasons related to video-recording interviews). We will provide a participant information sheet and ask for a separate consent form to be signed at the same time as the main SOCIAL study recruitment and consent respectively. With the volunteer's knowledge and agreement, we will assess the quality of social behaviour by video-recording two brief (5-10minute) informal social interactions. The first will be between them and their relative, and the second will be with a study researcher. This video-recording will then be watched and rated for evidence of difficulties in social behaviour using a standard assessment scale (the Social Behaviour Observation Inventory).

SOCIAL-Remote Monitoring sub-study

Up to 50 participants who are recruited from Camden and Islington NHS Foundation Trust or University College London (for practical reasons related to downloading the mobile phone app) will be asked to participate in the remote monitoring sub-study. These participants may be the same or may be different from those recruited for the SOCIAL-BO sub-study).

Participants will be required to have an Android smartphone. We will provide a participant information sheet and ask for a separate consent form to be signed at the same time as the main SOCIAL study recruitment and consent respectively.

For consenting participants, the researcher will support themto download a mobile phone application to their mobile phone. There is nothing further required from them – we would like them to continue using their phone as they normally would and the app will run continuously on their phone to collect data for the study:
- Number of phone-calls to and from their phone, the duration of the call and anonymised identity of the other phone: each telephone number will be anonymised using a code, rather than using the telephone number, which will allow the research team to count how many different telephone numbers contact or are contacted by the study participant.
- Number of text messages to and from their phone, and anonymised identity
- Number of contacts in phone contact list
- Number of nearby Bluetooth devices and number connected to their phone
- Location of phone, which is anonymised using a code
- Status of the app, and battery level of phone, used to clarify any reason for problems with the data collection.
The app will run in the background of the phone and not require participants to do anything active to provide data. If a participant requests that data collection is stopped, then the app can be turned off at any time by the research team and data collection will be stopped by our team after one year and we will support them to remove the app from their phone if they wish (although the app will not be collecting any information at that stage).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Social functioning is measured using the Social Functioning in Dementia (SF-DEM) Scale at baseline, 4 months, 8 months, 12 months

Secondary outcome measures
1. Social cognition including emotion recognition and theory of mind is measured using The Awareness of Social Inference Test short form at baseline and 12 months
2. Empathy is measured using the Interpersonal Reactivity Index at baseline and 12 months
3. Cognition is measured using the Addenbrooke's Cognitive Examination at baseline and 12 months
4. Quality of life is measured using the Quality of Life in Alzheimer's Disease scale at baseline and 12 months
5. Neuropsychiatric symptoms are measured using the Neuropsychiatric Inventory at baseline and 12 months
6. Depression is measured using the Cornell Scale for Depression in Dementia at baseline and 12 months
7. Activities of Daily living are measured using the Bristol Scale for ADLs at baseline and 12 months
8. Awareness of social behaviour is measured using the Revised Self-monitoring Scale at baseline and 12 months
9. Physical comorbidities are measured using the Charlson Comorbidity Index at baseline and 12 months

Overall study start date

01/07/2022

Completion date
30/06/2026

Eligibility

Key inclusion criteria
People with Alzheimer's dementia:
1. Clinical diagnosis of probable Alzheimer's disease dementia made by dementia specialist clinic.
2. Mini-mental state examination score >= 20 or Addenbrooke's Cognitive Examination III score >= 52 (consistent with mild dementia)
3. English speaking ability sufficient to be able to complete standardised social cognition tests (TASIT-S) which are only available in the English language

Additional criteria for SOCIAL-RM study:
4. Possess an Android smartphone

Family/friend informant:
1. Family/friend informant must see the person with Alzheimer's disease at least monthly to be able to report on social functioning and other symptoms.
2. English speaking to be able to complete English language questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 414; UK Sample Size: 414

Key exclusion criteria
People with Alzheimer's dementia:
1. Lack of mental capacity to consent to participate
2. Previous diagnosis of schizophrenia, severe traumatic brain injury, or autistic spectrum disorder
3. Aged under 50 years

Family/friend informant
1. Lack of mental capacity to consent to participate
2. Diagnosis of dementia or other serious mental illness
3. Aged under 18 years

Date of first enrolment

01/05/2023

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT
+44 20 7679 2000
uclh.randd@nhs.net

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Wellcome, WT

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: Dementias Platform UK for the main SOCIAL study data (not SOCIAL-RM or SOCIAL-BO). The data is expected to become available from June 2026 for 10 years. Data will be shared by Dementias Platform UK according to their data access policy (https://portal.dementiasplatform.uk/Apply/DataAccessPolicy) to all bona fide researchers to use data for health-related research that is in the public interest. Consent will be obtained by participants for this sharing.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Main study, Person with Alzheimer's disease version 1.0	20/03/2023	09/06/2023	No	Yes
Protocol file	version 1.2	26/05/2023	09/06/2023	No	No
Participant information sheet	Behavioural observation substudy, Informant version 1.0	20/03/2023	12/06/2023	No	Yes
Participant information sheet	Behavioural observation substudy, Person with Alzheimer's disease version 1.0	20/03/2023	12/06/2023	No	Yes
Participant information sheet	Main study, Consultee version 1.1	26/05/2023	12/06/2023	No	Yes
Participant information sheet	Main study, Informant version 1.1	26/05/2023	12/06/2023	No	Yes

Participant information sheet	Remote monitoring substudy, Person with Alzheimer's disease version 1.1	26/05/2023	12/06/2023	No	Yes
HRA research summary			20/09/2023	No	No