

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

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<b>Registration date</b> 02/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/06/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Paul Galdas

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

314095

ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

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

### Study type(s)

Treatment

### 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 (NWS) 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

Male

## 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

United Kingdom

England

## 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  
York  
United Kingdom  
YO31 8HE

**Sponsor information****Organisation**

University of York

**ROR**

<https://ror.org/04m01e293>

**Funder(s)****Funder type**

Charity

**Funder Name**

Movember Europe

# Results and Publications

## 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?
<a href="#">Results article</a>	Participant information sheet	12/06/2025	16/06/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes