# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
11/06/2021	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
20/09/2021	Completed	Results
Last Edited	Condition category	Individual participant data
10/10/2023	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>

### 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 faceto-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
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Dr Feroz Jadhakhan, f.jadhakhan@bham.ac.uk

### **Contact information**

### Type(s)

Scientific

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### Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

293809

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### Study type(s)

Other

### 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(s)

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  $\geq$  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.

### Key secondary outcome(s))

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.

### 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

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### 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

**United Kingdom** 

England

### 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

### **ROR**

https://ror.org/03angcq70

### Funder(s)

### Funder type

Government

### **Funder Name**

Midlands Engine

### **Results and Publications**

### 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

Participant information sheet

 Participant information sheet
 11/11/2025
 11/11/2025
 No
 Yes

 Study website
 11/11/2025
 11/11/2025
 No
 Yes