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| **Full title of trial** | **IDEA**: **I**ntervention to prevent **D**epressive symptoms and promote well-being in **EA**rly stage dementia: development and feasibility |
| **Short title** | **IDEA** |
| **Version and date of protocol** | Version 3, 9th May 2016 |
| **Sponsor:** | University College London (UCL) |
| **Sponsor protocol number** | 15/0910 |
| **Funder (s):** | Alzheimer's Society |
| **ISRCTN / Clinicaltrials.gov no:** | ISRCTN75503960 |
| **Intervention:** | Behavioural activation |
| **Single site/multi-site:** | Multi-site |

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## Protocol Version History

| Version Number | Date | Protocol Update Finalised By (insert name of person): | Reasons for Update |
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## Signatures

The Principal Investigator and the JRO have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, the UK Data Protection Act (1998), the Trust Information Governance Policy (or other local equivalent), the current Research Governance Framework, the Sponsor's SOPs, and other regulatory requirements as amended.

**Principal investigator**

Dr Vasiliki Orgeta

07/03/2016

Signature Date

UCL

**Sponsor**

07/03/2016

Sponsor representative

UCL Signature Date

# Contents

## List of abbreviations

| | |
|---|---|
| AE | Adverse Event |
| CI | Co-Investigator |
| CRF | Case Report Form |
| GAfREC | Governance Arrangements for NHS Research Ethics |
| GCP | Good Clinical Practice |
| ICF | Informed Consent Form |
| IDMC | Independent Data Monitoring Committee |
| ISF | Investigator Site File |
| ISRCTN | International Standard Randomised Controlled Trial Number |
| NHS R&D | National Health Service Research & Development |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| QA | Quality Assurance |
| QC | Quality Control |
| RCT | Randomised Controlled Trial |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |

# 1 Trial personnel

See protocol cover page for Principal Investigator (Principal) and Sponsor contact details.

| | |
|---|---|
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| Co-Investigators | Dr Rebecca Gould<br>Ms Rebecca Jones<br>Dr Claudia Cooper<br>Professor Gill Livingston |

# 2 Summary


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|---|---|
| **Objectives:** | The primary objective of the study is to develop a coping intervention based on behavioural activation to prevent depressive symptoms arising or worsening and promote well-being in people with early-stage dementia. The secondary objective is to assess the feasibility and acceptability of the intervention via a feasibility Randomised Controlled Trial (RCT) in order to inform a future fully powered RCT of clinical and cost-effectiveness. |
| **Type of trial:** | Feasibility RCT assessing the acceptability and feasibility of behavioural activation for preventing depressive symptoms for people with early-stage dementia |
| **Trial design and methods:** | Feasibility RCT. The acceptability of the intervention to people with dementia, willingness of clinicians to recruit participants and of participants to be randomised, will be collected for feasibility analysis. We will also collect data on recruitment, attrition and questionnaire completion rates and estimate 'numbers needed' to plan a fully powered RCT of clinical and cost-effectiveness. Feasibility data on acceptability, completion rates and attrition will be supplemented by qualitative data. |
| **Trial duration per participant:** | 8 months |
| **Estimated total trial duration:** | 20 months |
| **Planned trial sites:** | Multi-site |
| **Total number of participants planned:** | 100 (Development Phase Focus groups and Individual Interviews: 40; Feasibility Study: 60) |
| **Main inclusion/exclusion criteria:** | Inclusion criteria<br>People with early-stage dementia who have received a diagnosis in the last 6 months.<br>Additional inclusion criteria are:<br>1. living in the community<br>2. regular availability of a carer (or friend) to participate in the research and support the person with dementia in the intervention<br>3. Mild dementia (a Mini Mental State Examination score of ≥ 20)<br><br>Exclusion criteria |

| | |
|---|---|
| | Participants whose clinical team judges them to be at risk for self-harm (excluding neglect) to themselves or a risk to others. Participants who do not adequately understand verbal explanations or written information given in English or who have special communication needs. Participants who already take part in another intervention study will also be excluded. |
| **Statistical methodology and analysis:** | In line with current recommendations of Good Clinical Practice (GCP) in the analysis of feasibility studies, analyses will be descriptive, rather than statistically comparing the two groups on outcomes. We will conduct descriptive statistics for rates of recruitment, follow-up, attrition and adherence. We will calculate adherence to treatment by calculating the percentage in the Behavioural Activation group completing all sessions. Baseline characteristics of the sample will be presented using means and SDs or 95 CI% (as well as medians, IQR or percentages). |

# 3 Background and Rationale

***Background and existing research***

Dementia is the leading cause of disability in late life with economic costs to society projected as over £26B per year (1). There are over 800,000 people living with dementia in the UK, with the numbers of those affected expected to double in the next 30 years (2). It is a degenerative progressive illness causing global decline in intellectual functioning and activities of daily-living, putting older adults at risk of losing their independence (3). People with dementia are also at increased risk of experiencing depression (4,5), which has significant clinical implications (6-8). As the second most common behavioural and psychological symptom in dementia, depression is associated with increased cognitive and functional decline (9,10), a higher risk of premature institutionalisation (11), and reduced life expectancy (12,13). In line with current NHS policies focusing on the importance of 'Living Well with Dementia', studies suggest that accessing emotional, social and practical support after diagnosis (14) is an important psychological need for people with dementia (15-19). The National Dementia Strategy considers access to early support for people with dementia an important and timely objective (3).

It is currently estimated that up to 50% of patients experience depression at least once during the course of the disease (9). Major depressive disorder affects approximately 20% to 30% of people with dementia (5,6), with previous personal or family history of depression (20), being female (21), and a younger age at onset of dementia placing individuals at greater risk (22). Depressive symptoms occur at an even higher rate than clinical depression (21,23), tend to be highly persistent (6), and are often experienced during the early stages of the disease (8,24). Both depression and less severe depressive symptoms are sources of excess disability for people with dementia, increasing the risk of additional behavioural disturbances, and exacerbating functional decline (25). For this reason both major and subthreshold symptoms of depression are considered clinically important (21,26).

Despite the high burden of depression and associated disability among people with dementia, interventions that aim to prevent depressive symptoms are not available, although they are important for several reasons. First, depressive symptoms in dementia are very frequent with prevalence rates ranging from 10% to as high as 62% (5). Second therapeutic pharmaceutical agents, such as the antidepressants which have been properly tested are ineffective and have significant side effects (27). Third, it can be difficult to recognise depression and depressive symptoms in dementia making diagnosis more difficult (4), and limiting access to treatment. An intervention therefore that prevented or delayed depressive symptoms will reduce incidence as well as prevalence, supporting people in 'living well with dementia' and increasing their quality of life and possibly function despite experiencing a chronic and progressive disease.

