ISRCTN94091479 https://doi.org/10.1186/ISRCTN94091479

Behavioural Activation in Social IsoLation (BASIL): Benefiting from activities to improve your mood while you are socially isolating

Submission date
09/06/2020

Recruitment status
No longer recruiting

Registration date
09/06/2020

Overall study status
Completed

Last Edited
14/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

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 diabetes, asthma, heart problems) are more likely to experience depression, which can lead to poorer quality of life. As a result of the Covid-19 pandemic, older adults and those with long term physical health conditions were instructed by the UK government to follow social distancing/isolation guidelines (to include strict isolation for the most vulnerable in this group) to protect their own and other's health. This enforced isolation will lead to a disruption of daily routine, loss of social contact and loneliness; and this in turn may further increase the risk of depression and anxiety in this group.

Behavioural Activation (BA) is a type of talking therapy which might be useful for people who undergo social isolation. It aims 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.

We have already adapted BA to support older adults with long term physical health conditions and depression to improve their physical and emotional wellbeing. This will now be used to support older adults with long term physical health conditions who are now socially isolated. BA will be tested in a pilot (small) study called Behavioural Activation in Social Isolation (BASIL). In BASIL we will test whether this BA ('BA support') can be offered to older adults with long term physical health conditions to help prevent or reduce depression and loneliness during this period of Covid-19 enforced isolation.

Who can participate?
People who are 65 years and over and have two or more long term physical health conditions.

What does the study involve?
People who are suitable to take part in the study (participants) will be asked to complete a study questionnaire with a researcher over the telephone. They will then be randomly allocated (this is done by a computer, and is like flipping a coin) to either receive the BA support (50 participants)

or to continue with their usual care in addition to receiving information about sources of support for maintaining health and wellbeing (50 participants). No treatment will be withheld 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 a 4-6 week period. These sessions will involve working with a BASIL support worker who is trained in the BA support. Participants will also be provided with a booklet which the BASIL support worker will help them to work through. The BASIL support worker will help people to plan changes that aim to support their physical and emotional wellbeing during this period of Covid-19 restrictions. The sessions will take place over the telephone (or video call, depending on resources and participant preference). The first session may last around one hour and further sessions will usually last for about 30 minutes. The BASIL 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 after they have been in the study one month, three months and 12 months. Participants may also be asked if they would like to provide their feedback about taking part in the study and receiving the BA support sessions. BASIL support workers, health professionals and caregivers 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, 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 long term health conditions and who may also experience low mood, loneliness and/or social isolation. 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 pilot 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 the North East of England.

When is the study starting and how long is it expected to run for?
The study started in April 2020 and will run until December 2021. The study will start recruiting participants in June 2020.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research (PGfAR).

Who is the main contact?
Dr Liz Littlewood
liz.littlewood@york.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Liz Littlewood

ORCID ID
https://orcid.org/0000-0002-4606-4590

Contact details
Mental Health and Addiction Research Group
Department of Health Sciences
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321828
liz.littlewood@york.ac.uk

Type(s)
Scientific

Contact name
Prof David Ekers

ORCID ID
https://orcid.org/0000-0003-3898-3340

Contact details
Tees, Esk and Wear Valleys NHS Foundation Trust
Research & Development
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbrough
United Kingdom
TS6 0SZ
+44 (0)1642 283501
david.ekers@nhs.net

Type(s)
Scientific

Contact name
Prof Simon Gilbody

ORCID ID
https://orcid.org/0000-0002-8236-6983

Contact details

Mental Health and Addiction Research Group
Department of Health Sciences
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321370
simon.gilbody@york.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
249030

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 45854, IRAS 249030

Study information

Scientific Title
Behavioural Activation in Social IsoLation (BASIL-C19): A pilot randomised controlled trial of a behavioural activation intervention to mitigate depression and loneliness in older adults with long-term health conditions during the Covid-19 pandemic

Acronym
BASIL-C19

Study objectives
The overarching aim of the BASIL trials programme will be to determine whether the impacts of social isolation can be mitigated by preventing depression and loneliness.

This is a pilot trial and we will test our ability to capture our key primary and secondary outcomes. In addition, in this pilot trial we will establish important study estimates (recruitment; randomisation; retention; intervention delivery, engagement and acceptability) for a definitive randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/04/2020, Yorkshire and The Humber – Leeds West Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8018; leedswest.rec@hra.nhs.uk), ref: 18/YH/0380 (approved as substantial amendment 02 under existing MODS research programme)

Study design
A multicentre two arm parallel group individually pilot randomised controlled trial with embedded qualitative evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression and loneliness in older adults with long-term physical health conditions

Interventions
Participants will be randomly allocated 1:1 to either the behavioural activation intervention group or the usual care with signposting information 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 (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 previously adapted for older adults with multiple long term conditions (as part of the existing NIHR MODS programme of research RP-PG-0217-20006 https://www.fundingawards.nihr.ac.uk/award/RP-PG-0217-20006) and will be further adapted to consider social isolation

Participants will be offered up to 8 BA sessions over a 4-6 week period, delivered by trained 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). As part of the collaborative care framework, 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 section providers, in addition to signposting to reputable sources of self-help and information on maintaining physical and mental wellbeing.

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

Intervention Type
Behavioural

Primary outcome(s)
Self-reported depression severity (as measured by the Patient Health Questionnaire 9) at 1 month post-randomisation

Key secondary outcome(s))
At 1, 3 and 12 months post-randomisation (unless otherwise stated):
1. Depression (PHQ9) at 3 and 12 months post-randomisation
2. Anxiety (GAD-7)
3. Loneliness (De Jong Gierveld Scale - 11 items)
4. Health Related Quality of Life (SF-12v2)
5. A brief bespoke questionnaire will be used to collect health service use data at all study time-points (baseline and 1, 3 and 12 months post-randomisation)
6. In addition, we will capture estimates of rates of recruitment; randomisation; retention, intervention delivery and engagement. These will be described using a standard CONSORT flow diagram, and these will provide estimates to enable the design of a fully powered BASIL trial

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Older adults aged 65 years or over
2. Two or more long term physical health conditions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
96

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
15/06/2020

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Health Sciences
University of York
Heslington
York
United Kingdom
YO10 5DD

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
c/o Research and Development
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbrough
United Kingdom
TS6 0SZ

Sponsor information

Organisation
Tees, Esk and Wear Valleys NHS Foundation Trust

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type
Government

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

Results and Publications

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2021	13/10/2021	Yes	No
Results article	Long term results	12/10/2022	13/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	interview data from the embedded qualitative study describing acceptability	13/03/2023	14/08/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	Long-term results	21/06/2022	24/06/2022	No	No
Statistical Analysis Plan	version 1.0	02/03/2021	24/08/2022	No	No