

Mindfulness-based training to promote the well-being of NHS staff

Submission date 11/10/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/04/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of this research is to implement and evaluate mindfulness-based training programs for improving the psychological well-being of healthcare staff in the United Kingdom. Our two primary aims are to: 1) compare the effectiveness of two popular mindfulness interventions for improving staff well-being over a six-month evaluation period; and 2) increase understanding about how these workplace training programs produce their effects.

Who can participate?

Staff aged over 18 working at the host trust who had volunteered for the well-being training and research

What does the study involve?

We compared the effects of two popular mindfulness interventions currently being delivered in workplace settings: Mindfulness training (MT), and acceptance and commitment therapy (ACT). The MT and ACT programs were delivered to small groups of UK healthcare staff over 4 training sessions, with each session lasting 2 hours. To evaluate the effects of the two programs, we randomly allocated employees to attend MT, ACT, or to a waiting list comparison group. All participants completed a range of well-being questionnaires on five occasions that were spread across a six month evaluation period. We were particularly interested in investigating whether the two workplace training programs are equally effective for improving staff well-being, and whether they help to develop the same types of mindfulness and behavioural skills.

What are the possible benefits and risks of participating?

Staff members participating in this training are likely to experience improved well-being. More specifically, following attendance at the MT or ACT programs we expected to see improvements in general mental health, perceived stress, and sleep quality, and a reduction in work limitations due to stress-related difficulties. No significant risks were foreseen. Participation in all training techniques was presented as voluntary and invitational. Participants were informed about additional staff support services should they have felt the need for additional psychological intervention or support.

Where is the study run from?
South London and Maudsley NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
November 2011 to May 2013

Who is funding the study?
Guy's and St Thomas' Charity, UK

Who is the main contact?
Dr Paul Flaxman
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

G101017

Study information

Scientific Title

Comparison of two mindfulness interventions in the workplace: A randomised controlled trial

Study objectives

1. A mindfulness training (MT) program and a program based on acceptance and commitment therapy (ACT) will lead to improvements in employees' well-being over a six month evaluation period
2. The effects of both programs on employees' well-being will be mediated via the cultivation of a mindful (i.e., nonjudgmental or nonreactive) attitude towards difficult internal states
3. The ACT program will show a stronger effect on employees' propensity to engage in values-based action than the MT program

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/01/2012, King's College London Institute of Psychiatry R&D office (De Crespigny Park, Denmark Hill, London, SE5 8AF, UK; +44 (0)20 78480790; jennifer.liebscher@kcl.ac.uk), ref: R&D2012/003

Study design

A single-centre interventional randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Occupational health (promoting staff well-being and mental health)

Interventions

A single-centre study. Participants (NHS staff) were randomised to attend a 4-session group-format MT program, a 4-session group-format ACT program, or to a waiting list control group. Each training session in the MT and ACT programs lasted for 2 hours. Self-report study measures were administered on five occasions spread over a six-month evaluation period.

Mindfulness training: A 4-session group format staff training program based on the principles and practices of mindfulness-based stress reduction.

Acceptance and commitment therapy (ACT): A 4-session group format staff training program based on the principles and practices of acceptance and commitment therapy.

A waiting list control group: Participants allocated to this group were placed on a waiting list to receive either MT or ACT in six months time.

Participants were allocated to one of the three study conditions by a member of the research team using a block randomization procedure (via www.randomisation.com).

The MT and ACT programs were delivered by Dr. Vasiliki Christodoulou, a counselling psychologist and cognitive-behavioral therapist registered with the British Psychological Society and the UK's Health and Care Professions Council (HCPC). Dr. Christodoulou had previous experience of delivering both MT and ACT in clinical and non-clinical settings. Throughout the training delivery period, the trainer attended regular supervision with two clinical psychologists involved in the study

Intervention Type

Other

Primary outcome measure

General health measured using the general health questionnaire at five timepoints between baseline and 6-months

Secondary outcome measures

The following measures were also administered at all 5 measurement timepoints (baseline to 6-months):

1. Perceived stress scale
2. Abbreviated version of the Work Limitations Questionnaire
3. Sleep disturbance (subscale of the Physical Health Questionnaire)
4. Activity and circumstances change questionnaire
5. Behavioural activation for depression scale (BADS-10)
6. Three facets from the five facet mindfulness questionnaire (FFMQ)
7. The valuing questionnaire (VQ)
8. The acceptance and action questionnaire II (AAQ II)

Overall study start date

03/09/2010

Completion date

03/05/2013

Eligibility

Key inclusion criteria

1. Staff working at the host NHS trust
2. Aged 18 or over,
3. Volunteered for the well-being training and research

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

30/11/2011

Date of final enrolment

31/05/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

South London and Maudsley NHS Foundation Trust

Maudsley Hospital

Denmark Hill

London
United Kingdom
SE5 8AZ

Sponsor information

Organisation

City, University of London

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Sponsor type

University/education

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ROR

<https://ror.org/04489at23>

Organisation

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BR3 3BX
+44(0) 20 3228 6000.
vasochrist@hotmail.com

Sponsor type

Hospital/treatment centre

Website

<https://www.slam.nhs.uk/>

ROR

<https://ror.org/015803449>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' Charity

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 21/01/2022:

A first paper is being prepared to report comparison of the effects of MT and ACT on the primary outcome measure (GHQ-12); this study will also assess whether the effects of the programs on employees' general mental health are mediated via the same mindfulness skills. A second paper will examine effects of the two interventions on the trial's secondary outcomes, namely sleep quality, perceived stress, and work limitations.

A second planned paper will report on the effects of the two programs on secondary (non-clinical) outcome measures, particularly perceived stress, sleep quality, and work limitations.

Previous publication and dissemination plan:

A first paper is being prepared to report comparison of the effects of MT and ACT on the primary outcome measure (GHQ-12); this study will also assess whether the effects of the programs on employees' general mental health are mediated via the same mindfulness skills.

A second planned paper will report on the effects of the two programs on secondary (non-clinical) outcome measures, particularly perceived stress, sleep quality, and work limitations.

Intention to publish date

01/12/2022

Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing statement as of 21/01/2022:

The datasets generated during and/or analysed during the current study will be available upon request from: Dr. Paul Flaxman, City, University of London. Email: Paul.Flaxman.1@city.ac.uk. The raw data are in a SPSS file, saved on Dr. Flaxman's password protected University computer. The data will be available from January 2020 for a proposed period of 10 years, to support publication. Once we have published the main outcome and mediation findings, we are happy to respond to requests to share the full dataset with fellow researchers/ journal reviewers who wish to check our analyses, or for meta-analytic review purposes. Participants were informed at the study's outset of the team's intention to publish results of the study in scientific journals and through various NHS outlets. Participants were informed that they would not be personally identified in any reports of the findings. In the raw dataset, all job titles, tenure, and other person- and organisation-identifiable data will have been removed.

Previous individual participant data (IPD) sharing statement:

The datasets generated during and/or analysed during the current study will be available upon request from: Dr. Paul Flaxman, City, University of London. Email: Paul.Flaxman.1@city.ac.uk. The raw data are in a SPSS file, saved on Dr. Flaxman's password protected University computer. The data will be available from January 2020 for a proposed period of 10 years, to support publication. We are happy to respond to requests to share the full dataset with fellow researchers/ journal reviewers who wish to check our analyses, or for meta-analytic review purposes. Participants were informed at the study's outset of the team's intention to publish results of the study in scientific journals and through various NHS outlets. Participants were informed that they would not be personally identified in any reports of the findings. In the raw dataset, all job titles, tenure, and other person- and organisation-identifiable data will have been removed.

IPD sharing plan summary

Available on request