SOcial Cognition and functioning In ALzheimer’s dementia (SOCIAL): Analysis Plan

Introduction

Evidence of decline in social functioning, defined as how individuals interact in society and their own personal environment [1], is a diagnostic criterion for dementia [2], meaning that it is characteristic of the condition. Social functioning decline may precede dementia diagnosis by several years [3] and continues during disease progression with worse social functioning in those with more severe dementia [4]. These impairments are highly distressing to people with dementia and can have a hugely damaging effect on relationships with their families [5]. Developing dementia is the greatest fear for UK older adults [6] and the resultant loss of enjoyment in previous activities and impaired social relationships are particular concerns [7]. Having more frequent social contact with others is beneficial for people who do not have dementia as it confers better cognitive function and lower dementia risk [8] suggesting that there may also be a cognitive benefit to social functioning in those with dementia. Therefore, impaired social functioning in dementia is a public health concern and is highly distressing for people affected but we have little clear evidence on what causes social functioning impairment and a resultant absence of effective interventions for social functioning in dementia [9].

Social cognition deficits are likely crucial drivers of impaired social functioning. Successful social cognition requires processing of social information and signals from others and formulation of suitable responses. Several studies have shown that people with mild and moderate Alzheimer’s Dementia (AD) have theory of mind (ToM) deficits [10-12] including a study of 16 people with AD which indicated a specific pattern of deterioration in ToM following backwards developmental steps typical of the acquisition of theory of mind ability, where simple ToM levels are preserved but more complex levels are impaired [13]. People with AD have difficulty in tasks relying on detecting second order ToM i.e., predicting what another person is thinking about someone else’s thoughts/feelings. These difficulties are distinct from other cognitive impairments so do not simply reflect poor memory [14,15]. Other social cognitive domains including emotion recognition [16] and empathy [17] are also impaired. However, previous studies have been cross-sectional [18] or limited by imprecise measurement [15] meaning the effect of social cognitive impairments on clinically relevant social functioning of people with AD is unknown. This study will therefore aim to clarify whether social cognition deficits drive social function impairments in AD.

Secondary aims of this study are to improve measurement of social functioning in dementia. Questionnaire-based assessment of social functioning may lack detail on the quality of social functioning as they often do not ask about the engagement of the person with dementia. This was supported in the study’s preparatory patient and public involvement work as a discussion group of dementia family carers stated that the quality of social relationships was adversely affected. This study will therefore modify an approach used in frontotemporal dementia (FTD) to observe and rate the quality of social behaviour [19]. Questionnaires are also susceptible to recall bias, particularly in people with dementia, so we will remotely assess social functioning using an existing smartphone-based ‘passive sensing’ platform [20].

AIM(S) AND OBJECTIVES

The overall aim of this study is to test the hypothesis that impairment in social cognitive performance predicts social behaviour and functioning decline in people with AD.

Primary Objective

1. Examine whether social cognition impairment in people with Alzheimer's dementia is associated with decline in social functioning during the subsequent 1 year

Secondary Objectives

2. Investigate whether social cognitive impairment is associated with decline in activities of daily living and neuropsychiatric symptoms in people with Alzheimer's dementia.
3. Investigate whether social cognitive impairment in people with Alzheimer's dementia is associated with worse in quality of life, anxiety or depression in their family carer.
4. Investigate the feasibility, acceptability and validity of a novel remote digital monitoring app to assess social functioning in people with Alzheimer's dementia:
    a) Assess feasibility and acceptability of the use of the RADAR-Base remote monitoring mobile phone application in people with dementia, assessed by study recruitment rates, follow-up, and data missingness.
    b) Assess criterion and construct validity of the RADAR-base remote monitoring data to assess social functioning in people with Alzheimer's dementia, by examining correlation between a social functioning scale, cognitive assessment and activity of daily living scale, and RADAR-base metrics during 2 weeks. We hypothesise that greater social functioning, less severe cognitive impairment more ADL independence would correlate with more frequent mobile phone use and out-of-home travel
    c) Describe the 1y longitudinal changes in remote monitoring data in a sample of people with Alzheimer's disease dementia.

Data Collection and Management

This was a multi-site observational cohort study. The study received ethical approval from the Wales National Health Service (NHS) Research Ethics Committee 6 (23/WA/0157). All participants provided written informed consent.

