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Mindfulness Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia

Submission date
18/07/2016

Recruitment status
No longer recruiting

Registration date
21/07/2016

Overall study status
Completed

Last Edited
30/11/2020

Condition category
Mental and Behavioural Disorders

[ ] 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
Depression and dementia are major public health problems in the UK. Depression is very common in people with early stage dementia and reduces quality of life and speeds up cognitive (mental) decline. Mindfulness-based cognitive therapy (MBCT) is an effective depression prevention programme. There have been promising results showing the benefits of mindfulness interventions for people with dementia, suggesting that it could reduce depressive symptoms and slow deterioration in cognitive functions. The aim of this study is to test the study design for a future full study to determine the effectiveness of MBCT at reducing depressive symptoms in people with early stage dementia.

Who can participate?
Patients with mild to moderate depression and early stages of dementia

What does the study involve?
Participants are randomly allocated to receive either immediate or delayed access to an eight-week MBCT programme. Participants are assessed for depression before and after the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from the proposed treatment, which has very good evidence of its effectiveness for depression. There are no risks anticipated with participating in this study. Participants will be able to drop out at any stage if they wish to do so. If participants have any concerns following participation, they will be encouraged to use the contacts provided at information sheet.

Where is the study run from?
North East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
University of Oxford (UK)

Who is the main contact?
Dr Elisa Aguirre

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Mindfulness Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia

Acronym
N/A

Study objectives
The aim of this study is to recruit people experiencing mild to moderate depression who also have comorbid early stages of dementia.
The research questions of the study are outlined below.

Primary question:
1. Is the study design feasible - is it possible to identify this client group, recruit from memory services, randomise participants and collect data at baseline and follow up?

Secondary questions:
1. To what extent will participants adhere to the intervention?
2. Is the MBCT satisfactory/acceptable to participants?
3. How many participants will be needed for a sufficiently powered future RCT? (efficacy data at follow up will be used for the future sample size estimation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
HRA London City and East REC, REC: 16/LO/0578

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Comorbid depression and early stages of dementia

Interventions
This is a feasibility study to test the possibility of delivering the MBCT intervention for people with mild to moderate depression and comorbid early stages of dementia. In this RCT, 50% of participants will be randomly allocated to the immediate group (IA) and will receive MBCT immediately. The remaining 50% of participants will be allocated to the delayed access control (DAC) group. Both arms will also receive treatment as usual. The primary end point will be follow up after the intervention. Monitoring will continue up to a 6-month final exit point.

Intervention Type
Other

Primary outcome(s)
Depression will be assessed using the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988), a 19 item clinician-administered instrument. Information is gathered from interviews with the participant and an informant (e.g. family memory, staff member) and this information is used to rate five areas of depression (mood-related signs, behavioural disturbance, physical signs, biological functions and ideational disturbance). Each item had a three-point scale (0=absent, 1 = mild or intermittent, 2 = severe) with scores ranging from 0-38. The clinical cut off for significant depressive symptoms was a score of 8 and above (Alexopoulos et al., 1988; Burns, 2002). The CSDD has good reliability and validity and it is deemed to be the ‘gold standard’ for assessing depressive symptoms in PWD (Sheehan, 2012). Measured at baseline, after intervention (3 months) and 6 months.

Key secondary outcome(s))
Measured at baseline, after intervention (3 months) and 6 months:

1. Mini Mental State Examination (MMSE). Cognitive function will be measured by the Mini Mental State Exam (MMSE) (Folstein et al., 1975). This will be used as an outcome measure and a screening tool for inclusion. The MMSE involves the participant doing 11 simple tasks, such as orientation to time and place, attention, recall, language and visual construction. The MMSE is an extremely widely used tool for assessing cognition in dementia (Woodford & George, 2007).

2. Cornell Scale for Depression in Dementia (CSDD). Depression will be assessed using the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988), a 19-item clinician-administered instrument. Information is gathered from interviews with the participant and an informant (e.g. family memory, staff member) and this information is used to rate five areas of depression (mood-related signs, behavioural disturbance, physical signs, biological functions and ideational disturbance). Each item had a three-point scale (0=absent, 1 = mild or intermittent, 2 = severe) with scores ranging from 0-38. The clinical cut off for significant depressive symptoms was a score of 8 and above (Alexopoulos et al., 1988; Burns, 2002). The CSDD has good reliability and validity and it is deemed to be the 'gold standard' for assessing depressive symptoms in PWD (Sheehan, 2012).

3. Patient Health Questionnaire (PHQ-9). PHQ-9 is a freely available mood rating questionnaire consisting of nine questions mirroring DSM-IV depression diagnostic criteria and each rated 0–3 giving a maximum score of 27. Cut-off scores are used to label depression severity as:
3.1. 0–4: minimal depression
3.2. 5–9: mild depression
3.3. 10–14: moderate depression
3.4. 15–19: moderately severe depression
3.5. 20–27: severe depression

4. Quality of Life - Alzheimer's Disease Scale: Participant Version (QoL AD). Quality of life will be measured using the Quality of Life – Alzheimer's Disease scale (QoL-AD) (Logsdon, 1999), a 13-item self-report questionnaire. Information about several areas was gathered from the PWD and their carer, such as physical health, mood, friends, fun, self and general life. The measure has excellent internal consistency and inter-rater reliability. The content, criterion and construct validity are good (Logsdon, 1999).

5. Cognitive Affective Mindfulness Scale (CAMS-R). The Cognitive Affective Mindfulness Scale (Revised) (CAMS-R; Feldman, Hayes, Kumar, Greeson & Laurenceau, 2007) is a 12-item self-report questionnaire that measures trait mindfulness in day-to-day experience. Scores range between 0-48, with higher scores indicating higher levels of mindfulness. Each item (e.g. 'I try to notice my thoughts without judging them') is rated on a four-point scale of 1 ('rarely/not at all'), 2 ('sometimes'), 3 ('often') or 4 ('almost always'). The measure was used in the aforementioned pilot study (Chan, 2015; Churcher-Clarke, 2015a, unpublished) in people with dementia.

6. Generalized Anxiety Disorder 7-item (GAD-7) scale (Spitzer, 2007). The GAD-7 is a seven-item questionnaire focusing on symptoms of anxiety experienced in the past 2 weeks. Each item is rated according to the frequency of the described problem. The responses are scored as follows: 0='not at all', 1='several days', 2='more than half the days', 3='nearly every day'. Therefore, the maximum score is 21. Scores of 0–5 indicate mild anxiety, 6–10=moderate anxiety, 11–15 moderately severe anxiety and 15–21 severe anxiety.

7. Rating Anxiety in Dementia (RAID). Anxiety will be assessed using the Rating Anxiety in Dementia (RAID) scale (Shankar, Walker, Frost, & Orrell, 1999), an 18-item clinician-administered instrument. Information is gathered from interviews with the participant and an informant (e.g. family memory, staff member) and this information is used to rate four areas of anxiety (worry,

apprehension, vigilance, motor tension, autonomic hypersensitivity). Each item is rated on a four-point scale (0=absent, 1 = mild or intermittent, 2 = moderate, 3= severe) with scores ranging from 0-54. The clinical cut off for significant clinical anxiety was a score of 11 and above. The RAID is the most appropriate measure for assessing anxiety in PWD (Seignourel, Kunik, Snow, Wilson, & Stanley, 2008).

8. Control, Autonomy, Self-realisation and Pleasure (CASP-19)
9. Positive Psychology Outcome Measure (PPOM)
10. Engagement and Independence in Dementia Questionnaire (EID-Q)
11. Cognitive mediation questionnaire (Dagnan and Chadwick 1997)
12. Thought, feeling behaviour questionnaire (Oathamshaw and Haddock 2006).

We are currently in discussions about which of these measures are best to use. We will pilot how long measures we can complete in 90 minutes.

Weekly measures
PHQ-9, GAD-7 and CSDD will be collected after each mindfulness session, in line with the service protocol.

Carer measures
This will be conducted by the assessor in a private room in the memory clinic or in the participants home. The assessor will ask a member of staff or family member questions about the relevant participant's, mood, anxiety and quality of life. The information obtained will be used in combination with the information gathered from the interview with the participant to complete the following assessments:
1. Cornell Scale for Depression in Dementia (Alexopoulos, Abrams, Young and Shamoian, 1988)
2. Quality of Life Alzheimer's Disease Scale: Carer Version (QoL-AD, Logsdon, Gibbons, McCurry and Terri, 1999)
3. Rating Anxiety in Dementia (carer version)

Completion date
01/12/2017

Eligibility

Key inclusion criteria
Participants will be recruited and identified from memory services in North East London NHS Foundation Trust and memory services in Oxleas Foundation Trust.

Inclusion criteria: Treated or with a diagnosis of mild depression and a diagnosis of mild dementia according to DSM-IV criteria with a Mini Mental State Examination (MMSE) (Folstein et al., 1975) of 18 or above.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Have congenital learning disability
2. Present with severe depression or high risk of self-harm (e.g. suicidal intent) requiring urgent intervention
3. Are within 2 months of a bereavement
4. Are involved in other psychosocial intervention research
5. Have a diagnosis of psychosis

Date of first enrolment
01/06/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East London NHS Foundation Trust
United Kingdom
IG8 7XJ

Study participating centre
Oxleys NHS Foundation Trust
United Kingdom
GL55 6UR

Sponsor information

Organisation
University of Oxford (UK)

ROR

https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/05/2017	30/11/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes