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Managing Multiple Health Conditions in Older Adults (MODS): Benefiting from activities to help your mood and physical wellbeing

Submission date
10/08/2022

Recruitment status
No longer recruiting

Registration date
11/08/2022

Overall study status
Completed

Last Edited
22/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Older adults (those aged 65 years and over) who have long term physical health conditions (such as asthma, diabetes, heart problems) are more likely to experience depression. This combination of problems can lead to poorer quality of life and can be very costly to health and social care services.

Behavioural Activation (BA) is a form of psychological support that has been shown to help older adults with depression. Behavioural Activation helps people to think about the link between their mood and their behaviour. A core element of this psychological approach is to help people maintain or introduce activities which are important to them. Such activities may benefit physical and emotional wellbeing by helping people stay connected with the world and remain active. This BA support is provided within a collaborative care framework. This means that health professionals (such as the person's GP) can be involved to support a person's physical as well as emotional functioning, in a patient-centred way.

As part of the current Managing Multiple Health Conditions in Older Adults (MODS) programme of research, we have adapted BA ('BA Support') to focus on improving the physical and emotional wellbeing of older adults with long term physical health conditions and low mood or depression. We now need to test this BA Support with a large group of older adults with multiple long term health conditions and low mood or depression to find out whether the BA Support helps to maintain or improve physical and emotional functioning. We also want to find out whether this new form of BA support represents value for money.

We have also tested a similar form of this BA support in a related ongoing programme of work called Behavioural Activation in Social Isolation (BASIL-C19 – see ISRCTN94091479; BASIL+ - see ISRCTN 63034289), which began during the Covid-19 pandemic. The aim of the BASIL programme is to find out whether the BASIL BA intervention can prevent or reduce depression and loneliness in older people with multiple health conditions during isolation.

Who can participate?
People who are 65 years and over, have two or more long term physical health conditions, and who are also experiencing symptoms of low mood or depression.

What does the study involve?
People who are suitable and happy to take part in the study ('participants') will be asked to complete a study questionnaire with a researcher over the telephone (participants may also have the option of completing this questionnaire online or by completing the questionnaire at home and returning this in the post). Participants will then be randomly allocated (this is done by a computer, and is like flipping a coin) to either receive the BA Support (approximately 286 participants) or to continue with their usual care (approximately 286 participants). No treatment will be withheld from participants and all participants will continue to receive the care and support they might usually do whilst taking part in the study.

Participants who are allocated to the BA Support group will be offered up to eight BA Support sessions over up to a 4 month period. These sessions will involve working with a MODS support worker who is trained in the BA Support. Participants will also be provided with a booklet which the MODS support worker will help them to work through. The MODS support worker will help people to plan changes that aim to support their physical and emotional wellbeing. The sessions will take place over the telephone (or video call, depending on resources and participant preference), but if necessary sessions may take place face-to-face. The first session may last around one hour and further sessions will usually last for about 30 minutes. The MODS support worker may also speak with other professionals involved in the participant's healthcare.

All participants are asked to complete a study questionnaire over the telephone with a researcher, online or via the post after they have been in the study four months, eight months and 12 months. Participants may also be asked if they would like to provide their feedback about taking part in the study and being offered the BA Support sessions. MODS support workers, caregivers and health and social care professionals involved in the BA Support may also be invited to discuss their views and experiences of the study and the BA support.

What are the possible benefits and risks of participating?
It is not known whether taking part in this study will help participants since BA has not been used in this way before with this group of older adults, but participants may receive additional support which is not usually available to them. Taking part could help improve future support offered to older adults who have health conditions and who may also experience low mood or depression. There are no anticipated risks to people taking part in the study, but it will take up some of their time to complete the study questionnaires. Participants who receive the BA Support sessions will also spend some time working through the sessions and the associated activities.

Where is the study run from?
The MODS study is being run from the University of York, in collaboration with Tees, Esk and Wear Valley NHS Foundation Trust. Participants will be recruited from across England.

When is the study starting and how long is it expected to run for?
January 2022 to June 2024

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research (PGfAR) (UK)

Who is the main contact?
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Study website
https://sites.google.com/nihr.ac.uk/mods

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311214

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 311214, CPMS 52524

Study information

Scientific Title
Multimorbidity in Older Adults with Depression Study (MODS): A pragmatic fully-powered randomised controlled trial of usual care compared to a behavioural activation intervention to maintain or improve physical and mental functioning in older adults with long term health conditions and comorbid low mood/depression.