Participants and setting

Participants were required to meet the following inclusion criteria:

People with Alzheimer's dementia

1) Aged 50 years+
2) Clinical diagnosis of probable Alzheimer's disease dementia made by dementia specialist clinic; mixed dementia was excluded
3) Mini-Mental State Examination score (MMSE) ≥20, Addenbrooke's Cognitive Examination (ACE-III) score ≥52 [21], or Montreal Cognitive Examination (MoCA) score ≥13 within past 6 months (consistent with mild dementia) [22]. Or MMSE ≥23, ACE-III ≥64, MoCA≥16 if conducted within 6-12 months of screening for study. If no cognitive assessment within the past year is available, then as per section 5.1, repeat MMSE, ACE-III or MoCA as screening.
4) English speaking ability sufficient to be able to complete standardised social cognition tests (TASIT-S) which is only available in English language
5) Possessing mental capacity to consent to participate
6) No previous diagnosis of schizophrenia, severe traumatic brain injury, or autistic spectrum disorder

Family / friend informant

1) Family/friend informant aged 18 years+ who must see 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
3) Possessing mental capacity to consent to participate
4) No Diagnosis of dementia or other serious mental illness
5) English speaking ability sufficient to be able to complete standardised questionnaires

Participant dyads were recruited from ten National Health Service Memory Services (North London NHS Foundation Trust; Oxford Health NHS Foundation Trust; Devon Partnership NHS Trust; North East London Foundation NHS Trust; Northumbria Healthcare NHS Trust; Herefordshire and Worcestershire Health and Care NHS Trust; North Staffordshire Combined Healthcare NHS Trust; Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust; Somerset NHS Foundation Trust; Cambridgeshire and Peterborough NHS Foundation Trust). Potential participants were identified 1) by treating clinicians, 2) through checking electronic health records for people fulfilling eligibility criteria; 3) via Join Dementia Research, an on-line self-registration service that enables volunteers with memory problems or dementia, carers of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research.

Eligible participants were provided with a study information sheet, and at least 24 hours later the research team contacted the individual to discuss the study and arrange to meet them in person to answer their questions and obtain consent if they wish to participate in the study. Participants were required to have mental capacity to provide informed consent to participation, which we assessed using the UK Mental Capacity Act principles. At follow-up assessments, mental capacity was reassessed, and for those deemed to have lost capacity we followed their directions specified in the consent form to either 1) complete the study as long as they do not object, 2) withdraw from the study, 3) or speak to a friend or family as consultee/proxy decision maker to decide on their behalf if they complete the study.

Participants were then additionally invited to participate in the SOCIAL-Remote Monitoring (SOCIAL-RM) sub-study for which a further inclusion criteria of possessing an Android smartphone was applied. Potential participants for SOCIAL-RM who showed interest in the study were provided with a separate study information sheet relating to SOCIAL-RM and were given at least 24 hours to review it before the researcher contacted them to discuss the study, arrange to meet in-person and ask them to sign the SOCIAL-RM consent form.

Measurements

Data collected is summarised in figure 1.

Figure 1. SOCIAL study data collection schedule

		Domain	Scales	0m	4m	8m	12m
PwAD-rated scale		**Demographics**	Age, sex, ethnicity, language, marital status, education, occupation	■			
		Social Cognition	The Awareness of Social Inference Test-Short	■			Excl pt 2
			Interpersonal Reactivity Index (Empathic concern and Perspective taking subscales)	■			■
		Social functioning	Social Functioning in Dementia Scale	■			■
		General cognition	Addenbrooke's Cognitive Examination – version 3	■			■
		Quality of life	Quality of life in Alzheimer's Disease Scale	■			■
Informant-rated scale	About PwAD	**Social functioning**	Social Functioning in Dementia Scale	■	■	■	■
		Social behaviour	Revised Self-Monitoring Scale	■			■
		NPS	Neuropsychiatric Inventory	■			■
		Depression	Cornell Scale for Depression in Dementia	■			■
		ADLs	Bristol Activities of Daily Living Scale	■			■
		Comorbidities	Charlson Comorbidity Index	■			■
		Major life events since 0m	Bereavement, hospitalisation, move to care home or other accommodation				■
	About self	**Demographics**	Age, sex, ethnicity, language, marital status, education, occupation	■			
		Own mood	Hospital Anxiety and Depression Scale				■
		Own quality of life	Carer Dementia Quality of Life Scale				■

