

# Testing a new psychological intervention to support independence at home for people with dementia and their family or friends (NIDUS-Family study)

<b>Submission date</b> 16/09/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study is funded by the Alzheimer's Society and led by University College London with the University of Bradford. This study is part three of a large programme of work. In part one, the researchers carried out interviews with and observed family carers, people with dementia and health and social care professionals to investigate what helps and what stops people living with dementia being able to live independently in their own homes. The findings were used to design a psychological and social intervention called NIDUS-Family to improve the support received by people with dementia and their family/friends at home. This study aims to investigate whether the intervention works when compared with usual NHS and social care services.

### Who can participate?

People of any age or gender who have dementia and are living at home (not in a care home) and family members or friends of the person living with dementia who are in contact with them at least once a week and can speak English

### What does the study involve?

297 people living with dementia and their family member/friend will be randomly chosen to receive the NIDUS-Family intervention as well as their usual care from the NHS and social care services. 99 people living with dementia and their family member/friend will be randomly chosen just to receive their usual care from NHS and social care services without the NIDUS-Family intervention.

The NIDUS-family intervention involves eight face-face sessions with a researcher over 6 months followed by telephone calls to offer support and to see how people are doing. The intervention will be tailored to each participant depending on their preferences and needs for staying independent at home. The researcher will work with each participant to help them address their priorities and concerns around living independently at home. This might involve identifying who else can help, providing information, and problem solving together with the researcher. The intervention has been designed to provide support to people living with dementia and their

family member or friend in the following areas:

1. Accepting care and planning for the future
2. Communicating with people living with dementia, family and professionals
3. Managing challenging behaviours
4. Managing physical health conditions
5. Increasing exercise, activity and mobility
6. Managing low mood, anxiety and apathy
7. Offering carer wellbeing and support
8. Providing advice on safety and daily activities at home
9. Offering relaxation and stress management strategies
10. Improving sleep, diet and healthy routines

What are the possible benefits and risks of participating?

There may be no direct benefit to participants taking part in the study. However, by taking part, people living with dementia and their family members or friends are contributing to our understanding of whether the NIDUS-Family intervention can help people living with dementia be independent at home for longer. There is a risk that the topics that are discussed may cause emotional distress to participants. If this happens then the researcher will ask the participant if they wish to continue with the session, suggest a break, or move on from the topic, or the researcher will stop the session.

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 2019 to April 2024.

Who is funding the study?

The Alzheimer's Society (UK)

Who is the main contact?

Alexandra Burton, a.burton@ucl.ac.uk

## Contact information

### Type(s)

Public

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Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

271363

**ClinicalTrials.gov number**

**Secondary identifying numbers**

125937

## **Study information**

**Scientific Title**

Clinical and cost-effectiveness of a New psychological intervention to support Independence in Dementia (NIDUS) for family carers and people living with dementia in their own homes: A randomised controlled trial

**Acronym**

NIDUS-Family

**Study objectives**

This study is part three of a large programme of work. In the first part, we carried out interviews and observations with family carers, people with dementia and professionals on what helps and hinders independence at home. We used our findings to co-produce a psychological and social intervention to improve the support received by people with dementia and their family/friend at home. We piloted the intervention to make sure it was acceptable to the participants receiving it and the researchers delivering it. We will now test whether the intervention works. We aim to evaluate the effect of the NIDUS-Family intervention and usual care on goal attainment rated by family carers compared to routine care alone and determine whether NIDUS-Family with usual care is more cost-effective than usual care alone at 12-month follow up.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 06/01/2020, Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8222; camdenandkingscross.rec@hra.nhs.uk), ref: 19/LO/1667

## **Study design**

Randomized single-masked multi-site clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Home

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Dementia

## **Interventions**

The intervention is manualised and delivered in up to eight face-face sessions up to a 6-month period followed by fortnightly to monthly telephone follow-ups. Face-to-face sessions will be offered weekly/monthly and delivered in either the person's home or at the researcher's place of work, depending on participant preferences. It will be tailored to each participant depending on their preferences and needs for staying independent at home. In session one, the researcher will work through a manualised session to explore the participant's identified goals, and map them to a menu of training modules that will be offered to help them address priorities and concerns. The researcher will guide participant's to set and monitor progress with SMART goals, map their support networks and identify gaps, sign-post participants to existing resources and services, identify tasks and activities linked to achieving their goals and map goals onto intervention modules. The modules will include information and strategies addressing the following areas:

1. Accepting care, arranging and planning for the future
2. Communicating with people living with dementia, family and professionals
3. Managing behaviours and challenging behaviours
4. Managing physical health conditions
5. Exercise, activity and mobility
6. Managing low mood, anxiety and apathy
7. Carer wellbeing and support
8. Safety, environment, telecare, strategies, supporting functioning at home

9. Relaxation and stress management strategies

10. Sleep, diet and healthy routines

At the final appointment the researcher will bring together what has worked, both old and new strategies to help the participant put together a final individualised action plan. They will then conduct regular (fortnightly to monthly) telephone follow ups with participants up to 3 months after the final face-to face session to see how they are getting on and troubleshoot any problems.

