ISRCTN79256498 https://doi.org/10.1186/ISRCTN79256498

A feasibility trial supporting employees with a clinical diagnosis of a mental health complaint and receiving treatment for mental health problems to remain engaged and productive at work

Submission date
11/06/2021

Recruitment status
No longer recruiting

Registration date
20/09/2021

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aim
Mental health problems affect one in six workers each year and are the leading cause of organisational (e.g., sickness absence, presenteeism, lost productivity) and individual-level problems (e.g., stress, anxiety and depression). The literature suggests that support from the organisation in the form of better support from managers, work arrangements and/or increased mental health awareness might help employees who are struggling the most to stay at work. Currently, employees with mental health problems who are in contact with NHS services often do not receive enough support from the organisation to remain engaged and productive in the workplace. Without early support, it is likely that employees with these difficulties might struggle to function well at work which may result in absenteeism.
To address these issues, this study aims to test an innovative intervention to help employees with a clinical diagnosis of mental health to stay well and productive at work. This intervention will test the feasibility and acceptability of a novel type of mental health practitioner: a trained Mental Health Employment Liaison Worker (MHELW) who will liaise between employers, employees, and NHS service providers and provide dedicated, optimised support and advice to keep workers with mental health problems at work and productive. We also aim to understand how the MHELW intervention was delivered, its acceptability, as well as barriers and enablers of participation in, and engagement with, the intervention.

The overall objective of this project is:
To examine the feasibility, acceptability and preliminary estimates of a 3-month Mental Health Employment Liaison Worker (MHELW) intervention in supporting the mental health and productivity of employees with a clinical diagnosis of mental health problems who are working.

Who can participate?
Employees aged ≥18 years with a clinical diagnosis of a mental health disorder, currently

receiving care for mental health problems through NHS services. Exclusion criteria include employees, currently in acute mental health crisis as defined by their clinical team; currently on extended sick leave (>4 weeks); or receiving input from an Individual Placement and Support (IPS) worker; or planning to retire within the next 10 months and unable to complete intervention and evaluation. In order to take part, you will also need to be willing to work with the MHELW and attend joint sessions with your line manager delivered by the MHELW both face-to-face and online.

What does the study involve?
In order to take part in the study, we first need to understand whether you meet the study's eligibility criteria. A pre-screening questionnaire will be sent out through an online survey platform (Qualtrics). If employees are eligible, they will be allocated by chance (by a computer) to either receive the intervention (support from MHELW) or allocated to a control group at first instance, to receive the intervention with a delay of 3 months.
The intervention is structured around three topic areas: 1) How to stay well and productive at work, 2) How to have open conversations at work, 3) Dealing with challenging situations at work. The intervention specifically aims to increase engagement at work, interpersonal relationships at work and psychological flexibility.
Each employee or manager will overall attend three x 1-hour individual sessions and four 1-hour joint session. The intervention will involve a total of ten x 1-hour sessions with the manager. Employees and managers will be asked to complete a number o different questionnaires at baseline and at three-month post-intervention. They will be also invited to take part in an interview which is expected to last between 45 to 90 minutes. This will help us ascertain their views of the MHELW intervention and whether the support they have received helped them remain engaged and productive at work.

What are the possible benefits and risks of participating?
We do not anticipate any risk-taking part in this study. Participants may be randomly placed into a control group. The control group serves as a comparison for the intervention group to help us determine whether the intervention had an effect. Participants in the control group will be provided with the opportunity to be supported by a MHELW after a short delay following a 3-month period (the intervention period). During the interview, sometimes participants may be asked questions about certain topics which are sensitive or upsetting. Participants can refuse to answer any questions which they feel uncomfortable with, in such case the interview will be stopped immediately.

Where is the study run from?
The study is organised by the University of Birmingham (UK), in collaboration with the University of Warwick and the mental health charity Mind.

When is the study starting and how long it is expected to run for?
March 2021 to December 2022

Who is funding the study?
Midlands Engine (UK)

Who is the main contact?
Professor Steven Marwaha, s.marwaha@bham.ac.uk
Dr Arianna Prudenzi, a.prudenzi@bham.ac.uk
Dr Feroz Jadhakhan, f.jadhakhan@bham.ac.uk

Study website

https://mhpp.me/employers/pilot-trials/

Contact information

Type(s)
Scientific

Contact name
Prof Steven Marwaha

ORCID ID
http://orcid.org/0000-0002-0303-9942

Contact details
Institute for Mental Health
52, Pritchatts Road
Edgbaston
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)1214143665
s.marwaha@bham.ac.uk