Baseline

Consenting participants with Alzheimer's dementia first completed the following scales:

1. Sociodemographic information (e.g., age, sex, first language, marital status, ethnicity, education, dementia subtype)
2. Social Functioning in Dementia (SF-DEM) Scale [23] which is a validated scale for assessing social functioning in people with dementia. The scale consists of 20 questions which generates scores in three social functioning domains: time spent with other people, communicating with other people and sensitivity to other people.
3. The Awareness of Social Inference Test short form (TASIT-S) [24] which is an objective measure of three social cognition domains: emotion recognition (ER), sarcasm detection (SD), and theory of mind (ToM). For each domain, participants were presented with 9-11 videos lasting 15-60 seconds. For ER, participants were required to identify the dominant emotion of a character in the scene: happy, sad, angry, anxious, surprised, revolted, or neutral. For SD and ToM sections, each video had four associated questions probing participants' inferences about the social context, intent, and understanding of specified characters. These questions assess participants' understanding about what the characters are doing, trying to say, thinking, and feeling.
4. Interpersonal Reactivity Index (IRI) [25] which is a widely-used and validated scale comprising 28 questions assessing four different dimensions of empathy: the empathic concern for others, tendency to see others' perspectives, personal distress response to others' suffering, and empathy for fictional characters.
5. Addenbrookes Cognitive Examination-III (ACE-III) [26] which is a validated test of cognitive function for people with Alzheimer's dementia consisting of subdomains testing attention, verbal fluency, language, verbal memory and visuospatial function.
6. QOL-AD [27] which is a validated disease-specific scale assessing quality of life in people with Alzheimer's dementia comprising 13 items rated on a Likert scale.

A family or friend informant answered questionnaires on paper or through interview with the researcher depending on preference:

1. Sociodemographic information (e.g., age, sex, first language, marital status, ethnicity, education)
2. SF-DEM scale – carer-rated version [23].
3. Neuropsychiatric Inventory (NPI) [28] which assesses 12 neuropsychiatric symptoms of the person with dementia through ratings of frequency and severity.
4. Cornell Scale for Depression in Dementia (CSDD) [29] which asks the family or friend informant to rate the severity of 19 symptoms of depression in the person with dementia during the preceding week against a Likert scale.
5. Bristol Scale for ADLs (BADL) [30] which assesses 25 activities of daily living.
6. Revised Self-monitoring Scale (RSMS) [31] which is a 13 item questionnaire designed to measure an individual with dementia's awareness of social behaviour and sensitivity to subtle emotional expressions during face-to-face interaction.
7. Charlson Comorbidity Index (CCI) [32] which is the most widely-used measure of physical ill-health/multimorbidity validated in general populations.

4 and 8 month follow-up (+/- 1 month)

The family/friend informant was contacted by phone or email and asked to complete the SF-DEM scale – carer-rated by telephone interview with the researcher.

1 year follow-up (+/- 1 month)

This meeting was held in person at a university or NHS office, the participant's home, or, for family/friend informants unable to attend in person, virtually via Microsoft Teams.

The following information will be collected from the person with dementia:

1. Social Functioning in Dementia (SF-DEM) Scale
2. The Awareness of Social Inference Test short form (TASIT-Short) except the sarcasm detection subscale which we removed to reduce interview duration.
3. Interpersonal Reactivity Index (IRI)
4. Addenbrookes Cognitive Examination-III (ACE-III)
5. Quality of Life in Alzheimer's Disease scale (QOL-AD)

Then the family/friend informant provided

1. Information about any key changes to living situation of the person with dementia, e.g. living alone, change of accommodation
2. SF-DEM scale – carer-rated)
3. Neuropsychiatric Inventory (NPI)
4. Cornell Scale for Depression in Dementia (CSDD)
5. Bristol Scale for ADLs (BADL)
6. Revised Self-monitoring Scale (RSMS)
7. Charlson Comorbidity Index (CCI)
8. Hospital Anxiety and Depression Scale (HADS), [33] which is a commonly used scale comprising 14 questions to determine the levels of anxiety and depression that a person is experiencing which avoids reliance on aspects of these conditions that are common somatic symptoms of illness, so suitable for older people.
9. Carer Dementia Quality Of Life Scale (CDEMQOL), [34] which is designed to capture quality of life of family carers of people with dementia. It comprised 30 individual questions to assess carer quality of life, subdivided under five categories assessing different factors which influence quality of life.

SOCIAL Remote Monitoring Study

Following the main SOCIAL study assessments, for consenting participants we installed the RADAR-Base app on person with dementia's phone and logged them into the SOCIAL-RM study domain using a unique anonymised ID. The participant was asked not to interact with the app during the subsequent follow-up period up to 1 year. The app ran passively in the background of the phone to collect data, restarting automatically when the phone is switched on. It collected the following data:

- Telephone call time, duration, target (anonymised) and whether the call was incoming, outgoing, missed. Content was not recorded in any way: each telephone number was anonymised using a code, rather than using the telephone number allowing the research team to count how many different telephone numbers contacted or were contacted by the study participant.
- Phone message time, target (anonymised), length and whether the message was incoming, or outgoing. Message content was not recorded.
- Number of phone contacts added or removed.

- Relative location, through GPS or network using latitude and longitude coordinates (offset to a reference point meaning these do not reflect actual location but instead reflect degree of geographical movement).
- Other data relevant to the functioning of the app – battery life, RADAR-Base application status and participant interaction with phone.

All SOCIAL-RM participants received a £50 shopping voucher to compensate for data and battery use.

Participants were free to withdraw from the studies at any time in which case we would deactivate the app's data collection via the RADAR-Base server +/- instruct them to delete the app from their phone, meaning no more data would be collected from the app.

3. Analysis plan

3.1 Descriptive Analyses

We will first summarise the demographic and baseline characteristics (age, sex, ethnicity, marital status, education, occupational position based on grade of last employment using Office of National Statistics classification [35] (Higher managerial, administrative and professional occupations, Intermediate occupations, Small employers and own account workers, Lower supervisory and technical occupations, Semi-routine and routine occupations, Never worked and long-term unemployed), cognitive status) of the study population using appropriate statistics (means, medians, proportions). We will summarise clinical characteristics of participants population measured by ACE-III, SF-DEM, QOL-AD, NPI, BADL, CCI using appropriate statistics (means, medians, proportions).

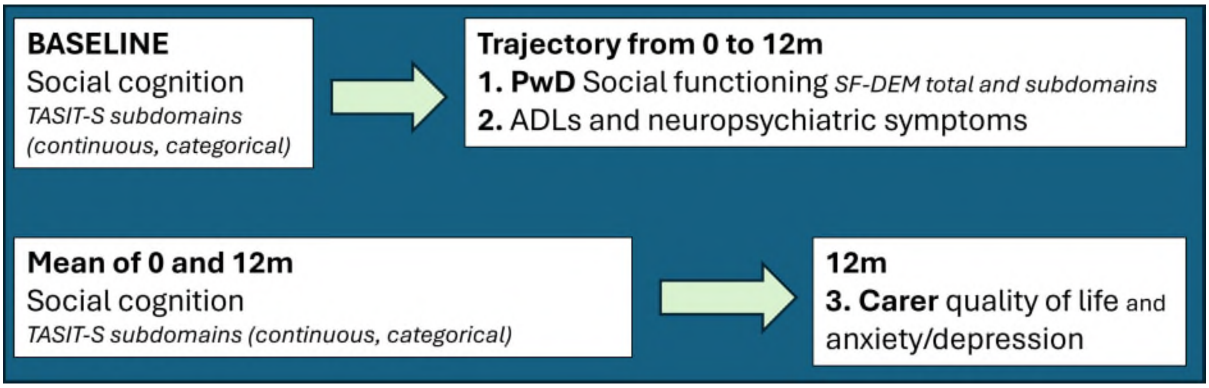
We will describe social functioning measured by proxy-rated SF-DEM (domains 1, 2, and 3 separately and total score) at 0, 4, 8, and 12m. We will describe social cognition measured by TASIT-S performance subscales separately using part 1 (emotion recognition), part 2 (sarcasm detection – measured only at baseline), part 3 (social inference). For emotion recognition we will use the summary score of dominant emotions correctly identified, and for part 2 and 3 we will use the four associated questions testing understanding about what the characters ‘think’, ‘do’, ‘feel’ and ‘say’ separately.

We will describe patterns of missing data and attrition during the study using a participant flow diagram, and use chi-squared test to examine which baseline characteristics are associated with subsequent study drop-out.

3.2 SOCIAL study

Planned analyses are summarised in figure 2.