The control group will receive their usual NHS and social care services.

Randomisation will be conducted by the Trial Manager, or if the Trial Manager is not available, by a member of the research team who is not involved in participant recruitment using a remote computerised web-based application, Sealed Envelope, provided by Priment clinical trials unit at University College London. Randomisation will occur at the level of the participant and will be blocked and stratified by site using a 2:1 ratio, i.e. two participant dyads (the person with dementia and their family carer) will be randomised to the intervention group for every one participant dyad randomised to the control. The 2:1 ratio was chosen to help enhance recruitment as more people will receive the intervention than not, and because the intervention is modular and highly individualised. By randomising more people to receive the intervention we will obtain a greater understanding of the intervention and the types of modules that people work on.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Functioning of the person with dementia assessed using family carer-rated Goal Attainment Scaling (GAS) at 12 months. The GAS questionnaire is valid, reliable and responsive to change in function in people with dementia living at home up to 12 months. Trained researchers will work with family carers and people with dementia to set SMART (Specific, Measurable, Achievable, Realistic and Timely) goals across domains of: cognition, instrumental activities of daily life/self-care, mood, behaviour and mobility. Family carers will evaluate 'performance' on a minimum of three and maximum of five goals set at baseline, on a 5-point scale ranging from 'much worse' to 'much better' than expected.

## **Secondary outcome measures**

1. Researcher-assessed rating of achievement of goals assessed using Goal Attainment Scaling questionnaire at 12-month follow-up
2. Functional independence (basic and instrumental activities of daily living) assessed by the carer using the Disability Assessment for Dementia scale at 12-month follow-up
2. Quality of life of the person with dementia assessed by the carer using the DEMQOL proxy scale at 12-month follow-up
3. Neuropsychiatric symptom severity assessed by the carer using the Neuropsychiatric Inventory-Questionnaire at 12-month follow-up
4. Carer's quality of life using the CarerQol scale at 12-month follow-up
5. Apathy assessed by the carer using the brief Dimensional Apathy Scale at 12-month follow-up
6. Carer's anxiety and depression assessed using the Hospital Anxiety and Depression Scale at 12-month follow-up
7. Potentially abusive behaviours assessed using the Modified Conflict Tactics Scale at 12-month follow-up
8. Services and support received by the person with dementia assessed using the Client Services

Receipt Inventory (CSRI) including home care, hospitalisations, respite and all-cause time to transition from home 12-month follow-up.

9. Achievement of goals assessed by the person with dementia (if they are able) using Goal Attainment Scaling before and after the intervention

10. Quality of life of the person with dementia assessed by the person themselves (if they are able) using the DEMQOL scale before and after the intervention

**Overall study start date**

01/07/2019

**Completion date**

30/04/2024

## Eligibility

**Key inclusion criteria**

People with dementia:

1. People with a documented diagnosis of dementia of any severity who are living in their own homes (including sheltered accommodation, where staff are not on site 24 hours a day) alone or with others
2. people with dementia who have a family carer willing to participate in the study

Family carers:

3. In regular (at least weekly face-to-face or telephone contact) with the person with dementia
4. Can speak English sufficiently well to participate in the intervention

**Participant type(s)**

Patient, Carer

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

297 dyads (594 participants in total)

**Total final enrolment**

604

**Key exclusion criteria**

1. People living with dementia who are receiving palliative care support and considered to be in the last 6 months of their life.
2. Family carers who lack capacity to consent
3. Currently enrolled in another intervention trial/research study
4. Unable to identify three or more goals

**Date of first enrolment**

02/03/2020

**Date of final enrolment**

06/05/2022

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****UCL Division of Psychiatry**

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**Study participating centre****University of Bradford, Faculty of Health Studies / Centre for Applied Dementia Studies**

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**Study participating centre****Anglia Ruskin University**

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**Study participating centre****Queen Mary University of London**

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# Sponsor information

## Organisation

University College London

## Sponsor details

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## Sponsor type

University/education

## Website

<https://www.ucl.ac.uk/joint-research-office/>

## ROR

<https://ror.org/02jx3x895>

# Funder(s)

## Funder type

Charity

## Funder Name

Alzheimer's Society

## Alternative Name(s)

alzheimerssoc

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Associations and societies (private and public)

## Location



# Results and Publications

## Publication and dissemination plan

- 1. We will feedback a summary of the results to participants if they indicate that they would like to receive this.
- 2. We will write up our findings for publication in a peer-reviewed journal and for conference presentations.
- 3. We will produce policy briefings for parliamentary, civil servants and other policy consultations and engagements. We will hold a NIDUS conference at the end of the programme of work to discuss the role of NIDUS outputs in supporting the independence of people with dementia. This will be a focus for a media campaign.

## Intention to publish date

02/02/2024

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Published as a supplement to the results publication, Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	Protocol of embedded process evaluation	02/12/2021	09/05/2022	Yes	No
<a href="#">Other publications</a>		09/06/2022	10/06/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		01/02/2024	02/02/2024	Yes	No