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

Submission date
16/09/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
08/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
271363

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s))
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

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)
Carer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

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Sponsor information

Organisation
University College London

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
United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2024	02/02/2024	Yes	No
Results article		08/01/2026	08/01/2026	Yes	No
Protocol article		02/12/2021	09/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Protocol of embedded process evaluation	09/06/2022	10/06/2022	Yes	No
Other publications	Economic evaluation	17/02/2025	06/11/2025	Yes	No