Figure 1. SOCIAL study analyses



1. Examine whether social cognition impairment in people with Alzheimer's dementia is associated with decline in social functioning during the subsequent 1 year

We will analyse the cross-sectional association of baseline TASIT-S scores with SF-DEM domains using linear regression in 1) unadjusted models, 2) models sequentially adjusted for age and sex, 3) years of education and ethnicity (White / other), 4) additionally adjusted for cognitive function (ACE-III total score).

We will then analyse the longitudinal association of TASIT-S scale performance with trajectories of SF-DEM scores at 0, 4, 8 and 12 month follow-up using mixed linear models with random intercept and slope. We will first use TASIT-S scale scores as continuous variables, and then tertiles of TASIT-S performance. Analyses will be adjusted as above. These analyses will use available data without imputation.

In subgroup analyses, we will stratify analyses by socio-economic status defined by occupation type. We will also conduct a sensitivity analysis excluding people with Alzheimer's dementia for whom English was not their first language, and a further sensitivity analysis with multiple imputation for missing data.

2. Investigate whether social cognitive impairment is associated with decline in activities of daily living and neuropsychiatric symptoms in people with Alzheimer's dementia.

We will then analyse the association of baseline TASIT-S scale performance with BADL and NPI total scores at 0 and 12 month follow-up using mixed linear models with random intercept and slope. We will first use TASIT-S scale scores as continuous variables, and then tertiles of TASIT-S performance. Analyses will be adjusted as above. These analyses will use available data without imputation.

3. Investigate whether social cognitive impairment in people is associated with decline in quality of life, anxiety or depression in their family carer.

We will analyse the association between mean TASIT-S scale performance across 0 and 12months (continuous and in tertiles) by the participants with Alzheimer's dementia and their family carer's total C-DEMQOL score (and subscales) and anxiety and depression (measured by HADS subscales) at 12 months, using linear regression. These analyses will be 1) unadjusted, 2) adjusted for age and sex of the person

3.3 SOCIAL-Remote Monitoring study

1. Assess feasibility and acceptability of the use of the RADAR-Base remote monitoring mobile phone application in people with dementia, assessed by study recruitment rates, follow-up, and data missingness.

We will describe the flow of participants through the study, and reasons given by SOCIAL study participants for not participating in SOCIAL-RM. We will compare the characteristics of the SOCIAL-RM participants with the SOCIAL study participants who refused participation in SOCIAL-RM.

We will describe the collected data from the n=7 participants: duration of follow-up, number of days for which data was collected, gaps in data collection and reasons for this.

2. Assess criterion and construct validity of the RADAR-base remote monitoring data to assess social functioning in people with Alzheimer's dementia, by examining correlation between a social functioning scale, cognitive assessment and activity of daily living scale, and RADAR-base metrics over 2 weeks. We hypothesise that greater social functioning, less severe cognitive impairment more ADL independence would correlate with more frequent mobile phone use and out-of-home travel

Cross-sectional criterion validity:

We will calculate the correlation of the proxy-rated SF-DEM 'Spending time with other people' and 'Communicating with other people' domains with RADAR-base app metrics during month 1:

1) Number of outgoing phone calls made
2) Number of different phone numbers contacted
3) Number of outgoing text messages sent
4) Number of different text messages corresponded with
5) Number of different nearby Bluetooth devices
6) Number of times app registers phone leaving home address

Cross-sectional construct/convergent validity:

We will calculate the correlation of ACE-III score and Bristol ADL scale with the RADAR-base app metrics listed above.

3. Describe the 1y longitudinal changes in remote monitoring data in a sample of people with Alzheimer's disease dementia.

We will describe participants changing cognitive status from baseline to 1year (ACE-III) and longitudinal changes in app use using multilevel linear models:

1) Number, diversity and duration of outgoing and incoming phone calls
2) Number, and diversity of text messages sent and received
3) Geolocation

4. Timeline and responsibilities

Final data collection will be completed in February 2026. Data will be cleaned and prepared during March 2026 before analysis beginning April 2026.

5. Dissemination

This study will provide information about longitudinal changes in social cognition and functioning in people with Alzheimer's dementia, and the feasibility, acceptability and validity of using digital remote monitoring in observational or interventional research studies to assess social functioning in older adults with Alzheimer's disease dementia. We will disseminate through academic publications and in conferences and a lay summary for study participants and published on UCL website and blogs.

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