ISRCTN48636092 https://doi.org/10.1186/ISRCTN48636092

Preventing the deterioration of mental health for men working on the NHS frontline

Submission date	Recruitment status	[X] Prospectively registered
11/10/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/11/2022	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/06/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The BALM (Behavioural Activation for Low Mood and Anxiety in Male Frontline NHS Workers) study involves the development, delivery and evaluation of an early intervention that aims to prevent the common mental health challenges (low mood, anxiety, depression) faced by male frontline NHS workers. Frontline National Health Service (NHS) staff are at increased risk of mental health difficulties. Male frontline workers often do not seek help and might be more affected than the general population. Behavioural Activation is an effective treatment that can be used as an early intervention to help stop these difficulties from getting worse. It is particularly suited for adaptation as a gender-sensitive intervention because of its practical, action-oriented strategies that are consistent with a strengths-based masculinities approach; meaning it reinforces men's sense of autonomy, control and independence. The aim of this study is to develop the Behavioural Activation intervention so it appeals to male frontline NHS workers to help address low mood and anxiety and prevent a worsening of mental health.

Who can participate?
Men who are a frontline NHS worker

What does the study involve?
We will first develop a self-help Behavioural Activation booklet tailored specifically for men who are working on the NHS frontline. As part of this, we will talk to men from different NHS frontline jobs to ensure the booklet is designed in a way that is helpful and appealing to them. In the second part of the study, we will evaluate how effective the intervention is. We will recruit 45 men at risk of low mood who are working on the NHS frontline. We will send the booklet to them, and train BALM coaches to help them use the booklet. Following a topic guide, we will evaluate whether it helped their mood and also interview them (n = 20) and the BALM coaches (n =10) to find out how useful they found it. We will then potentially roll the intervention out across the NHS.

Half of the participants will be assigned by chance to receive either haploidentical SCT or standard of care. We will monitor participants for 2 years to see if haploidentical SCT cures people of SCD and is a good value for the NHS.

What are the possible benefits and risks of participating?
Possible benefits of taking part in the study are it could better equip men to deal with the stresses and strains of working in the NHS and enable them to enjoy life more. In addition, data will allow the researchers at the University of York to increase their knowledge of men's health, improving their understanding of how to enhance the wellbeing of men working in an NHS role. Possible disadvantages of taking part in the study are it will require men to complete a couple of short study questionnaires and the Behavioural Activation intervention sessions with coaches which will take time.

Where is the study run from?
Department of Health Sciences, University of York (UK)

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Professor Paul Galdas, paul.galdas@york.ac.uk (UK)

Study website
https://www.balmprogramme.co.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
314095

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53718, IRAS 314095

Study information

Scientific Title
Behavioural Activation for Low mood and anxiety in Male NHS frontline workers: The BALM programme

Acronym
BALM

Study objectives
Adapting and tailoring the design and delivery of a behavioural activation intervention will improve mental health outcomes and improve rates of engagement and adherence to treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2022, South West – Frenchay Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 1048106; frenchay.rec@hra.nhs.uk), ref: 22/SW/0113

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Prevention of low mood and anxiety

Interventions
This pre-post intervention study (n = ~45) will assess engagement, retention, effectiveness and acceptability or satisfaction with the intervention from male participants' and coaches' perspectives. Quantitative analysis will involve data collection at pre-treatment and two follow-up time points at 4 and 6 months using the following standardised outcome measures; the PHQ-9 to measure depression severity, the GAD-7 to measure anxiety severity and the SF-12 to measure health-related quality of life). The proportion of participants who show deterioration, no change or improvement in symptoms will be determined using pre-post effect sizes for the three measures.
Qualitative analysis will explore men's experiences, the acceptability of the intervention, and barriers and facilitators to delivery. In-depth, face-to-face interviews will be conducted with men who complete the BALM study (n = ~20) and coaches who support the delivery of the intervention (n = ~10). Considering the complex work pattern of frontline workers and the potential for Covid-19 restrictions, these will be conducted confidentially via telephone or video call unless the participant requests a face-to-face interview.
Participants will be purposively selected using a maximum variation approach to ensure representation from different demographics and occupational groups such as nurses, doctors, paramedics, porters and maintenance staff. Participants will be recruited from North West Ambulance Service (NWAS) NHS Trust, Tees, Esk and Wear Valleys(TEWV) NHS Foundation Trust and York and Scarborough Teaching Hospitals NHS Foundation Trust. Interview data will be analysed thematically using the Framework Approach and an a priori coding frame based on study objectives which focus on acceptability or satisfaction and the theoretical framework of acceptability (TFA), whilst also allowing for the emergence and exploration of any unanticipated themes. Coproduction will involve the formation of an advisory group consisting of a range of NHS stakeholders to advise on study materials, the conduct of research and dissemination of findings; and a consensus group consisting solely of men working in NHS roles across a variety of settings, to inform the development and tailoring of the intervention and delivery materials.
The research will span 24 months and be divided into two workstreams. Workstream one (1 to 8 months) is centered on adapting the Behavioural Activation intervention and will involve the recruitment of an advisory group and initial meetings to advise on study materials, along with the formation and conduct of the consensus group to advise on the iterative development of the intervention materials. Workstream two (9 to 24 months) will involve recruitment and training of coaches, recruitment of participants, intervention delivery, data collection, write-up and dissemination. Coaches delivering the intervention will be trained by BALM clinicians and will include a range of individuals from across a variety of settings (e.g. academia, primary care, secondary care, voluntary/third sector etc.). Information about BALM and the coach role will be circulated to relevant practitioner groups managers or service leads such as health and wellbeing boards within hospital trusts. Interested practitioners will discuss their suitability for the coach role with a clinical member of the BALM study team.

Intervention Type
Behavioural

Primary outcome measure
Depression and/or anxiety measured using standardised PHQ-9 or GAD-7 questionnaires at baseline, 4 and 6 months

Secondary outcome measures

The following outcomes will be measured at baseline, 4 and 6 months:
1. Assessment of the acceptability or satisfaction with the intervention from both male participant and coach viewpoints (including barriers and facilitators to implementation) during in-depth interviews
2. Levels of uptake, adherence or drop-out among participants measured by the number of participants recruited to the study against the target of 45. Drop-out will be measured by the number who withdraw or who leave the study, and adherence to the intervention will be assessed through the qualitative study through interviews with participants and coaches.
3. Health-related quality of life measured using the SF-12 questionnaire

Overall study start date
01/03/2022

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Identify as a man
3. Frontline worker (as defined by the NHS workforce census)
4. Score in the subclinical range (5-14) on the PHQ-9 or GAD-7

The inclusion criteria for the one-to-one interviews will be participants or coaches involved in the BALM intervention.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Total final enrolment
45

Key exclusion criteria
1. Currently receiving treatment for a mental health condition
2. Previously diagnosed with bipolar disorder, schizophrenia or other psychoses

Date of first enrolment

01/01/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West Ambulance Service NHS Trust
Ladybridge Hall
399 Chorley New Road
Bolton
United Kingdom
BL1 5DD

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
York Hospital
Wigginton Road
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YO31 8HE

Sponsor information

Organisation
University of York

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
Movember Europe

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal 2024/25

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary		28/06/2023	No	No
Results article	12/06/2025	16/06/2025	Yes	No