***Why is this study necessary?***

Depressive symptoms in dementia are at least twice as common compared to the general population of cognitively healthy older adults (28), they reduce quality of life (29,30), and increase 'excess disability' (9,31). People with dementia and depression are more likely to use inpatient services (32) and their carers experience greater stress and depression (33,34). The Global Consortium for Depression Prevention (35), recommends that targeting those at increased risk and improving their access to effective strategies should be an important future objective. Treatment of depression in dementia represents an important challenge and there are currently no effective treatments. Given poor efficacy of antidepressants, there is increasing recognition that these should not be offered due to the increased risk of side-effects, and limited efficacy. Despite these recommendations, about a third of people with Alzheimer's disease (AD) are prescribed antidepressants in the community (36,37), which is three times the rate of older people in the community without dementia, indicative of a high need to manage depressive symptoms.

Although data on financial costs associated with depressive symptoms or depression in people with dementia are limited, it is reasonable to assume that the combination of these disorders places an enormous emotional burden for patients and their families, which may result in even greater direct health care costs and indirect costs to caregiving compared to each condition alone. Given limited treatment options available offering interventions that prevent depressive symptoms is even more critical and timely. A recent Cochrane Review on the effects of psychological treatments for people with dementia found that there is promising evidence that psychological treatments may contribute significantly to reducing depressive symptoms but definitive evidence is lacking (38). Given therefore limited efficacy of antidepressants (27,40), psychological treatments have the potential to be of benefit (38, 41). Coping-based psychological interventions have shown to be effective in preventing or at least delaying the onset of major depressive disorder (42), in several populations at risk (43) such as patients with stroke (44), older adults experiencing chronic pain (45), or sub-threshold depression (46), and carers of people with dementia (47).

Currently little is known about the clinical and resource implications of implementing behavioural activation for people with dementia. Since there is a climate of caution in relation to the use of antidepressants for people with dementia, further research is needed to investigate use of more acceptable and accessible psychological interventions for preventing depressive symptoms. A psychological intervention therefore may be a potentially effective intervention offered early in the course of depressive illness. This study aims to establish the feasibility of a fully powered RCT,

conducting necessary preparatory work, which will produce important evidence to inform the mental health care of people with dementia.

Study design: Feasibility RCT, of 2 treatment arms (Behavioural Activation vs treatment as usual) over 8 weeks. The primary aim of the present study will be to develop a novel coping intervention to prevent depressive symptoms in people with early-stage dementia. This intervention has the potential to be rolled out for people with dementia nationally and therefore be manualised, practical and scalable. The secondary objective will be to examine the feasibility and acceptability of the intervention by conducting a feasibility RCT.

## 3 Assessment and Management of Risk

Generally we do not anticipate any risks to people with dementia through participation. The information sheets will provide participants with information about the possible benefits and known risks of taking part in the trial. Participants will be given the opportunity to discuss this with the researcher prior to consenting to the study. There appear to be no documented harmful side effects from taking part in behavioural activation interventions. The only potential risk we can identify associated with the proposed research is that people may find either the intervention or the assessments upsetting or distressing, for example highlighting pleasant activities that they can no longer do, or do so independently. However given previous preventive trials of behavioural activations in several populations, and the Cochrane review published by the PI on psychological interventions for people with dementia, this is expected to be infrequent. Most people find behavioural activation sessions enjoyable, and feel comfortable in taking part in these types of interventions. At any point where a participant or carer becomes uncomfortable with the assessments they will be discontinued. The researcher running the sessions and completing the assessments will be advised to discontinue the assessment/intervention sessions, and participants will be given further support and will be debriefed as necessary. For example, they will be encouraged to speak to one of the team members, and/or ring the Alzheimer's Society National Dementia Helpline (see Participant Information Sheets). Local lone working policies for all staff involved will apply in relation to assessment and management of risk for UCL staff.

## 4 Objectives

Primary: The primary objective of the study is to develop a coping intervention based on behavioural activation to prevent depressive symptoms arising or worsening and promote well-being in people with early-stage dementia.

Secondary: The secondary objective is to assess the feasibility and acceptability of the intervention via a feasibility RCT in order to inform a future fully powered RCT of clinical and cost-effectiveness.

# 5 Trial design

Study design: Feasibility RCT, of 2 treatment arms (Behavioural Activation vs treatment as usual) over 8 weeks, assessing the acceptability and feasibility of behavioural activation for preventing depressive symptoms in early-stage dementia (see Figure 1, in Appendix 1).

# 6 Selection of Participants

## 6.1 Inclusion criteria

People with early-stage dementia who have received a diagnosis in the last 6 months.

Additional inclusion criteria are:

1. living in the community
2. regular availability of a carer (or friend) to participate in the research and support the person with dementia in the intervention
3. Mild dementia (a Mini Mental State Examination score of ≥ 20)

## 6.2 Exclusion criteria

Participants whose clinical team judges them to be at risk for self-harm (excluding neglect) to themselves or a risk to others. Participants who do not adequately understand verbal explanations or written information given in English or who have special communication needs. Participants who already take part in another intervention study will also be excluded.

## 6.3 Recruitment

*Sample*

The study will recruit 40 participants for consultations in the development of the intervention (focus groups and individual interviews, for further details see ***Stage 2a: Work Package 2***), and a total of 60 people with dementia and their carers in the feasibility RCT. People with dementia will be recruited from Memory Clinics and Community Mental Health Teams (CMHTs). The control condition will be usual care, and use of drugs will be documented for both conditions. Recruitment will take place in two NHS Trusts, the Camden and Islington Foundation Trust (C&IFT), and the Barnet, Enfield and Haringey Mental Health Trust. We predict that a minimum of one dyad per week will be recruited into the study. This is based on previous experience from the REMCARE trial, during which the lead Applicant recruited an average of 8 people with dementia per month in London, and the recently completed iCST trial which recruited on average 9 people per month.

*Recruitment Strategy*

People with dementia living in the community and their carers will be recruited from a variety of settings including CMHTs, memory clinics, outpatient clinics, and day centres. Essential baseline

information will be recorded at registration, with people with dementia individually randomised using an adaptive scheme. People on cholinestarease inhibitors or antidepressant medication will continue taking them. The researcher and the PI will make close links with the local memory clinic and community mental health teams through regular attendance and contact.

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed by the Sponsor (or it's delegated representative), and
2. Been issued an 'NHS permission letter'.

