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Feasibility of the NIDUS-family intervention for independence at home

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
01/05/2019

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
Jessica Budgett
j.budgett@ucl.ac.uk
(updated 02/06/2020, previously:
Alexandra Burton
a.burton@ucl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Ms Jessicca Budgett

Contact details
University College London
Maple House 6th Floor Wing A
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)2076799031
j.budgett@ucl.ac.uk

Type(s)
Scientific

Contact name
Prof Claudia Cooper

ORCID ID
http://orcid.org/0000-0002-2777-7616

Contact details
UCL Division of Psychiatry
Maple House
6th Floor
149 Tottenham Court Road
London
United Kingdom
W1T 7NF

+44 (0)203 549 5875
claudia.cooper@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2018

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

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
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
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

Sponsor details
Joint Research Office
Maple House 1st Floor
149 Tottenham Court Road
London
England
United Kingdom
W1T 7NF
+44 (0)20 3447 5557
uclh.randd@nhs.net

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. The researchers will feedback a summary of the results to participants if they indicate that they would like to receive this
2. They will write up the findings for publication in a peer-reviewed journal and for conference presentations

Intention to publish date
31/12/2020

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
Other publications		08/10/2020	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No