

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

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

Dr Vasiliki Orgeta

v.orgeta@ucl.ac.uk

## Contact information

**Type(s)**

Public

**Contact name**

Dr Vasiliki Orgeta

**ORCID ID**

<https://orcid.org/0000-0001-8643-5061>

**Contact details**

University College London

Division of Psychiatry (formerly Mental Health Sciences Unit)

6th Floor, Maple House

149 Tottenham Court Road

London

United Kingdom

W1T 7NF

02076799294

v.orgeta@ucl.ac.uk

## Additional identifiers

## 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

## **Primary study design**

Interventional

## **Study design**

Feasibility study. Randomised controlled intervention trial

## **Study type(s)**

Prevention

## **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(s)**

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.

## **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

United Kingdom

England

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

## 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**

# Results and Publications

## 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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results  | 01/02/2019   | 14/01/2020 | Yes            | No              |
| <a href="#">Protocol article</a>     | protocol | 08/02/2018   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |