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Is self-help mindfulness-based cognitive therapy beneficial for healthcare staff? A pilot randomised controlled trial

Submission date
07/11/2014

Recruitment status
No longer recruiting

Registration date
25/11/2014

Overall study status
Completed

Last Edited
21/12/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Stress and other mental health difficulties are among the most common reasons for staff sickness absence in the National Health Service (NHS) in the UK and cultivating greater compassionate care has been identified as vital within the NHS. Providing more psychological support for NHS staff has the potential to reduce stress, improve well-being, reduce the number of working days lost to sickness absence and improve job satisfaction. It may also result in greater retention of staff and an improvement in the quality of patient care. Mindfulness is a mind-body approach to well-being. It is designed to help people change how they feel about experiences and reduce levels of stress and anxiety. Evidence suggests that group mindfulness-based interventions (treatments) can help a wide range of people, including healthcare staff. Self-help mindfulness-based interventions (MBIs) have the potential to provide this treatment in a low-cost, accessible and acceptable way and there is growing evidence that self-help MBIs can lead to lower levels of stress, anxiety and depression for a number of different groups of people. However, little is known about the potential of self-help MBIs for healthcare staff. This study is a small-scale, or pilot, study that will help in the development of a larger, full-scale one.

Who can participate?
Healthcare workers aged at least 18 that work in a particular mental health NHS trust, that have not previously completed a mindfulness-based programme, are happy to not use any other form of psychological treatment during the course of the study and have English language reading skills good enough to read and understand a self-help book.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given an unguided 8-week MBI (MBCT-SH) intervention and those in group 2 are placed in a wait-list (control). The MBCT-SH intervention uses a self-help book with a CD of audio-guided mindfulness practices ‘Mindfulness: a practical guide to finding peace in a frantic world’ (Williams & Penman, 2011). Staff levels of stress, compassion for others, and sickness absence alongside with depression, anxiety, self-compassion, burnout and well-being are assessed before the study begins, when the study ends and 3 months later.

What are the possible benefits and risks of participating?
Potential benefits of taking part include contributing to research on how to support healthcare staff well-being as well as directly benefiting from the self-help course. The self-help course teaches participants to bring non-judgmental awareness to current experiences, allowing them to come and go without trying to control them. This can mean becoming more aware of difficult thoughts and feelings that are present which some people can find troubling, and this presents a risk in the study. In order to address this, participants are signposted to sources of support, including contacting the study Chief Investigator who is a clinical psychologist and mindfulness teacher.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2014 to June 2015

Who is funding the study?
Sussex Partnership NHS Foundation Trust (UK)

Who is the main contact?
Dr Clara Strauss
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A pilot randomised controlled trial of self-help Mindfulness-Based Cognitive Therapy (MBCT) for healthcare staff

Acronym
MindSHINE (Mindfulness Self-Help Intervention for NHS Employees)

Study objectives
It is not appropriate to conduct hypothesis testing in a pilot study as, by definition, the study is likely to be underpowered. Rather, this pilot RCT aims to establish if trial procedures are successful and the study also aims to calculate the between-group effect size for Mindfulness-Based Cognitive Therapy self-help (MBCT-SH) in comparison to the waitlist control condition for primary outcome measures. These effect sizes will be used to conduct a sample size calculation for a definitive trial. If the effect sizes are in favour of MBCT-SH then funding for a full trial will be sought.

There are three specific main aims of this pilot study:
1. To establish if trial procedures are successful prior to a definitive trial
2. To investigate whether MBCT-SH appears to be beneficial for participants in reducing stress and in improving psychological wellbeing (i.e. if effect sizes are in the direction hypothesised for the definitive trial)
3. To investigate whether MBCT-SH for NHS employees has the potential to improve the quality of patient care (i.e. if effect sizes on the measure or other-compassion are in the direction hypothesised by the definitive trial)

Primary hypotheses for the definitive trial will be:
1. MBCT-SH participants in comparison to waitlist control participants will show a reduction in symptoms of stress and this improvement will be maintained at the three months follow-up.
2. MBCT-SH participants in comparison to waitlist control participants will show improvements in other-compassion and this improvement will be maintained at the three months follow-up
3. MBCT-SH participants in comparison to waitlist control participants will show a reduction in the number of sickness absence days from the three months preceding the intervention to the three months following the intervention.

Secondary hypotheses for the definitive trial are that MBCT-SH participants, in comparison to waitlist control participants, will show improvements in mindfulness, self-compassion, anxiety, depression, burnout and mental well-being, and these improvements will be maintained at the three-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
As this study is for NHS staff it does not require NHS ethics approval. According to NRES, where NHS staff are participants then R&D approval is needed but NRES approval is not needed. The study has R&D approval in the host trust (Sussex Partnership NHS Foundation Trust) with approval number 5043-2014.

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mental health

Interventions
Mindfulness-Based Cognitive Therapy (MBCT) is an 8-week group intervention with a wealth of evidence for effectiveness at improving mental health, including for healthcare staff. This study will use a self-help version of MBCT as the tested intervention. Participants in the MBCT-SH condition will be given a copy of the self-help book 'Mindfulness: A practical guide to finding peace in a frantic world' by Mark Williams and Danny Penman (2011), with Mark Williams being one of the people who developed the original MBCT course. This book provides four introductory chapters followed by an 8-week self-guided MBCT course, including mindfulness practices provided on an accompanying CD. Participants will receive a standardised weekly email to encourage them to continue with the self-help course but no specific individualised, tailored support will be given.