Type(s)
Scientific

Contact name
Dr Feroz Jadhakhan

ORCID ID
http://orcid.org/0000-0002-4545-3703

Contact details
Institute for Mental Health
52, Pritchatts Road
Edgbaston
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)1214143665
f.jadhakhan@bham.ac.uk

Type(s)
Scientific

Contact name
Dr Arianna Prudenzi

ORCID ID
http://orcid.org/0000-0002-5185-2807

Contact details
Institute for Mental Health
52, Pritchatts Road
Edgbaston
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)1214143665
a.prudenzi@bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293809

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 6.0 , IRAS 293809, CPMS 49326

Study information

Scientific Title
Supporting managers and their employees with Mental hEalth problems to remain eNgaged and producTive at wORk (MENTOR): A feasibility randomised controlled trial testing a workplace intervention delivered by a Mental Health Employment Liaison Worker (MHELW)

Acronym
MENTOR

Study objectives
This is a feasibility pilot trial aiming to test whether a Mental Health Employment Liaison Worker (MHELW) intervention is acceptable and feasible in supporting employees with a mental disorder and currently receiving treatment by an NHS healthcare provider to remain engaged and productive, compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2021, University of Birmingham's Science, Technology, Engineering and Mathematics, Research Ethics Committee (Research Support Group C Block Dome (room 137)

Aston Webb Building University of Birmingham Edgbaston B15 2TT, UK; +44 (0)121414 8101; s.l.cottam@bham.ac.uk), ref: ERN-20-1813

Study design
Feasibility randomized controlled trial with a 3-month MHELW intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Clinical diagnosis of a mental disorder

Interventions
Manualised intervention involving 10 x 1-hour meetings with a Mental Health Employment Liaison Worker (MHELW) over a three-month period. Employees and line managers will receive 7 sessions each, 3 of which are individual and 4 of which are joint sessions.
The control group will receive the same intervention with a delay of 3 months.

Randomisation will be carried out via a computer-generated random allocation sequence by a researcher independent to the study.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability outcomes:
1. Recruitment in a 5-month recruitment period measured using participant records
2. Retention rate as measured by attendance at the post intervention assessment
3. Estimates of eligible participants recruited, failures to recruit due to recruitment issues, and participants dropping out due to feasibility issues measured using participant records at 3 months
4. Completion rate of study questionnaires (employee and line manager) at baseline and 3 months for both intervention and control groups, reported as percentage missing data for each assessment schedule at baseline and 3 months
5. Participants attending ≥ 70% of the sessions (5 out of 7 individual sessions) measured using participant records
6. Estimate agreement rate of MHELW, whether each of the intervention sessions were delivered as intended measured using self report by MHELW at 3 months

7. Estimates of failures to recruit due to lack of acceptability, participants dropped out due to lack of acceptability, and adverse or serious adverse events measured using participant records at 3 months

Other outcomes:
8. Work productivity (measured at baseline and 3 months) measured by the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH) scale.

Secondary outcome measures
Intended secondary outcomes (measured at baseline and 3 months): Employee
1. Job satisfaction measured using the Indiana Job Satisfaction Scale
2. Anxiety measured using the General Anxiety Disorder-7
3. Depression measured using the Patient Health Questionnaire-9
4. Health-related quality of life measured using the Euro-Qol-five-dimensional scale
5. Sense of control using the Sense of Control scale
6. Decisional conflict using the Decisional Conflict scale
7. Days taken off sick in the last month (self-reported)

Intended secondary outcomes (measured at baseline and 3 months): Line manager
1. Mental health knowledge measured using the mental health knowledge scale (MAKS)
2. Attitude about mental health measured using personal depression stigma scale
3. Managers' self-efficacy surrounding mental health measured using general self-efficacy scale
4. Managers' intentions to promote mental health in the workplace measured using safety promotion intention scale
5. Job related burnout measured using the Shirom-Melamed burnout scale
6. Individual work performance measured using the individual work performance questionnaire

Process Evaluation
The process evaluation will use a mixed methods approach.

