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Behavioural activation in social isolation (BASIL+): Benefiting from activities while you socially isolate to help your mood and wellbeing

Submission date
05/02/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
25/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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 asthma, diabetes, 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 physical health conditions, including long-term health conditions, have been 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 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. Furthermore, some element of social isolation may well persist through successive waves of the Covid-19 pandemic.

Behavioural Activation (BA) is a form of support which might be useful for people who become socially isolated. 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.

We have already adapted BA ('BA Support') to support older adults with long term physical health conditions and depression to improve their physical and emotional wellbeing. This BA Support will now be used to support older adults with physical health conditions (including long-term health conditions) who are socially isolated and at risk of depression and loneliness. We have now tested this BA Support in a pilot study called Behavioural Activation in Social Isolation (BASIL-C19 - see ISRCTN94091479). We now need to test this BA Support in a much larger group of people to determine whether the BA Support can benefit older adults with physical health conditions to help prevent or reduce depression and loneliness during isolation. The results will be useful in mitigating the psychological impacts of Covid-19, and will be helpful beyond the pandemic in understanding how best to prevent or mitigate depression or loneliness in older people, and especially those who are socially isolated.

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

health condition which may require self-isolation (or 'shielding') due to Covid-19, and who may be 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. They will then be randomly allocated (this is done by a computer, and is like flipping a coin) to either receive the BA Support (approximately 295 participants) or to continue with their usual care in addition to receiving information about sources of support for maintaining health and wellbeing (approximately 295 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 up to a 12 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 isolation. 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 or online 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 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 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 BASIL+ 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?
October 2020 to February 2023

Who is funding the study?
The study is funded by the National Institute for Health 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/basil

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293203

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 293203, CPMS 47687

Study information

Scientific Title
Behavioural Activation in Social IsoLation (BASIL+): A pragmatic fully-powered randomised controlled trial of a behavioural activation intervention to mitigate depression and loneliness in older adults with long-term health conditions during isolation

Acronym
BASIL+

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

In our pilot BASIL trial (BASIL-C19 - ISRCTN94091479) we have tested our ability to deliver the study and to capture our key primary and secondary outcomes. The next phase of the BASIL research programme is to undertake a definitive randomised controlled trial (BASIL+) to determine the clinical and cost-effectiveness of the BA intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/12/2020, Yorkshire and The Humber – Leeds West Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44(0)207 104 8018; leedswest.rec@hra.nhs.uk), ref: 20/YH/0347

Study design
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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Depression and loneliness in older adults with 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 (BASIL 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 has now been further adapted to consider social isolation in the BASIL pilot trial (ISRCTN94091479).

Participants will be offered up to 8 BA sessions over up to a 12 week period, delivered by trained BASIL 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, BASIL 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, 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 measure
Self-reported depression severity (as measured by the Patient Health Questionnaire-9) at 3 months post-randomisation.

Secondary outcome measures
Measured at baseline, 1, 3 and 12 months post-randomisation (unless otherwise stated):
1. Depression (PHQ9) at baseline, 1 and 12 months post-randomisation
2. Loneliness (De Jong Gierveld Scale - 11 items)
3. Anxiety (GAD-7)
4. Social Networks and Isolation (Lubben Social Network Scale – 6 items)
5. Health-Related Quality of Life (SF-12v2 and EQ5D-3L)
6. A brief bespoke questionnaire will be used to collect health service use data

Overall study start date
01/10/2020

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Older adults aged 65 years or over
2. Two or more long-term physical health conditions OR a health condition that may indicate they are within a ‘clinically extremely vulnerable’ group in relation to Covid-19
3. Depressive symptoms as indicated by a score of ≥5 on the Patient Health Questionnaire-9 (PHQ9)

Participant type(s)
Patient

Age group
Senior

Lower age limit

65 Years

Sex
Both

Target number of participants
392

Total final enrolment
435

Key exclusion criteria
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
08/02/2021

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Research and Development
Flatts Lane Centre
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TS6 0SZ

Study participating centre

Department of Health Sciences
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United Kingdom
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Study participating centre
St Nicholas Hospital
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
The Good Practice
409 Kings Road
London
United Kingdom
SW10 0LR

Study participating centre
Musgrove Park Hospital
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Taunton
United Kingdom
TA1 5DA

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre

Humber Teaching NHS Foundation Trust
Trust HQ
Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
Shipley
United Kingdom
BD18 3LD

Study participating centre
Vauxhall Health Centre (Liverpool PCN)
Vauxhall Health Centre
Limekiln Lane
Vauxhall
Liverpool
United Kingdom
L5 8XR

Study participating centre
Age UK Leeds
Bradbury Building
Mark Lane
Leeds
United Kingdom
LS2 8JA

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
Bridge Park Plaza
Bridge Park Road
Leicester
United Kingdom
LE4 8PQ

Study participating centre
Llanedeyrn Health Centre
Maelfa Llanedeyrn
Cardiff
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CF23 9PN

Sponsor information

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type
Government

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

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
30/11/2023

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?
Protocol article	version 1.1	24/03/2022	25/03/2022	Yes	No
Statistical Analysis Plan		26/09/2022	21/10/2022	No	No
HRA research summary			28/06/2023	No	No
Results article	Embedded cost utility analysis	01/02/2024	05/02/2024	Yes	No
Other publications		19/01/2025	25/04/2025	Yes	No