Intervention Type
Behavioural

Primary outcome measure
1. Stress: The stress subscale of the Depression Anxiety Stress Scales (DASS-21). The DASS-21 is a short version of the 42-item DASS. The DASS-21 is a set of three 7-item self-report scales designed to measure stress, depression, and anxiety. Each of the 21 items describes a negative state and participants are asked to use a 4-point Likert-type scale to rate the extent they have experienced this state over the past week. The DASS-21 subscales have been found to validly measure stress, anxiety and stress; in non-clinical populations, as well as tapping a more general dimension of psychological distress. The internal consistency and concurrent validity of the scale and subscales have been reported to be in the acceptable to excellent ranges.
2. Compassion for Others: The Compassion Scale adapted for this study. We will use an adapted version of Neff and Pommiers scale. This 24-item scale measures compassion directed towards others and is based upon a definition of compassion adopted from Neffs model of self-compassion. Neffs model proposed that compassion entails kindness, common humanity, and

mindfulness. The compassion scale is composed of six subscales based on six factors: kindness vs indifference, common humanity vs separation, and mindfulness vs disengagement. The internal consistency, concurrent and convergent validity of the scale have been reported to be good. The adapted version includes 10 additional questions to broaden to scope of the measure in order to measure multiple aspects of compassion for others.
3. Sickness Absence: The number of days of sickness absence in the three months prior to the intervention and in the three months following the intervention, as recorded by the trust Human Resources department, will be used as a measure of days of sickness absence taken by participants

Secondary outcome measures

1. The anxiety and depression subscales of the Depression Anxiety Stress Scales (DASS-21): The anxiety and depression subscales of the DASS-21 will be used as a secondary outcome measure in the pilot and main trial. The internal consistency and concurrent validity of the scale and subscales have been reported to be in the acceptable to excellent ranges.
2. Five-Facet Mindfulness Questionnaire Short Form (FFMQ-SF): This 24-item scale assesses five facets of mindfulness. It has been reported to have good indices of reliability and validity. The FFMQ-SF will be used in the pilot and main trial to asses whether the MBCT-SH intervention has the intended effect of increasing mindfulness skills.
3. Self-compassion Scale Short Form (SCS-SF): The SCF-SF will be included in the pilot and main trial as a secondary outcome measure. Self-compassion is an important aspect of mindfulness (Kuken et al., 2010) not included in the FFMQ-SF. The 12-item SCS-SF yields a total self-compassion score. It has reported to have good reliability, validity, and internal consistency (Cronbachs alpha = 0.86). Further, it was found to have the same factor structure and to correlate almost perfectly with the longer form of the SCS (r = 0.98).
4. Short Warwick-Edinburgh Mental Well-being Scale (SWEMWS): The short version of the Warwick-Edinburgh Mental Wellbeing Scale is a 7-item measure of wellbeing. This will be used in the pilot and main trial to evaluate the effects of the intervention beyond changes in symptoms of psychological distress. It has been found to have good reliability, validity and internal consistency.
5. The Maslach Burnout Inventory (MBI): The MBI will is a 22-item self-report inventory using a Likert scale that measures three facets of job-related burnout: emotional exhaustion, depersonalisation, and reduced personal accomplishment. Several studies have found mindfulness-based interventions to be effective in decreasing job burnout as measured using the MBI. The MBI is the most widely used measure of burnout in the field, and its psychometrics and validity are well evidenced.
6. Intervention adherence: The number of participants in the MBCTSH intervention group who sufficiently complete the intervention will be recorded via self-report questions on the post-intervention questionnaire. Sufficient completion of the intervention is defined in line with the MBCT literature as at least 50% adherence to the intervention. In this study, 50% adherence for participants in the MBCT self-help intervention condition is defined as:
6.1. Reading at least 50% of the MBCT-SH book
6.2. Engaging with at least 4 mindfulness practices during the intervention
7. Participant Engagement: Participant engagement will be measured using a brief questionnaire that participants in the intervention group will be asked to complete weekly. The questionnaire will participants to indicate the duration and frequency of their engagement with the intervention materials (for example, time spent reading the book, number of chapters/pages read or online modules completed) and mindfulness exercises and practices (for example, duration and frequency of practice), on a Likert-type scale, in the past week. After the intervention has ended, all participants will be asked the same questions but in reference to the duration of the intervention.

Overall study start date
10/11/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Adults aged 18 or older
2. Are currently employed by the host mental health NHS trust in a role that involves direct delivery of healthcare, this is operationalised as having at least one day per week of direct contact with patients
3. Are currently in work
4. Are willing to refrain from engaging in another form of psychological intervention during the course of the study
5. Have not previously completed a mindfulness-based intervention where 'completed is defined as having undertaken 50% or more of a face-to-face delivered mindfulness-based intervention
6. Have self-reported sufficient English language reading ability to read and understand the self help book

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2014

Date of final enrolment
26/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sussex Partnership NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from Dr Clara Strauss (c.y.strauss@sussex.ac.uk) upon reasonable request.

IPD sharing plan summary
Available on request