Overall study start date
23/03/2021

Completion date
05/12/2022

Eligibility

Key inclusion criteria
1. Adult workers with a clinical diagnosis of a mental disorder, who are currently receiving treatment by an NHS healthcare provider
2. Employees with a clinical diagnosis of a mental disorder
3. Employees currently receiving care for mental health problems through NHS services
4. Aged ≥18 years
5. Able to give written informed consent
6. Fluent in English
7. Willing to work with the MHELW and their business line manager

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28 per arm

Key exclusion criteria
1. Currently in acute mental health crisis as defined by their clinical team
2. Currently on extended sick leave (i.e., >4 weeks)
3. Receiving input from an Individual Placement and Support (IPS) Worker
4. Planning to retire within the next 10 months and unable to complete intervention and evaluation

Date of first enrolment
11/06/2021

Date of final enrolment
15/09/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Perfect Home
Eagle Court 2, Hatchford Way
Sheldon
Birmingham
United Kingdom
B26 3RZ

Study participating centre
Pathfinder Schools
Greening road
Rothwell
Northampton
United Kingdom
NN14 6BB

Study participating centre
CCM Group Ltd
3-4 Nunn Brook road
Huthwaite
Nottingham
United Kingdom
NG17 2HU

Study participating centre
Mice and Dice Ltd
17, Pool Dam
Newcastle
United Kingdom
ST4 2RP

Study participating centre
tna Europe
166, Clapgate lane
Birmingham
United Kingdom
B32 3DE

Study participating centre
Birmingham City Council
Council House
Victoria square
Birmingham
United Kingdom
B1 1BB

Study participating centre
The Royal Wolverhampton NHS Foundation Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 OQP

Study participating centre
Leicester City Football Club
King Power Stadium
Filbert Way
Leicester
United Kingdom
LE2 7FL

Study participating centre
University of Warwick
Wellbeing support services
Coventry
United Kingdom
CV4 7AL

Study participating centre
D2N2 Local enterprise partnership
8, Experian way
ng2 business park
Nottingham
United Kingdom
NG2 1EP

Study participating centre
NTT UK Ltd
Darwin house
Lichfield South
Birmingham Road
Lichfield
United Kingdom
WS14 0QP

Study participating centre
Conference Care
Hinckley
Leicester
United Kingdom
LE10 3EY

Study participating centre

H and W chamber of commerce
Severn House
Prescott Drive
Worcester
United Kingdom
WR4 9NE

Study participating centre
Micronclean Ltd
Holly road
Skegness
United Kingdom
PE25 3AX

Study participating centre
KP Snacks
5th Floor, The urban building
3-9 Albert Street
Slough
United Kingdom
SL1 2BE

Study participating centre
WJ
WJ North
7, Brockway
Knutton
Newcastle Under Lyme
United Kingdom
ST5 6A2

Study participating centre
Colas rail Ltd
25, Victoria street
London
United Kingdom
SW1H 0EX

Study participating centre
Street Heaven
The point, Weaver road

Lincolnshire
United Kingdom
LN6 3QN

Study participating centre
Jaguar Land Rover
Abbey road
Whitley
Coventry
United Kingdom
CV3 4LF

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Infirmary square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Cap Gemini
Stafford park II
Telford
Staffordshire
United Kingdom
TF3 3AY

Study participating centre
Noble Events
Grange barn
Syston Road
Cossington
Leicester
United Kingdom
LE7 4UZ

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
The Barberry, Research and Innovation Department
25, Vincent Drive

Edgbaston
Birmingham
United Kingdom
B15 2FG

Sponsor information

Organisation
University of Birmingham

Sponsor details
Aston Webb Building
Room 117
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 415 8011
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Midlands Engine

Results and Publications

Publication and dissemination plan

We aim to publish our main trial findings in high impact, peer reviewed and open access journals (e.g., Lancet, BMJ). We will also publish our results on our Mental Health Productivity Pilot (MHPP) website (https://mhpp.me/).

Intention to publish date
20/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored on the University of Birmingham server. Access to personal data personal is limited to the trial management team, the CI and the Research Fellows. The pseudo-anonymised study data and anonymised interview transcript will be deleted after 10 years from the Research Data Store on the University of Birmingham servers. Study data and personally identifiable data collected in this study will be stored in password protected files stored on the University of Birmingham Research Data Store (RDS) and back-up following UoB back-up and retention policy. All personal data is stored in a master file, separate from the outcome data collected as part of the study. The master file and the outcome data will only be accessible by the CI and the study research fellow. The master file will also contain participants pseudo-anonymised study IDs. The master file will exist as a password protected *.xlsx file on RDS of the University of Birmingham servers. A separate password protected file consisting only of contact data (Name, email address and phone number and postal address) without pseudo-anonymised study IDs, will be accessible to UoB trial management team (CI, and research fellow) stored on RDS of the University of Birmingham servers. Participants has agreed to their pseudo-anonymised research data being used in future research which has ethics approval. Once we have analysed the results, we will publish them in peer-reviewed medical or healthcare journals. We will also publish our results on our Mental Health Productivity Pilot (MHPP) website (https://mhpp.me/), and the study findings will also be summarised in the final study report. Participants will not be identified in any publication.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/04/2023	27/04/2023	Yes	No