

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

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|--|---|--|
| Submission date 29/10/2015 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/01/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/01/2020 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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 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 to 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

Contact name

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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 ($MMSE \leq 20$)
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

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Sponsor information**Organisation**

University College London

Sponsor details

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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 |