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IDEA: Intervention to prevent depressive symptoms and promote well-being in early stage dementia

Submission date
29/10/2015

Recruitment status
No longer recruiting

Registration date
08/01/2016

Overall study status
Completed

Last Edited
14/01/2020

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
People with dementia are at risk of feeling depressed, sad and losing their enjoyment of life. This hinders their ability to perform everyday activities even more, poses them at risk of going to a care home earlier than they otherwise would have, and affects their quality of life. There are currently no known effective treatments as medications such as anti-depressants don't work and have significant side effects. This study aims to develop a non-drug intervention (treatment) to prevent depression in people with early-stage dementia and test its feasibility (how easy it will be to use and how possible it is to use as a treatment). The intervention will be developed by combining evidence from studies using similar interventions for depression in older people, and by consulting people with dementia, their carers and professionals who support them. We will then find out whether this intervention is feasible and acceptable by conducting a pilot study, in order to establish the feasibility of running a bigger study at a later date.

Who can participate?
People with early-stage dementia who have received a diagnosis in the last 6 months. Carers of people with dementia also take part.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive their usual treatment and the Behavioral Activation intervention. Those in group 2 receive only their usual treatment. For those participants in group 1 (and their carers) the intervention is delivered by a graduate psychologist. It involves identifying pleasant activities for the person with dementia and supporting them in engaging in these in every-day life. They are also taught simple skills of coping with stress (i.e. relaxation techniques), and make a plan of employing pleasant activities in the future with the support of the psychologist and the family carer. This study allows researchers to to find out how feasible it is to recruit people with dementia and their families to take part, and how many sessions participants are able to complete. This information may be used develop a bigger study at a later date.

What are the possible benefits and risks of participating?
There is no guarantee that the study will help people with dementia and their families, but the information provided in this study will help improve services for promoting well-being in people with early-stage dementia. There are no specific risks from taking part. If participants' mood worsens considerably during the study, they will be referred to services that can help. Participants will receive all interventions that they would otherwise have received had they not taken part in this study.

Where is the study run from?
PRIMENT Clinical Trials Unit, University College London Medical School (UK)

When is the study starting and how long is it expected to run for?
October 2015 to May 2019

Who is funding the study?
Alzheimer's Society (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
IDEA: Intervention to prevent Depressive symptoms and promote well-being in EArly stage dementia: development and feasibility

Acronym
IDEA

Study objectives
The IDEA study will assess the feasibility and acceptability of behavioral activation for preventing depressive symptoms in people with early-stage dementia, such as number of people consenting to the trial, and number completing the intervention. Secondary research questions include barriers to recruitment and intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camberwell St Giles Research Ethics Committee, 01/06/2016, ref: 16/LO/0540

Study design
Feasibility study. Randomised controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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
Early-stage dementia

Interventions
Participants will be randomly allocated to two treatment arms - treatment as usual or treatment as usual plus the Behavioral Activation intervention.

The intervention is an 8-session coping-based psychological intervention of behavioral activation delivered by a psychology graduate at the person's home.

Intervention Type
Behavioural

Primary outcome measure
1. Number of eligible participants that consent to the study, and number of those finding the intervention acceptable using 95 Confidence Intervals %
2. Number of dyads recruited per month and any barriers or facilitators to recruitment
3. Follow-up rates and number completing each outcome measure proposed for the main trial
4. Number of sessions attended
5. Standard deviations and correlations between repeated-measurements

Outcomes will be measured at 4 and 8 months.

Secondary outcome measures
People with dementia:
1. Depressive symptoms - Cornell Scale for Depression in Dementia (CSDD)
2. Self-rated and carer-rated dementia-specific quality of life for the person with dementia – DEMQOL
3. Neuropsychiatric symptoms - Neuropsychiatric Inventory (NPI)
4. Health services utilisation - Client Service Receipt Inventory (CSRI)

Carers:
1. Carers' mental health - Hospital and Anxiety Depression Scale (HADS)
2. Carers' quality of life - EuroQoL EQ-5D (EQ-5D) and the Short Form-12 Health Survey (SF-12)

Outcomes will be measured at 4 and 8 months.

Overall study start date
31/10/2015

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. People with mild dementia (MMSE ≤ 20)
2. People with dementia who have received a diagnosis in the last 6 months
3. Living in the community
4. Available family carer who can assist the person with dementia in the intervention and can act as an informant (weekly contact)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
63

Key exclusion criteria
People at risk of suicide (clinicians' judgement)

Date of first enrolment
03/10/2016

Date of final enrolment
28/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
PRIMENT Clinical Trials Unit
UCL Medical School
Upper 3rd Floor
Royal Free Campus
Rowland Hill Street
London
NW3 2PF
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
N/A

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

Publication and dissemination plan
We will consult our PPI representatives in relation to audience for dissemination, and the communication channels that will be used. We will develop and disseminate regular newsletters informing clinicians and mental health professionals in the relevant Trusts of the progress of the study. We will disseminate the study findings in peer-reviewed publication journals. Study findings will also be presented at research conferences, and local symposiums. We will also inform GPs and other key dementia care professional groups.

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	08/02/2018		Yes	No
Results article	results	01/02/2019	14/01/2020	Yes	No
HRA research summary			28/06/2023	No	No