ISRCTN13871025 https://doi.org/10.1186/ISRCTN13871025

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

Submission date
11/10/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
04/04/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 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
Paul.Flaxman.1@city.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Paul Flaxman

ORCID ID
https://orcid.org/0000-0002-6417-2499

Contact details
City, University of London
Psychology Department
Northampton Square
London EC1V 0HB
London
United Kingdom
EC1V 0HB
+44(0)2070408484
Paul.Flaxman.1@city.ac.uk

Type(s)
Scientific

Contact name
Dr Vasiliki Christodoulou

Contact details
University of Central Lancashire (Cyprus)
12 – 14 University Avenue Pyla, 7080 Larnaka, Cyprus
Larnaka
Cyprus
7080 Larnaka
+357 24694149
Vchristodoulou2@uclan.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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.Vasilki 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(s)
General health measured using the general health questionnaire at five timepoints between baseline and 6-months

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

ROR
https://ror.org/04489at23

Organisation
South London and Maudsley NHS Foundation Trust

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

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