ISRCTN11723441 https://doi.org/10.1186/ISRCTN11723441

Randomised controlled trials of interventions to improve NHS staff stress and wellbeing

Submission date
14/06/2017

Recruitment status
No longer recruiting

Registration date
16/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims:
The 2016 NHS Staff Survey found that 37% of staff reported feeling unwell due to work-related stress and pressure and the cost of sickness absence in the NHS has been estimated at £2.4 billion a year or 2.5% of the entire NHS budget. In addition, there is a need to improve the delivery of effective, safe and compassionate patient care. A recent review found that CBT-based stress management interventions (a program which aims to reduce stress by changing the way people think and behave) have the strongest evidence for effectiveness in workplace settings in reducing stress and mental health symptoms. There has also been a growing interest in mindfulness-based interventions (MBIs: programs which help people to become more aware of themselves and everything around them) for healthcare staff, which several studies have shown to be effective. Although both of these programs have been shown to be effective, it is unknown whether the benefits are seen on objective indicators of work-related stress, such as sickness absence, or if they expend to helping staff provide higher quality care.

Who can participate?
Adults currently employed at a participating hospital trust.

What does the study involve?
Participants are given a preference as to whether they wish to take part in a one day CBT-based stress management workshop or an eight or nine session MBI. Staff will then be randomly allocated to either start their preferred intervention in the immediate future (within three months) or at a later date (in at least six months). Participants are invited to complete questionnaires about stress, depression, anxiety, compassion, wellbeing, burnout, mindfulness (for those undertaking the MBI), sickness absence, and being present at work online at the start of the study, after completing the program and then six months later. The first ten participants in each program who complete these measures are also invited to take part in an optional phone interview about their experiences.

What are the possible benefits and risks of participating?
Potential benefits of participating include the opportunity to undertake a course which has been found to promote positive mental health and wellbeing and contributing to research which may inform the implementation of wellbeing courses across the NHS to improve outcomes in other

staff. There is a risk that some course techniques may involve reflecting on thoughts, feelings, and experiences, which can sometimes be distressing. Participants are free to stop taking part at any time, without having to give a reason.

Where is the study run from?
1. Sussex Partnership NHS Foundation Trust (UK)
2. Surrey and Borders NHS Foundation Trust (UK)
3. Kent and Medway Partnership NHS Foundation Trust (UK)
4. Sussex Community NHS Foundation Trust (UK)

When is study starting and how long is it expected to run for?
February 2017 to October 2018

Who is funding the study?
Health Education England; Kent, Surrey, and Sussex (UK)

Who is the main contact?
1. Ms Jenny Gu (public)
2. Dr Clara Strauss (scientific)

Contact information

Type(s)
Public

Contact name
Ms Jenny Gu

Contact details
School of Psychology
University of Sussex
Falmer
United Kingdom
BN1 9RH

Type(s)
Scientific

Contact name
Dr Clara Strauss

Contact details
School of Psychology
University of Sussex
Falmer
United Kingdom
BN1 9RH

Additional identifiers

EudraCT/CTIS number

IRAS number
224584

ClinicalTrials.gov number

Secondary identifying numbers
IRAS Project ID: 224584

Study information

Scientific Title
Randomised controlled trials of mindfulness-based and cognitive behavioural therapy-based (CBT-based) courses to improve NHS staff stress and wellbeing with participant preference

Study hypothesis
Primary hypothesis:
For NHS staff both interventions will be more effective compared to wait-list at reducing stress at post-intervention.

Secondary hypotheses:
Both interventions will be more effective than wait-list at:
1. Reducing anxiety symptoms
2. Reducing depression symptoms
3. Reducing work-related burnout
4. Improving compassion for self and others
5. Improving wellbeing
6. Reducing sickness absence
7. Improving mindfulness (administered to participants randomised to the mindfulness intervention or waiting list for the mindfulness intervention only)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jarrow Health Research Authority, 31/05/2017, ref: 18/HRA/0049.

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Condition
Stress and wellbeing

Interventions
Participants will be given a choice between two interventions:

Intervention 1: Group Mindfulness-Based Cognitive Therapy (MBCT). This is an 9-week group intervention (including an orientation session) where participants are trained in mindfulness meditation techniques and techniques from CBT. The groups will closely follow the MBCT manual (Segal et al., 2002, 2012) and will be led by MBCT teachers. Each group will consist of 10 to 15 participants. Each session will take 2 hours and participants will be invited to complete approximately 45 minutes per day of homework. Content in the sessions will include guided mindfulness practices, inquiry into experiences following practices, weekly homework review, and teaching/discussion of CBT skills. The teachers will have completed MBCT teacher training and will meet accreditation criteria set out by the UK Network of Mindfulness Teacher Trainers.

