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Behavioural activation self-help for well-being in people with dementia

Submission date
24/08/2015

Recruitment status
No longer recruiting

Registration date
27/08/2015

Overall study status
Completed

Last Edited
10/12/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with dementia (PwD) have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. It is very common that PwD show signs of depression, such as low mood or lack of motivation. Although there are a number of measures in place to help PwD who are suffering from depression, the support that can be offered is limited and does not meet the global need. Behavioural activation (BA) is a type of therapy which works on the principal that depression is a set of learned behaviours, such as avoidance, withdrawal and overthinking, which can be "un-learned". In the USA, BA has been shown to be a promising treatment, which can prevent depression from escalating. BA has an advantage over traditional cognitive behavioural therapy (CBT) because it relies on the use of self-help materials rather than needing to be run by a fully trained therapist, and so it can be taught to carers to use in an out-patient setting. The aim of this study is to find out how practical a self-help BA intervention, guided by mental health workers (Psychological Wellbeing Practitioners), supported by informal carers would be for PwD.

Who can participate?
Adults with dementia, who show symptoms of depression, being looked after at least once a week by an informal carer (i.e. partner, family member). The carers are also participants of this study.

What does the study involve?
Patients with dementia and their informal carers are given workbooks at the start of the study. The workbook for the patient with dementia provides friendly, written information about their condition. The carer workbook provides help and support to help the carers manage their role. The patients and their informal carers are offered up to 12 support sessions with a Psychological Wellbeing Practitioner (PWP). Session 1 involves a face-to-face assessment to decide whether the patient is suitable for the programme. Session 2 consists of the PWP explaining the steps of the intervention to both parties. Sessions 3-11 are brief telephone 'check-ins' with the informal carer (the number of these 'check-ins' is decided in session 2). The final session involves a face-to-face session designed to try to stop the patient from having a low mood again. At each of the

face-to-face sessions, questionnaires designed to measure the general health and level of anxiety of the patient is completed. These questionnaires are also completed by the informal carer every week before the telephone sessions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. BeMe Cornwall (UK)
2. Memory Service/Complex Care and Dementia Team (UK)

When is the study starting and how long is it expected to run for?
October 2015 to October 2016

Who is funding the study?
1. Cornwall Partnership NHS Foundation Trust (UK)
2. South West Academic Health Sciences Network (UK)

Who is the main contact?
1. Professor Paul Farrand (Scientific)
2. Dr Joanne Woodford (Public)
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06316

Study information

Scientific Title
Behavioural activation written self-help to improve mood, well-being and quality of life in people with dementia supported by informal carers (the PROMOTE study): a feasibility study

Acronym
PROMOTE

Study objectives
The present study is a single arm feasibility study to examine behavioural activation based self-help to target low mood, wellbeing and improve quality of life in people with dementia, supported by their informal carers and guided by mental health workers (Psychological Wellbeing Practitioners).
The following research questions will be examined:
1. Are clinicians willing to recruit participants?
2. What are the participant response rates?
3. What number of respondents meet the inclusion criteria?
4. What barriers to recruitment do people with dementia and their informal cares experience?
5. How feasible and acceptable are data collection procedures to participants and researchers?
6. How feasible and accessible are treatment procedures to participants?
7. How feasible and accessible are treatment procedures to psychological wellbeing practitioners?

Ethics approval required

Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, 16/11/2015, ref: 15/LO/1689

Study design
Single-arm single-centre feasibility study

Primary study design
Interventional

Secondary study design
Feasibility study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
People with dementia experiencing difficulties with wellbeing, low mood, or depression

Interventions
A written behavioural activation (BA) based self-help intervention has been developed, based on existing BA based self-help interventions. The written material consists of two workbooks, one designed for the person with dementia and the second for the informal carer to aid supporting the person with dementia work through the intervention. The BA workbook for people with dementia follows national guidance for developing dementia friendly written information (DEEP, 2013) and was informed by qualitative interviews with people with dementia. The informal carer workbook provides to help support the person with dementia implement the BA techniques and also provides additional support for carers to manage in the caring role, informed by an existing self-help intervention for carers of stroke survivors. The informal carer workbooks were further informed by two focus groups with informal carers.
Setting: BeMe primary care mental health service commissioned under IAPT (Improving Access to Psychological Therapies programme), within Cornwall Partnership NHS Foundation Trust (CFT). Face-to-face sessions will be offered in BeMe offices, community settings or the participants' home to ensure inclusion into the study for all those wishing to participate.
Therapists: Qualified Psychological Wellbeing Practitioners trained through the IAPT programme to deliver low intensity CBT based interventions for depression and anxiety.
Support: A Psychological Wellbeing Practitioner will guide the use of the BA intervention, providing a maximum of 12 sessions over 3 months.
Session 1: Face-to-face initial assessment with person with dementia with informal carers acting as informant if required, lasting up to 50 minutes to establish suitability for the BA self-help intervention.
Session 2: Face-to-face support session with the person with dementia and informal carer, lasting up to 40 minutes. The session will mainly consist of the PWP explaining the steps of the intervention to both the person with dementia and the informal carer.
Sessions 3 – 11: Brief telephone support 'check-ins' with the informal carer, lasting up to 10