## 6.4 Informed consent

Participants will be in the mild stages of dementia, and therefore would generally be expected to be able to provide informed consent for participation, provided that appropriate time and care has been taken by the researchers to explain the research, and they had sufficient time to make a decision. It will be helpful for a family member or other supporter to be involved, and we would ensure this is done wherever possible. The PI or designee will explain that participants are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason. It will be made clear to both participants and family carers that no disadvantage will accrue if they choose not to participate. In instances were the participant's level of impairment increases, so that they are no longer able to provide informed consent, the provisions of the Mental Capacity Act will be followed. The initial giving of informed consent provides a clear indication of the person's likely perspective on continuing at this point, and family carers will be consulted in this regard. We will follow current guidance from the British Psychological Society on evaluation of capacity when seeking consent, which is regarded as a continuing process rather than a one-off decision. Willingness to continue participating will be continually checked through discussion with participants during the study. At any point where a participant or carer becomes uncomfortable with the assessments they will be discontinued.

It is the responsibility of the PI, or a person delegated by the PI to obtain written informed consent from each participant prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards. The person taking consent will be suitably qualified and experienced, and will have been delegated this duty by the PI/CI on the Staff Signature and Delegation of Tasks. **"Adequate time"** will be given for consideration by the participant before taking part. Consent will be sought at least 24 hours after being given the study documentation. Potential participants will receive information about the study no less than 24 hours prior to making a decision about taking part. No trial procedures will be conducted prior to the participant giving consent by signing the Informed Consent Form (ICF). Consent will not denote enrolment into trial. Only after written consent is given and the baseline assessments are completed, will randomisation take place. A copy of the signed ICF will be given to the participant. The original signed form will be retained in the trial files at the co-ordinating site. The Participant Information Sheet (PIS) and ICF will be reviewed and updated if necessary throughout the trial (e.g. where new safety information becomes available) and participants will be re-consented as appropriate.

# 7 Interventions

## 7.1 Name and description of intervention under investigation

***Development of the Intervention***

We will develop the intervention using guidance by the Medical Research Council (MRC) for developing and evaluating complex interventions (48). These guidelines emphasise that development *should focus on outcome*, *how change will take place* and should be *guided* by *theory* and *evidence.* We will apply and use theoretical models of behavioural treatment of depression and coping in dementia including the Cochrane systematic review (49,50), which focus on pleasant events, and teaching patients and carers specific skills and strategies to promote behaviour change. The second source of information guiding the development of the intervention will be consultations with key stakeholders (people with dementia, their carers, and professionals who support them), and experts. We will conduct a systematic review prior to consultations to identify preventive interventions for depressive symptoms in late life. The development phase will follow the recent UK-based model of a manualised coping-based strategies intervention for carers of people with dementia (47). The proposed intervention will aim to:

(1) increase the use of effective coping strategies for people with early-stage dementia by:

(a) identifying pleasant activities for the person with dementia and agreeing which activities to implement (the person is supported by the psychology graduate and the carer during this process)

(b) setting goals about implementing these activities supported by homework activities

(c) monitoring and reviewing activities weekly

(d) teaching specific simple skills coping with stress (e.g. signal breath, walking) (51)

(e) discussing accessing help (e.g. assertiveness with service providers),

(c) make a plan for the future, with information recorded in each dyads' manual so it is easily accessible after the intervention has finished

The intervention will be an individual home-based manualised programme, comprised of a total of 8 sessions. Participants and carers can repeat a session or a part of a session when necessary, and each of the sessions will last approximately 45 minutes (with homework between the sessions).

The key aims and stages of the development of the intervention are described in detail below.

**Development of the Intervention**

***An intervention package for preventing depressive symptoms and promoting well-being in early-stage dementia:*** We will develop a manual of the intervention, through the following stages:

***Stage 1: Work Package 1.*** We will draft a pilot manual based on a review of key components of preventive psychological approaches for depressive symptoms in late life (i.e. Coping with Depression course, (52)). The review will ask the following research questions: *Research Question 1:* what theories and conceptual frameworks have informed preventive interventions for depressive symptoms in

cognitively healthy older people, those experiencing cognitive impairment or chronic illness? *Review Question 2:* What are the effects of these interventions, how have they been evaluated and what are their key intervention components?

***Stage 2a: Work Package 2.*** We will present our manual to service users and dementia care professionals. Specifically we will conduct 3 focus groups (1 with people with dementia, 1 with carers and 1 with professionals) as well as a set of individual interviews (n = 10), to identify key issues around psychosocial management of depressive symptoms in early-stage dementia and to collect data on the suitability of the manual. We will analyse data using framework analysis methods which apply a case and theme based approach in synthesising data (53, 54) and will seek advice from a qualitative expert. Reaching 'theoretical saturation' will be closely monitored and when necessary, repeat consultations will be conducted (55).

***Stage 2b***. ***Work Package 2.*** We will ask experts to comment on the first draft of the intervention manual by organising an Expert Professionals Workshop. Patients and carers, clinical psychologists, consultant psychiatrists, and other mental health professionals will provide feedback on the first draft of the intervention manual. Based on the findings of the qualitative data from the focus groups and individual interviews, and expert consultations we will develop the second draft of the intervention manual.

***Stage 3***. ***Work Package 3.*** *Field testing, and further refinement of the Intervention*

During this stage, the psychology graduate delivering the intervention will be trained to use the intervention, and all elements of the training process will be recorded in a separate manual for therapists, providing guidance in delivering the intervention. The intervention will then be field-tested with 15 people with early-stage dementia and their carers in order to identify key issues around suitability of materials and adaptations to the intervention, and if required adaptation of the intervention manual. On the basis of these findings we will develop the third draft of the intervention manual, which we will test in the feasibility RCT.

## 7.2 Storage and handling of drug at site

This section is Not Applicable to this project.

## 7.3 Accountability of drug

This section is Not Applicable to this project.

## 7.4 Concomitant medication

This section is Not Applicable to this project.

### 7.5 Dosages, modifications and method of administration

This section is Not Applicable to this project.

## 8 Trial procedures

### 8.1 Pre-intervention assessments

There are no specific pre-intervention assessments other than screening participants for inclusion criteria and the baseline assessments. People with dementia that meet the inclusion criteria and their carers will be recruited from several settings and existing networks (i.e. Community Mental Health Teams for Older People (CMHTs), Memory Clinics, Outpatient Clinics, Day centres). Baseline information required for eligibility will be recorded by memory clinics, day centres, and CMHTs. Participants will be recruited by engaging with professionals in the above settings and will be identified by the researcher using the networks above. We will use RCT methodology with remote randomisation, which will be provided by Sealed Envelope. There is a Master Services Agreement between UCL and Sealed Envelope in place. The PI will complete a trial registration form to be completed with all the details for the study and then signed off by a UCL Research Contract Manager, at University College London. See Section 8.4 for details of assessment procedures.

All pre-treatment procedures will be carried out as specified in the schedule of assessments (Appendix 4).

*Treatment as usual*

This study is designed to be a pragmatic trial, and no participants will be denied access to any treatment that they would have access to have they not taken part in the study. Both groups will also receive care as usual, details of which will be recorded for each participant. The treatment as usual control group (TAU) will not receive any additional intervention. We will assess the feasibility of collecting service use data, which will allow us to identify services received in both groups and any changes that occur.

### 8.2 Randomisation Procedures

*Allocation to trial groups*

A total of 60 people will be recruited (56,57), which will allow calculation of 95% Confidence Intervals (CI) in the acceptable ranges for continuation to the main trial with the minimum size needed to estimate acceptability being 56 expected value 75% (95% CI = 59-87%). Participant randomisation will be undertaken centrally by the coordinating trial team at UCL using a randomisation system provided by Sealed Envelope and signed off by a UCL Research Contract Manager. Following participant consent, and confirmation of eligibility (see section 8.1 for pre-treatment assessments), the randomisation procedure described below will be carried out. Sealed Envelope will provide access to randomisation. Remote randomisation to treatment will be conducted by an adaptive web

randomisation service (Sealed Envelope). There is a Master Services Agreement between UCL and Sealed Envelope in place which covers all the work completed by this service provider from UCL. When the agreement is made for this study the Chief Investigator will complete a trial registration form (to be completed with the details for the study) and signed off by a UCL Research Contract Manager. Participants who satisfy the criteria will be eligible. We will record details of participants who do meet the inclusion criteria but are not randomised to inform the future fully powered RCT, which will consist of demographic and clinical details, and reasons of not consenting to the trial.

Participants will be considered as enrolled into the trial following: consent, pre-treatment assessments (see section 8.1), confirmation of eligibility, completion of the randomisation process, allocation of the participant trial number and intervention by the central coordinating team at UCL.

## 8.3 Intervention procedures

The proposed intervention will aim to:
(1) increase the use of effective coping strategies for people with early-stage dementia by:
(a) identifying pleasant activities and agreeing to a plan of which activities to implement
(b) setting goals about implementing these
(c) monitoring and reviewing activities (on a weekly basis)
(d) teaching specific simple skills coping with stress (51)
(e) discussing accessing help
(c) make a plan for the future
The intervention will be an individual home-based manualised programme, comprised of a total of 8 sessions. Participants and carers can repeat a session or a part of a session when necessary, and each of the sessions will last approximately 45 minutes (with homework between the sessions). The intervention will be delivered by a psychology graduate who will be trained in the intervention by the team. The psychology graduate will be supervised monthly by one of the CIs who is a Clinical Psychologist (Dr Rebecca Gould).

*Adherence to treatment protocol*

We will develop a manual guiding therapists in delivering the intervention. This manual will describe the key components of the intervention and will also specify training elements. We will also test the feasibility of measures assessing treatment adherence, such as audiotaping some of the sessions, and competency assessment, by developing a checklist for use in the main trial. This checklist will assess whether behavioural activation was the overall modality applied and if other therapeutic models were prominent in the therapy (i.e. cognitive therapy).

## 8.4 Subsequent assessments and procedures

This section describes all proposed outcome measures and assessments at each home visit.

*Proposed outcome measures*

Feasibility outcome measures

- The acceptability of the intervention for people with dementia and their carers (number of those finding the intervention acceptable)
- Willingness of clinicians to recruit and people with dementia to be randomised (number of dyads recruited per month and any barriers or facilitators to recruitment)
- Number of eligible participants that consent to the study
- Follow-up rates and number completing each outcome measure proposed for the main trial
- Number of sessions attended
- Standard deviations of outcome measures to estimate the sample size in a fully powered RCT

The acceptability of the programme to people with dementia, willingness of clinicians to recruit participants and of participants to be randomised, will be collected for feasibility analysis. We will also collect data on recruitment, attrition and questionnaire completion rates and estimate 'numbers needed' to plan a fully powered RCT of clinical and cost-effectiveness. Feasibility data on acceptability, completion rates and attrition will be supplemented by qualitative data. During qualitative interviews information will be collected on which outcomes will be of value to people with dementia, data relevant to the trial process itself, the randomisation procedure, and the methods of data collection.

*Proposed clinical outcome measures*

These will be evaluated for suitability for the main trial. Depressive symptoms is proposed as the outcome for the future fully powered study. Carers will complete generic health and quality of life measures (EQ-5D, SF-12), and resource use questionnaires to examine feasibility of cost-effectiveness analysis. Questionnaires will be completed at baseline, 4 and 8-months after randomisation.

*Primary outcomes*

1. depressive symptoms - *Cornell Scale for Depression in Dementia (CSDD)* (58). The CSDD, is a 19-item interviewer administered measure, using information by interviewing the person with dementia and their carer. Symptoms are described to the carer as they appear on the scale. Where there is a discrepancy between the carer and the researcher's ratings the carer is re-interviewed before making a final judgment.

*Secondary outcomes*

1. self-rated and carer-rated dementia-specific quality of life for the person with dementia – *DEMQOL* (59). The DEMQOL measures quality of life, by covering five domains, including daily activities, health and well-being, cognitive functioning, social relationships and self-concept. The scale uses both self and carer-rated reports of quality of life administered to the person with dementia and carer.

2. neuropsychiatric symptoms - Neuropsychiatric Inventory *(NPI)* (60). The NPI assesses 10 behavioural disturbances occurring in people with dementia, using a screening strategy to minimise administration time by examining and scoring only those behavioural domains with positive responses to screening questions. Both frequency and severity of each behaviour are determined, with both validity and reliability for the measure established.

3. health services utilisation - Client Service Receipt Inventory *(CSRI)* (61). We will use the CSRI to collect feasibility data on the use of health and social care services provided by public or non-public

bodies, and information on carer's costs and participant's use of health and social care services in order to inform the full trial. We will also collect data on medications for mental health, carer's provision of unpaid care and employment status, and any out-of-pocket costs to both participant and carer.

4. carers' mental health - Hospital and Anxiety Depression Scale *(HADS)* (62). Depressive symptoms in carers will be measured using the Hospital Anxiety and Depression Scale (HADS), a self-completed measure, generating scores for both generalised anxiety and depressive symptoms, used widely to identify caseness for clinically significant depression and anxiety.

5. carers' quality of life - EuroQoL EQ-5D *(EQ-5D)* (63) and Short Form-12 Health Survey *(SF-12)* (64). Carer health-related quality of life, will be measured using the three-level response version of the European Quality of Life-5 Dimensions (EQ-5D™). The EQ-5D is a standardised instrument for use as a measure of health outcome, applicable to a wide range of health conditions, providing a simple descriptive profile and a single index value for health status. Carers' mental and physical health, will be measured by the Short Form questionnaire-12 items (SF-12).The SF-12 measures health by scoring standardised responses, which are expressed in terms of two meta-scores: the physical component summary (PCS) and the mental component summary (MCS). A schedule of all trial assessments and procedures is set-out in Appendix.

## 8.5 Samples

### 8.5.1 Laboratory assessments

This section is Not Applicable to this project.

### 8.5.2 Translational research samples

This section is Not Applicable to this project.

### 8.5.3 Sample storage and transfer

This section is Not Applicable to this project.

## 8.6 Discontinuation/withdrawal of participants

In consenting to participate in the trial, participants are consenting to intervention, assessments, follow-up and data collection. A participant may be withdrawn from the trial whenever continued participation is no longer in the participant's best interests, but the reasons for doing so must be recorded (whenever possible). Reasons for discontinuing the trial may include:

- disease progression whilst on therapy
- intercurrent illness
- patients withdrawing consent

The decision to withdraw a participant from treatment will be recorded in the CRF and ISFs. If a participant explicitly states they do not wish to contribute further data to the trial their decision must be respected and recorded in the CRF.

### 8.7 Definition of End of Trial

The expected duration of the trial is 20 months from recruitment of the first participant (8 months on average for individual participants). The end of trial is the date of the last follow up home visit of the last participant.

## 9 Recording and reporting of adverse events

### 9.1 Unblinding

*Protection against bias*

In trials of psychological interventions, therapists and participants can not be blind to which intervention they are delivering or receiving. However assessors conducting assessments with participants, should not be aware of which treatment arm they belong to. All follow-up assessments after the intervention will be conducted by a researcher who is blind to treatment allocation. Given that participants may occasionally and inadvertently inform researchers of the treatment they are receiving, we will reduce this effect by providing explicit reminders to participants. We will record instances of loss of blinding to inform procedures for the main trial.

**Emergency unblinding:**

This section is Not Applicable to this project as it is a single-blinded trial. We will seek advice on issues of blinding by the UCL Research Service and Senior Trialists in the Division of Psychiatry.

### 9.2 Notification of reportable protocol violations

A reportable protocol violation is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The CI or designated individual will notify the sponsor of any protocol violation.

### 9.3 Trust Incidents and Near Misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses will be reported to the Trust through DATIX as soon as the individual becomes aware of them. A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a) It is an accident or other incident which results in injury or ill health.
b) It is contrary to specified or expected standard of patient care or service.
c) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d) It puts the Trust in an adverse position with potential loss of reputation.
e) It puts Trust property or assets in an adverse position or at risk of loss or damage.

## 10 Data management

### 10.1 Confidentiality

All data will be handled in accordance with the UK Data Protection Act 1998. The Case Report Forms (CRFs) will not bear the participant's name or other personal identifiable data. The participant's initials, date of birth and trial identification number, will be used for identification and this will be clearly explained to the patient in the Patient information sheet. Patient consent for this will be sought. All participant information will be stored in accordance with the UK Data protection Act 1998 guidance, with all personally identifiable information, stored in locked cabinets and stored separately from study data which will be anonymised and saved on password-protected computers at University College London. Each participant will be assigned an identification code, which will be used in all data storage, and will not contain any names or other personally identifiable information. After completion of the study all personal details will be deleted. If any person in the study tells us that they or someone else is being harmed we will ask their permission to disclose the information to the Older People's Community Mental Health Team (or Memory Clinic) or other appropriate responsible person. We respect confidentiality but cannot keep it a secret if anyone is being harmed (See Participant Information Sheets).

## 10.2 Data collection tools and source document identification

Data will be collected from sites on trial specific CRFs or data collection tools such as electronic CRFs. Source data contained in source documents will be accurately transcribed on to the CRFs. Methods to maximise completeness of data will be applied when necessary. The PI will have the primary responsibility of ensuring all data entered in the CRFs are accurate. A delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database (PI, CIs, Trial statistician, Research Assistant).

## 10.3 Completing Case Report Forms

All CRFs will be completed and signed by staff that are listed on the site staff delegation log and authorised by the PI to perform this duty. The PI will be responsible for the accuracy of all data reported in the CRF. In line with UCL Data Protection Policy trial documentation and anonymous data will be securely kept for a period of 20 years following completion of the trial. All data of all sites taking part in this project will be kept and monitored at UCL. The PI and or a designated individual will be responsible for any data queries.

## 10.4 Data handling

In the study, data will be collected from patients in accordance with the patient consent form, patient information sheet and section 8.4 of this protocol. UCL, as the study sponsor will act as the data controller for the study. The PI, the study Statistician or a designated individual will process, store and dispose of the data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. All data will be stored centrally at a locked filing cabinet at UCL controlled by the PI. The data will not be transferred to any party not identified in this protocol and will not to be processed and/or transferred other than in accordance with the patients' consent.

*Quality control*

Compliance to GCP is now a requirement for all clinical trials. Accurate records will be kept, in line with the research protocol, in relation to recruitment, randomisation and data collection. We will collect and manage data in a systematic way, and researchers will be trained, supervised and supported. Compliance to GCP, and Quality Control (QC) will be monitored in the beginning monthly and every three months subsequently. The PI will ensure that all records are maintained and participant confidentiality is assured. We will perform a QC to a sample of data during the first weeks of data collection. Investigator Site Files (ISF) and a Master file will also be kept that will source all documents of the study.

# 11 Statistical Considerations

## 11.1 Primary Outcome

Feasibility primary outcome

- The acceptability of the intervention for people with dementia and their carers which will be measured by the number of those finding the intervention acceptable

## 11.2 Secondary outcome(s)

- Willingness of clinicians to recruit and people with dementia to be randomised (number of dyads recruited per month and any barriers or facilitators to recruitment)
- Number of eligible participants that consent to the study
- Follow-up rates and number completing each outcome measure proposed for the main trial
- Number of sessions attended
- Standard deviations of outcome measures to estimate the sample size in a fully powered RCT

*Proposed clinical outcome measures*

- These will be evaluated for suitability for the main trial. Depressive symptoms is proposed as the outcome for the future fully powered study. Carers will complete generic health and quality of life measures (EQ-5D, SF-12), and resource use questionnaires to examine feasibility of cost-effectiveness analysis. Questionnaires will be completed at baseline, 4 and 8-months after randomisation. For further details see Section 8.4.

## 11.3 Sample size calculation

*Proposed sample size for feasibility trial*

No formal power calculations are undertaken in feasibility studies, instead sufficient participants are recruited in order to determine factors such as attrition and recruitment rates and how these are related to feasibility for a full scale RCT. A total of 60 people will be recruited (56,57), which will allow calculation of 95% Confidence Intervals (CI) in the acceptable ranges for continuation to the main trial with the minimum size needed to estimate acceptability being 56 expected value 75% (95% CI = 59-87%). We will recruit to the study over 15 months, with an average of 4 dyads recruited per month.

## 11.4 Planned recruitment rate

People with dementia will be recruited from Memory Clinics and Community Mental Health Teams (CMHTs). Recruitment will take place in two NHS Trusts, the Camden and Islington Foundation Trust (C&IFT), and the Barnet, Enfield and Haringey Mental Health Trust. We predict that a minimum of one dyad per week will be recruited into the study, based on previous experience from the REMCARE trial, and the recently completed iCST trial. The recruitment period is 17 months inclusive of the

development phase of the intervention and feasibility trial. The start date for the feasibility RCT is August 2017. Full details of timeline appear in Appendix 2.

## 11.5 Randomisation methods

The Sealed Envelope service will provide the randomisation and feasibility data that will be useful to collect in order to inform the main trial. The main purpose of randomisation is to test its feasibility and acceptability for people with dementia and their carers. Random allocation lists will be generated by Sealed Envelope.

## 11.6 Statistical analysis

### 11.6.1 Summary of baseline data and flow of participants

Essential baseline information will be recorded which will include quantitative and qualitative information. This will include specifics of diagnosis of dementia, psychiatric illness, and use of medications such as cholinestarease inhibitors or antidepressants. Details of demographic data will also be recorded such as gender, education, living status, and ethnicity. The feasibility trial will also produce a consort flow diagram in order to inform the main trial.

### 11.6.2 Primary outcome analysis

In line with current recommendations of GCP in the analysis of feasibility studies, analyses will be descriptive. We will conduct descriptive statistics for rates of recruitment, follow-up, attrition and adherence. We will calculate adherence to treatment by calculating the percentage in the Behavioural Activation group completing all sessions. Baseline characteristics of the sample will be presented using means and SDs or 95 CI% (as well as medians, IQR or percentages). We will also calculate descriptive statistics for outcome measures, at baseline, 4 months, and 8 months, and changes in scores from baseline (means, SDs, IQRs), in order to derive estimates for the fully powered RCT. All analyses will be undertaken using SPSS.

### 11.6.3 Secondary outcome analysis

Several clinical outcome measures will be evaluated for suitability for the main trial. Depressive symptoms are proposed as the outcome for the future fully powered study. For further details of all proposed clinical outcome measures for the full trial see section 8.4.

### 11.6.4 Sensitivity and other planned analyses

Missing data and non-compliance to the intervention will be measured as primary outcomes for this feasibility trial. A more detailed statistical analysis plan will be produced as a separate document by the Project Statistician. Formal records will be kept of the statistical analysis plan and how it can inform the main RCT.

# 12 Record keeping and archiving

At the end of the trial, all essential documentation will be archived securely by the PI for a minimum of 20 years from the declaration of end of trial. Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether each site complied with all applicable regulatory requirements. The sponsor will notify the coordinating site (where all data will be stored) when trial documentation can be archived. All archived documents will continue to be available for inspection by appropriate authorities upon request.

# 13 Oversight Committees

Trial Steering Committee

A Trial Steering Committee (TSC) has been set-up and will include an independent Chair and two independent members, along with the study's CI, and other study collaborators. The Committee will meet once a year. The TSC will be combined with the Independent Data Monitoring Committee, given that this is a small feasibility RCT study. The TSC will discuss issues related to data collection, ethical issues and other incidents.

*Research governance and conduct of the trial*

The trial will be conducted in line with the Helsinki Declaration. University College London is the nominated sponsor.

## 13.1 Trial Management Group (TMG)

The Trial Management Group (TMG) will include the PI and Co-Investigators (CIs) and trial staff (Research Assistant). The TMG will be responsible for overseeing the trial. The group will meet regularly twice a year, and will send updates to the TSC members. The TMG will review recruitment figures, incidents and substantial amendments to the protocol prior to submission to the REC. All CIs will be kept informed of substantial amendments by the PI or other designated individual.

*Expertise of the Advisory Board*

Dr Vasiliki Orgeta, PI and Lead Applicant. Dr Vasiliki Orgeta is a Senior Research Associate, at the Division of Psychiatry, UCL and specialises in the development and evaluation of psychosocial interventions for people with dementia, and has led several trials (i.e. the REMCARE and iCST trials). Her research focuses on systematic reviews and meta-analyses of psychosocial interventions in dementia and MCI. She led the Cochrane Review of psychological treatments for people with dementia.

Professor Gill Livingston, CI and Academic Supervisor of the Lead Applicant. Professor Gill Livingston is a Professor of Psychiatry of Older People, at the Division of Psychiatry, UCL. She is an expert trialist in dementia, and specialises in neuropsychiatric symptoms for people with dementia, including treatment and management of depression in people with dementia. She was the PI of the LASER-AD study, investigating natural history and progression of depression in dementia. Most recently she was

the PI of the START trial, a RCT evaluating a manual based coping strategy intervention (START, STrAtegies for RelaTives), promoting the mental health of family carers of people with dementia.

Dr Claudia Cooper, CI and Clinical Academic, Mentor of the Lead Applicant. Dr Claudia Cooper is a Reader in Old Age Psychiatry, at the Division of Psychiatry, UCL. She specialises in the mental health of older people and carers of people with dementia. She is an expert in the epidemiology and prevention of elder abuse, and the provision of quality and equality in dementia care.

Dr Rebecca Gould, CI and Advisor for the IDEA Intervention. Dr Rebecca Gould is a Clinical Psychologist. She specialises in the use of psychological interventions for older people and people with dementia. Her research interests include systematic reviews and meta-analyses of psychological interventions in late life, such as cognitive behavioural therapy.

Rebecca Jones, CI and Project Statistician. Rebecca Jones is a Senior Research Associate, at the Division of Psychiatry, UCL, and specialises in medical statistics.

## 13.2 Other committees

Membership of the TSC (which will incorporate IDMEC), has been agreed and can be seen below.
*TSC Members*
Professor Cornelius Katona (Chair), Honorary Professor, Division of Psychiatry, Faculty of Brain Sciences, UCL, Independent Member
David Prothero, Family Carer, Uniting Carers for dementia (UKfd), Independent Member
Sylvia Bailey, Member of the Public, Public governor of the Black Country Partnership NHS Foundation Trust and Shadow Public Governor of the Dudley and Walsall Mental Health Trust, Independent Member
Dr Vasiliki Orgeta, (PI)
Professor Gill Livingston, (CI)
Rebecca Jones, Trial Statistician

The role of the TSC is to provide overall supervision of the trial, recommendations in relation to data monitoring, and, on consideration of this information, recommend any appropriate amendments/actions for the trial as necessary. Note that given that this is feasibility trial the TSC is also acting as an IDMEC. The TSC will also act on behalf of the funder and Sponsor, and will provide independent advice on data and safety aspects of the trial. Meetings of the Committee will be held twice a year to review progress and address any issues as necessary. Since the TSC is acting as the IDMC, it can recommend premature closure of the trial.

# 14 Ethical requirements and patient and public involvement

**Ethics**

The sponsor will ensure that the trial protocol, PIS forms, ICFs, GP letter and submitted supporting documents have been approved by the appropriate Research Ethics Committee (REC), prior to any participant recruitment. The protocol, all other supporting documents including and agreed

amendments, will be documented and submitted for ethical and regulatory approval in line with Governance Arrangements for NHS Research Ethics (GAfREC) and Quality Assurance (QA) guidelines. The study will be approved by the appropriate local governance procedures such as National Health Service Research & Development (NHS R&D). Ethical concerns arising from the study will be reviewed by the TSC and IDMEC. All researchers will receive training in line with the GCP guidelines. The study has been registered as a clinical trial and has been allocated an International Standard Randomised Controlled Trial Number ISRCTN number ID (ISRCTN75503960). As the intervention is psychological the trial is not covered by the Medicines for Human Use (Clinical Trials) Regulations 2004.

Amendments will not be implemented prior to receipt of the required approvals. Before any NHS site may be opened to recruit participants, the PI/CI or designee must receive NHS permission in writing from the Trust Research & Development (R&D). It is the responsibility of the PI/CI or designee at each site to ensure that all subsequent amendments gain the necessary approvals, including NHS Permission (where required) at the site. This does not affect the individual clinician's responsibility to take immediate action if thought necessary to protect the health and interest of individual participants (see section 9.6 for reporting urgent safety measures). An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The PI will prepare the APR. Within 90 days after the end of the trial, the PI/Sponsor will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

The PI will supply the Sponsor with a summary report of the trial, which will then be submitted to the REC within 1 year after the end of the trial.

**Patient and public involvement (PPI)**

We have consulted local user groups of carers and people with dementia, and professionals supporting them to ensure the project is likely to be meaningful for people with dementia. We conducted an initial consultation via the local Mental Health NIHR Clinical Research Network (DeNDRoN, mental health**,** neurological disorders). Feedback from this consultation suggested that this will be an important intervention to offer to people with dementia, and their families. We have received further feedback about this project from people with dementia via The Camden Minds Support group which forms part of the Dementia Engagement & Empowerment Project (DEEP), bringing together groups of people with dementia across the UK, consulting researchers and advocating for changes in policies affecting the lives of people with dementia. People with dementia commented that they thought the intervention will be a useful one, providing opportunities to 'talk about feeling low' and finding ways to feel better. Further comments have been received by lay volunteers from the Alzheimer's Society. These emphasised the importance of incorporating social elements to the intervention as this will be help keep depression 'at bay', and incorporating pleasant activities (this will be a key component of the intervention).

We will develop a dissemination strategy that will identify the groups who will need to be communicated of the results and the methods we will use in order to disseminate the study's findings. The strategy will be developed at an early stage in consultation with the Patient and Public Involvement (PPI) group members. 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.

The *Patient and public involvement* group for the project comprises of the following members:

Tracey McDermott, PPI member. Tracey McDermott is the Dementia Befriending Project Coordinator, for Age UK Camden. She has worked in support services for people with dementia and their families for many years.

Gillian Harrison, PPI member. Gillian Harrison is an ex carer and an Alzheimer's network volunteer for over 10 years. She also has advised and provided expertise on patient and public involvement in many projects for NIHR.

## 15 Monitoring

The sponsor will determine the appropriate level and nature of monitoring required for the trial. Standard Operating Procedures (SOPs) of the Sponsor will be followed. Risk will be assessed on an ongoing basis and adjustments will be made accordingly. The degree of monitoring will be proportionate to the risks associated with the trial. A trial specific oversight and monitoring plan has been established. The trial will be monitored in accordance with the agreed plan. We will follow GCP by monitoring participants for suicide risk throughout the duration of the trial and in all contacts with participants. If any risk of self-harm or harm to others is detected the PI will contact the NHS Clinical Team and the person who referred the participant. We will monitor data of the Cornell Scale for Depression in Dementia (CSDD) which allows us to screen for suicidal ideation via the question: "During the past week, has your relative had any thoughts that life is not worth living or that s/he would be better off dead? Has s/he had any thoughts of hurting or even killing him/herself? Incidents will be recorded and reported to the IDMEC, TSC, sponsor of the trial and ethics committee and if serious or life threatening will be reported within 15 days of knowledge.

## 16 Finance

This project is funded by the Alzheimer's Society, as part of a Senior Fellowship Award to the PI. This fellowship award covers the salary of the PI. There are no financial interests for the PI, CIs or programme management or TSC members.

## 17 Insurance

University College London holds insurance against claims from participants for injury caused by their participation in the trial. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this trial is being carried out in a hospital, the hospital continues to

have a duty of care to the participant of the trial. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this trial without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the PI, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Hospitals selected to participate in this trial shall provide negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London, upon request.

## 18 Publication policy

A publication dissemination policy will be developed as part of this project. Publications arising directly or indirectly from the IDEA project will adhere to the UCL and BMJ (2009) guidelines on authorship and contributorship. These state that 'authorship credit should reflect substantial contribution to:

- conception and design, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content;
- and final approval of the version to be published.

All these conditions must be met. All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings.

## 19 Intellectual property

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCLH. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL. Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section (Section 19) shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of UCL. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

# 20 Appendices

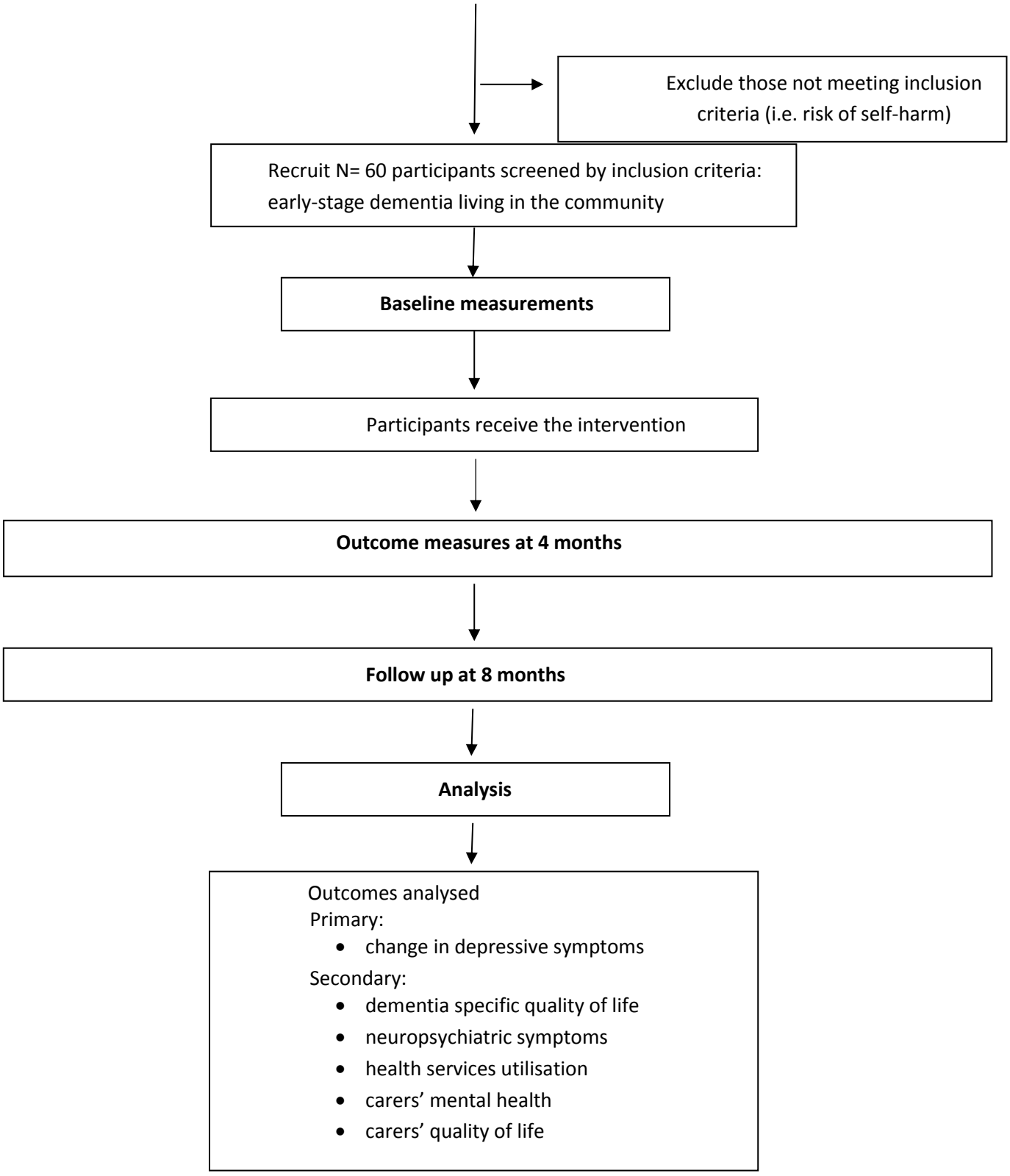


Figure 1. Flow diagram of recruitment and follow-up of participants in the feasibility RCT and outcomes assessed for suitability for the full trial.

## Appendix 1 - Flow diagram of recruitment and follow-up of participants

*IDEA Project timetable and milestones*

| | |
|---|---|
| February 2016 | Start of the IDEA Project |
| February 2016 – July 2016 | Ethics Approval |
| May 2016 – October 2016 | Appointment of Research Assistant |
| February 2016 – September 2016 | Systematic review of Behavioural Activation interventions for older people – Work Package 1 |
| August 2016 – October 2016 | First draft of the IDEA Intervention Manual – Work Package 1 |
| November 2016 – January 2018 | Recruitment for Work Package 2 & 3 |
| November 2016 - February 2017 | Consultations with users, carers and dementia care professionals about the IDEA Intervention Manual – Work Package 2 |
| February 2017 | Consultation with Experts/ Experts Workshop about the IDEA Intervention Manual - Work Package 2 |
| March 2017 | Analyses of Qualitative data - Work Package 2 |
| March 2017 | Second draft of the IDEA Intervention Manual - Work Package 2 |
| February 2017 – April 2017 | Development of all Intervention Materials |
| April 2017 – May 2017 | Field-testing of the Intervention |
| May 2017 – July 2017 | Intervention Refinement – Final draft of the IDEA Intervention Manual |
| August 2017 – January 2017 | Feasibility RCT |
| October 2017 – March 2018 | Follow-up assessments at 4 months |
| February 2018 – July 2018 | Follow-up assessments at 8 months |
| July 2018 – October 2018 | Analyses of feasibility data |
| May 2018- October 2018 | Publication of qualitative findings |
| February 2019 – July 2019 | Publication of feasibility RCT findings |
| November 2019 | Dissemination event |
| August 2019- January 2020 | Grant Application for main Trial |

## Appendix 2 - Project timetable and milestones

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## Appendix 3 - References

| | **Screening (Pre-treatment assessment)** | **Intervention phase** | | | | | | | | **1st Follow-up Visit** | **2nd Follow-up Final visit** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit No: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| | Day 1 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 1 | Day 1 |
| Window of flexibility for timing of visits: | N/A | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 2 weeks | e.g. +/- 4 weeks | e.g. +/- 4 weeks |
| Informed Consent | X | | | | | | | | | | |
| Eligibility confirmation | X | | | | | | | | | | |
| Protocol Assessments | Cornell Scale for Depression in Dementia | | | | | | | | | Cornell Scale for Depression in Dementia | Cornell Scale for Depression in Dementia |
| | DEMQOL (Quality of Life) | | | | | | | | | DEMQOL (Quality of Life) | DEMQOL (Quality of Life) |
| | Neuropsychiatric Inventory | | | | | | | | | Neuropsychiatric Inventory | Neuropsychiatric Inventory |
| | Client Service Receipt Inventory | | | | | | | | | Client Service Receipt Inventory | Client Service Receipt Inventory |
| | Hospital and Anxiety Depression Scale (Carer anxiety and depression) | | | | | | | | | Hospital and Anxiety Depression Scale (Carer anxiety and depression) | Hospital and Anxiety Depression Scale (Carer anxiety and depression) |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | EuroQoL EQ-5D (Carer Quality of life) | | | | | | | | | EuroQoL EQ-5D (Carer Quality of life) | EuroQoL EQ-5D (Carer Quality of life) |
| | Short Form questionnaire-12 (Carer mental health) | | | | | | | | | Short Form questionnaire-12 (Carer mental health) | Short Form questionnaire-12 (Carer mental health) |
| Intervention Assessment | | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | Behavioural activation session with graduate psychologist | | |
| Intervention Assessment | | | | | | | | | Behavioural activation Qualitative Interview | | |
| Randomisation | X | | | | | | | | | | |
| Adverse Events review | X | X | | | X | | | | X | X | X |

## Appendix 4 – Schedule Assessments