Acronym
MODS (WS3 & WS4)

Study objectives

The overarching aim of the MODS programme is to develop a feasible, acceptable, clinical and cost-effective brief psychological intervention (behavioural activation within a collaborative care framework) to maintain or improve physical and mental functioning in older adults with long term physical health conditions and comorbid low mood/depression.

The current phase of the MODS research programme is to conduct a definitive randomised controlled trial to determine the clinical and cost effectiveness of the MODS intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/05/2022, Yorkshire & The Humber – Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; leedswest.rec@hra.nhs.uk), ref: 22/YH/0071

Study design
A multicentre two arm parallel group individually randomized controlled trial with embedded qualitative evaluation and economic evaluation.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Physical health conditions and co-morbid low mood or depression in older adults.

Interventions
Participants will be randomly allocated 1:1 to either the behavioural activation intervention group or the usual care group.

Active intervention: Behavioural Activation (BA) within a Collaborative Care framework.
BA aims to help people maintain or introduce activities which are important to them; such activities may benefit their physical and emotional wellbeing by helping people to stay connected with the world and remain active. The practitioner (MODS support worker) and participant work together to develop a collaborative treatment plan that seeks to reinstate or introduce behaviours that connect people to sources of positive reinforcement (valued activities).

The BA intervention has been adapted for older adults with multiple long-term conditions as part of earlier phases of the MODS research programme.

Participants will be offered up to 8 BA sessions over up to a four-month period, delivered by trained MODS support workers and supported by a self-help booklet. Sessions will be delivered over the telephone (and/or via video call where feasible and acceptable; with face-to-face visits as an option where this would facilitate study inclusion and were feasible for the MODS support worker). As part of the collaborative care framework, MODS support workers will liaise with other professionals relevant to the participant's healthcare needs as appropriate (to include for example medication management).

Control intervention: usual care as provided by current NHS and/or third sector providers.

The duration of treatment and follow-up for both groups is 12 months post-randomisation.

Intervention Type
Behavioural

Primary outcome measure
Self-reported quality of life and functioning (as measured by the Short Form 12 version 2) at 4 months post-randomisation.

Secondary outcome measures
Collected at baseline, 4, 8 and 12 months post-randomisation (unless otherwise stated):
1. Quality of life and functioning (SF12v2) at baseline, 8 and 12 months post-randomisation
2. Depression status according to DSM-5 criteria (SCID-5)
3. Depression severity (PHQ9)
4. Anxiety (GAD7)
5. Physical function (Nottingham Extended Activities of Daily Living Scale)
6. Loneliness (De Jong Gierveld Scale - 11 items)
7. Social Networks and Isolation (Lubben Social Network Scale – 6 items)
8. Health Related Quality of Life (EQ5D-3L)
9. Chronic pain (Graded chronic pain scale revised – two questions)
10. A bespoke questionnaire will be used to collect health service use data.

Overall study start date
01/01/2022

Completion date
06/06/2024

Eligibility

Key inclusion criteria
1. Older adults aged 65 years or over
2. Two or more long-term physical health conditions
3. Depressive symptoms as indicated by the presence of sub-threshold depression or major depressive disorder, according to the Structured Clinical Interview for DSM-5 Axis 1 disorders depression subscale (SCID).

Participant type(s)

Patient

Age group
Senior

Sex
Both

Target number of participants
572

Key exclusion criteria
Older adults who:
1. Have cognitive impairment
2. Have bipolar disorder/psychosis/psychotic symptoms
3. Have alcohol or drug dependence
4. Are in the palliative phase of illness
5. Have active suicidal ideation
6. Are currently receiving psychological therapy
7. Are unable to speak or understand English

Date of first enrolment
15/08/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Research and Development
Flatts Lane Centre
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Study participating centre
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Study participating centre
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Sponsor type
Hospital/treatment centre

Website
https://www.tewv.nhs.uk/

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type

Not defined

Funder Name
National Institute for Health and Care Research Programme Grants for Applied Research

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/10/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No