minutes each. Telephone 'check-ins' involve checking progress made with the intervention and agreeing next steps, providing guidance and encouragement around the use of the BA self-help workbooks and support the informal carer problem solve any difficulties experienced with the BA intervention. The number of telephone 'check-ins' will be decided collaboratively between the PWP and informal carer, but a maximum of 9 'check-ins' will be offered.
Final Session: a face-to-face relapse prevention session will be held with the person with dementia and the informal carer, lasting a maximum of 40 minutes.
In-session outcome measurements: The patient health questionnaire (PHQ-9) and GAD-7 anxiety questionnaire will be completed at each support session with the person with dementia during face-to-face sessions by the informal carer before each telephone check-in session.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measurements will mainly pertain to the feasibility aims of the study and will be assessed post-treatment (3 months). Specifically we are interested in examining the following:
1. Number of potential dyads (people with dementia and informal carer) that can be accessed per week
2. Response rates calculated for GP, PCPD and memory service recruitment
3. Identified barriers to recruitment
4. Percentage of dyads who complete the post-treatment (3 month) outcome measures
5. Time taken to administer the screening measures
6. Time taken to administer the baseline assessment
7. Time taken to administer the follow-up assessments
8. Acceptability of data collection procedures to people with dementia and informal carers
9. Clinician competence in terms of delivering the proposed intervention (levels of PWP competence and adherence to protocol as determined by therapy tapes)
10. We will also begin to explore barriers in terms of clinical delivery of the intervention. Feasibility study throughput (sample size) will allow an initial exploration of these factors however proper assessment will not be possible due to the small sample size.
10.1. Waiting list times
10.2. Session length
10.3. Number of sessions
10.4. Settings of sessions (BeMe, community, home)
10.5. Number of missed appointments
10.6. Number of missed outcome item measures
10.7. PWP attrition
10.8. Acceptability interviews with PWPs

Secondary outcome measures
Person with Dementia
1. Depressive symptoms measured by the CSDD and GDS-12R at baseline and 3 months
2. Quality of life measured by the DEMOL and EQ-5D-3L at baseline and 3 months

Informal Carer
1. Depressive symptoms measured by the PHQ-9 at baseline and 3 months
2. Anxiety symptoms measured by the GAD-7 at baseline and 3 months
3. Carer Burden measured by the ZBI-12 at baseline and 3 months
4. Quality of life measured by the SF-12 and ES-5D-3L at baseline and 3 months

5. Health and public service used for both the person with dementia and informal carer measured by the adapted CSRI at baseline and 3 months

Overall study start date
03/10/2015

Completion date
10/10/2016

Eligibility

Key inclusion criteria
Person with Dementia Inclusion Criteria:
1. A probable diagnosis of dementia, in accordance with ICD-10 (World Health Organisation, 1992) or Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (American Psychiatric Association, 1994) or DSM-5 (American Psychiatric Association, 2013) criteria for a dementia.
2. Mild to moderate dementia severity as defined by Mini-Mental State Examination (MMSE) scores of 12 to 24;
3. A score of 4 or more on the Geriatric Depression Scale (GDS-12R)
4. If participants are receiving antidepressant medication, they have been on a stable does for one month at baseline.
5. If participants taking acetyl-cholinesterase inhibitors or Memantine, they have been on a stable does for one month at baseline.
6. Residing at home
7. Sufficient proficiency in English to read and engage with the written BA self-help material.
8. Must have an informal carer (defined as a partner, family member or friend) who has regular contact (at least weekly) with the person with dementia.

Informal Carer Inclusion Criteria
1. Aged 16 years or over
2. Self-identified informal carer of a person with dementia;
3. Has regular contact (at least weekly) with the person with dementia;
4. Willing to support the intervention, including increasing regular contact to facilitate supporting the intervention if required.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Person with Dementia Exclusion Criteria:
1. A score of above 24 or below 12 on the MMSE

2. A score of below 4 on the GDS-12R
3. A co-morbid diagnosis of post-traumatic stress disorder (PTSD), psychosis, type I and II bipolar disorder, personality disorder
4. Current alcohol abuse defined as use of alcohol so severe that it interferes with the person with dementia's ability to perform normal activities in daily life and interfere with engagement with the intervention
5. Current abuse of either prescription or street drugs
6. Currently receiving formal psychotherapy
7. A reading impairment that would prevent the use of written BA self-help material
8. A score of 2 or more on Q9 of the PHQ-9 (Kroenke & Spitzer, 2002) indicating the participant is experiencing "thoughts that you would be better off dead or of hurting yourself in some way" for more than half the days over the proceeding fortnight
9. Acutely suicidal and / or a history of persistent self-injury

Informal Carer Exclusion Criteria:
1. A score of 2 or more on Q9 of the PHQ-9 (Kroenke & Spitzer, 2002) indicating the participant is experiencing "thoughts that you would be better off dead or of hurting yourself in some way" for more than half the days over the proceeding fortnight
2. A score of 20 – 27 on the PHQ-9 indicating severe levels of depression
3. A diagnosis of post-traumatic stress disorder (PTSD), psychosis, type I and II bipolar disorder, personality disorder
4. Current alcohol abuse defined as use of alcohol so severe that it interferes with the carer's ability to perform normal activities in daily life
5. Current use of either prescription medication in a non-prescribed manner or street drugs
6. Difficulties reading or following the written BA self-help material

Date of first enrolment
10/10/2015

Date of final enrolment
10/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
BeMe Cornwall
Cornwall Partnership NHS Foundation Trust
Trevellis House
Lodge House
Liskeard, Cornwall
United Kingdom
PL14 4EN

Study participating centre
Memory Service/Complex Care and Dementia Team
Cornwall Partnership NHS Foundation Trust
Penwith CMHT
Bolitho House
Laregan Hill
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United Kingdom
TR18 4NY

Sponsor information

Organisation
University of Exeter

Sponsor details
The Innovation Centre
Rennes Road
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EX4 4RN

Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cornwall Partnership NHS Foundation Trust

Funder Name
South West Academic Health Sciences Network

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report
3. Conference presentations

Intention to publish date
31/01/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/08/2016	10/12/2020	Yes	No
HRA research summary			28/06/2023	No	No