Intervention 2: One day Cognitive Behavioural Therapy (CBT)-based stress management workshop. This workshop will teach participants CBT-based stress management techniques and will be facilitated by two mental health practitioners. Participants will also be given self-help resources to take away. Each workshop will consist of around 10 to 20 participants.

They will then be randomised to receive their preferred intervention in the the immediate future (within the next 3 months; intervention arm), or at a later time (in 6 months' time or later; waitlist arm), in a ratio of 1:1. Block randomisation, with researchers blind to block size, will be conducted.

Participants randomised to start their preferred intervention in the immediate future will be assessed at baseline, post-intervention, and follow-up (6 months from post-intervention). They will be asked to complete the same set of self-report measures at each time point, with the exception of demographic questions (baseline only) and engagement questions (post-intervention and follow-up only). Participants randomised to the waitlist arm will be asked to complete self-report measures at baseline and post-intervention only.

Intervention Type
Other

Primary outcome measure
Stress is measured using the stress sub-scale from the short version of the Depression Anxiety and Stress Scales (DASS-21) at baseline, post-intervention, and six months follow-up.

Secondary outcome measures
1. Depression is measured using the depression subscale from the short version of the Depression Anxiety and Stress Scales (DASS-21)
2. Anxiety is measured using the anxiety subscale from the short version of the Depression Anxiety and Stress Scales (DASS-21)

3. Compassion is measured using the Compassion Scale
4. Wellbeing is measured using the Short Warwick Edinburgh Mental Wellbeing Scale
5. Burnout is measured using the Maslach Burnout Inventory – Human Services Survey
6. Mindfulness is measured using the 15-item Five Facet Mindfulness Questionnaire (FFMQ)
7. Sickness absence. This will be the number of sickness absence days taken in the three months following the intervention period (e.g., the three months following the end of the intervention for intervention participants). Equivalent data from the same three-month period in the previous calendar year will be obtained as a baseline measure for each participant. Participants will also be asked to self-report sickness absence in the past three months at all time points.
8. Presenteeism is measured using items from the Institute for Medical Technology Assessment Productivity Cost Questionnaire

All outcome measures, with the exception of objective sickness absence data which are requested at the end of the study, will be administered at baseline and post-intervention to all participants and additionally at six-month follow-up for intervention participants. The FFMQ will be administered to participants randomised to MBCT or waiting list for MBCT only. Demographic data (e.g., gender, age, ethnicity, marital status, education level) will be recorded at baseline only and engagement measures (e.g., number of days/week using the preferred intervention) will be administered at post-intervention and follow-up only, for those randomised to the intervention arms.

Overall study start date
14/02/2017

Overall study end date
31/10/2018

Eligibility

Participant inclusion criteria
1. Employed by (or working in an honorary/voluntary capacity for) Sussex Partnership NHS Foundation Trust, Surrey and Borders NHS Foundation Trust, Kent and Medway Partnership NHS Foundation Trust, or Sussex Community NHS Foundation Trust
2. Currently in work (i.e. not currently on sick leave)
3. Have sufficient English language ability to understand intervention information and questionnaire content
4. Aged 18+ years

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

The study aims to recruit 600 staff into the MBCT part of the trial and 1000 staff into the CBT-based workshop part of the trial.

Total final enrolment
234

Participant exclusion criteria
There are no exclusion criteria

Recruitment start date
01/07/2017

Recruitment end date
01/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Priority House
Hermitage Lane
Maidstone
United Kingdom
ME16 9PH

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Leatherhead
United Kingdom
KT22 7AD

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
1st Floor Millview Hospital,
Nevill Avenue
Hove
United Kingdom
BN3 7HZ
+44 (0)300 304 4389
ResearchGovernance@sussexpartnership.nhs.uk

Sponsor type
Other

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
Health Education England; Kent, Surrey, and Sussex

Results and Publications

Publication and dissemination plan

Findings will be written up for publication in a peer-reviewed journal article. The intention to publish date is around one year after the overall trial end date. Findings from this trial may also be disseminated in poster and oral presentations at conferences and seminars.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made 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?
Participant information sheet	version V1	24/04/2017	21/09/2017	No	Yes
Protocol article	protocol	02/04/2018		Yes	No
Results article		18/02/2021	11/07/2023	Yes	No