

Feasibility of the NIDUS-family intervention for independence at home

Submission date 01/04/2019	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/05/2019	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/06/2023	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The researchers carried out interviews and observations with family carers, people living with dementia and professionals on what helps and hinders independence at home. They used their findings to co-produce an intervention for people with dementia and their family carers to improve the support received by people living with dementia in their own homes. They now wish to pilot this intervention to see how acceptable and feasible it is to deliver in practice from the family carer, person with dementia and researcher perspectives.

Who can participate?

Family carers and people with a dementia diagnosis who live at home

What does the study involve?

A trained researcher delivers the intervention to family carers/people living with dementia in up to eight sessions over a six-month period. The intervention is tailored to each individual's preferences and needs and involves setting and monitoring progress with goals and priorities, signposting people to existing resources and services, and identifying activities that participants can take part in to help them achieve their goals. Participants are asked to complete questionnaires on goal attainment, quality of life, activities of daily living, symptoms and service use. Participants and researchers are asked about their experiences of delivering and receiving the intervention.

What are the possible benefits and risks of participating?

There may be no direct benefit to taking part in the study, but by taking part, participants are contributing to the development of an intervention that may help family carers and people living with dementia to be independent at home for longer. Their experiences of receiving the intervention will be used to modify it before it is tested in a larger study. No risks are foreseen, but it is possible that some topics discussed may be upsetting if participants are finding it difficult to be independent at home.

Where is the study run from?

1. Camden and Islington NHS Foundation Trust (UK)
2. Bradford District Care NHS Foundation Trust (UK)

3. South West Yorkshire Partnership NHS Foundation Trust (UK)

4. Westcliffe Medical Centre (UK)

When is the study starting and how long is it expected to run for?

December 2018 to February 2020 (updated 02/06/2020, previously: May 2020)

Who is funding the study?

Alzheimer's Society (UK)

Who is the main contact?

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(updated 02/06/2020, previously:

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Scientific

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Additional identifiers

Protocol serial number
41451

Study information

Scientific Title

Assessing the feasibility and acceptability of a psychological intervention for family carers and people living with dementia in their own homes: a feasibility study for stream two of the NIDUS (New interventions for Independence in Dementia) programme

Study objectives

To determine the feasibility and acceptability of a psychological intervention (NIDUS-family) for maintaining independence at home for people with dementia and their family carers through:

1. Piloting recruitment and assessment processes for the planned full trial of the intervention
2. Exploring family carers' and people living with dementia's experiences of receiving the intervention, and researchers' experiences of delivering it by conducting semi-structured qualitative interviews and using the findings to refine the intervention for the full trial
3. Evaluating intervention acceptability to family carers, through qualitative methods and completion of a semistructured questionnaire
4. Assessing fidelity of delivery of the manualised intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/04/2019, London - Camden & Kings Cross Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; Tel: +44 (0)20 7972 2561; Email: nrescommittee.london-camdenandkingscross@nhs.net), ref: 19/LO/0423, IRAS project ID: 259249

Primary study design

Interventional

Study design

Non-randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dementia

Interventions

The study will recruit 15 family carers and people with a dementia diagnosis who live at home through NHS memory services and GP practices. A trained researcher will deliver the intervention to family carers/people living with dementia in up to eight sessions over a six-month period. The intervention will be tailored to each individual's preferences and needs and will involve setting and monitoring progress with goals and priorities, signposting people to existing resources and services and identifying activities that participants can take part in to help them achieve their goals. Participants will be asked to complete questionnaires on goal attainment, quality of life, activities of daily living, symptoms and service use. Participants and researchers will be asked about their experiences of delivering and receiving the intervention.

Intervention Type

Behavioural

Primary outcome(s)

There is no primary outcome measure as it is a feasibility study but the study will be measuring:

1. The proportion of eligible people approached who agreed to take part in the study, measured at the end of the recruitment period (month 3)
2. Acceptability of the intervention measured using qualitative interviews and a 5-point Acceptability Likert Scale at 6 months
3. Fidelity to intervention delivery, measured using a fidelity analysis of audio-recordings of intervention appointments over a 6-month period

Key secondary outcome(s)

The outcome measures being piloted are:

1. Functioning of the person with dementia measured using Goal Attainment Scaling (GAS) (primary outcome in the full RCT)
 2. Functional independence (basic and instrumental activities of daily living) measured using Disability Assessment for Dementia scale
 3. Quality of life of the person with dementia measured using DEMQOL or DEMQOL proxy
 4. Neuropsychiatric symptoms measured using Neuropsychiatric inventory
 5. Family carer quality of life measured using C-DEMQOL & Carerqol
 6. Family carer burden measured using Zarit Burden Inventory
 7. Family carer anxiety and depression measured using Hospital Anxiety and Depression Scale
 8. Health and social care service use measured using Client Services Receipt Inventory
 9. Potentially abusive behaviour measured using Modified Conflict Tactics Scale
- All measured at baseline and 6 months

Completion date

29/02/2020

Eligibility

Key inclusion criteria

1. People with a documented diagnosis of dementia of any severity who are living in their own homes: alone and with others, and who have a family carer willing to participate in the study
2. Family carers who are in regular (at least weekly face-to-face or telephone contact) with the person with dementia
3. Family carers who can speak English

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

38

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

Date of first enrolment

01/05/2019

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Camden and Islington NHS Foundation Trust

St. Pancras Hospital

4 St. Pancras Way

London

United Kingdom

NW1 0PE

Study participating centre

Bradford District Care NHS Foundation Trust

New Mill

Victoria Road

Saltaire

Shipley

Bradford

United Kingdom
BD18 3LA

Study participating centre

South West Yorkshire Partnership NHS Foundation Trust

Trust Headquarters

Fieldhead

Ouchthorpe Lane

Wakefield

United Kingdom

WF1 3SP

Study participating centre

Westcliffe Medical Centre

157 Westcliffe Rd

Shipley

Bradford

United Kingdom

BD18 3EE

Sponsor information

Organisation

University College London

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Alzheimer's Society; Grant Codes: AS-PR2-16-002

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 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?
Results article		23/11/2020	29/03/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		08/10/2020	14/06/2023	Yes	No