Implementing workplace-adapted mindfulnessbased stress reduction in private companies

Submission date 14/02/2022	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol 	
Registration date	Overall study status	Statistical analysis plan	
15/02/2022	Completed	[X] Results	
Last Edited 16/03/2023	Condition category Mental and Behavioural Disorders	Individual participant data	

Plain English summary of protocol

Background and study aims

Mindfulness-based interventions (MBIs) are being implemented in many private and public workplaces. Previous research has shown MBIs in workplace settings to be effective in reducing perceived stress, symptoms of anxiety and depression as well as enhancing well-being. Recent research indicates that workplace MBIs facilitate enhanced communication and collaboration within the workplace. Practising mindfulness enables a greater awareness of one's own patterns of behaviour and can in effect enable individuals to be less reactive in situations of stress. Moreover, practising mindfulness facilitates greater compassion for yourself and others. These parameters may positively affect the psychological work environment. Prevously, the MBIs implemented in workplace settings varied in both the content and the length of the intervention. Therefore, there is a need to investigate the feasibility and impact of a documented effective MBI in workplace settings. One such intervention is the manualized programme, Mindfulness-based Stress Reduction (MBSR). Consequently, the aims of this study are:

1. To systematically develop a workplace-adapted Mindfulness-based Stress Reduction (MBSR) programme

2. To evaluate the feasibility of implementing a workplace-adapted MBSR program in small and medium-sized private companies

3. To evaluate the impact of a workplace-adapted MBSR programme on mental health and psychological work environment

Who can participate?

All employees and managers from small and medium-sized private companies

What does the study involve?

The study involves employees and managers from four small and medium-sized private companies. Each company receives an intervention consisting of three elements:

1. An obligatory 2-hour introductory session on mental health and mindfulness for all employees and managers

 A 10-week workplace-adapted MBSR-programme for self-selecting employees and managers
 The offer of participating in a workshop on further implementation of mindfulness in the company for selected managers and employee representatives All employees and managers receive electronic questionnaires at the start of the study, after the intervention and at 12 months follow-up. Selected employees and managers are asked to participate in focus group interviews at the start of the study and after the intervention.

What are the possible benefits and risks of participating?

Previous research has found MBSR effective in reducing stress, symptoms of depression and anxiety and enhancing well-being. There are indications that mindfulness in a workplace setting may facilitate healthier work environments with more constructive conflict management. There are no known risks of participating.

Where is the study run from?

The study is run from Denmark in a collaboration between the Danish Center for Mindfulness, Department of Clinical Medicine, Aarhus University and Southern University of Denmark

When is the study starting and how long is it expected to run for? January 2020 to February 2022

Who is funding the study? The Velliv Association (Denmark)

Who is the main contact: Lise Juul lise.juul@clin.au.dk

Contact information

Type(s) Principal Investigator

Contact name Dr Lise Juul

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 1715

Study information

Scientific Title

The feasibility and impact of implementing workplace-adapted mindfulness-based stress reduction in small and medium-sized private companies on the mental health and psychological work environment: a mixed-methods, quasi-experimental study

Study objectives

Hypotheses:

1. The mental health of individuals will improve following participation in a workplace-adapted Mindfulness-based Stress Reduction (MBSR) programme

2. Enhanced awareness through practising mindfulness will improve pro-social behaviour and interpersonal relations

3. Enhancements in pro-social behaviour and interpersonal relations among those choosing to participate in a workplace-adapted MBSR-programme are expected to affect the psychological work environment in the entire company

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/02/2020, The Danish Data Protection Agency (Carl Jacobsens Vej 35, 2500 Valby, DK; +45 (0)33193200; dt@datatilsynet.dk), ref: 2016-051-000001/1715

Study design

Quasi-experimental interventional trial without control group

Primary study design Interventional

Secondary study design Non randomised study

Study setting(s)

Other

Study type(s) Prevention

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

Individual mental health and psychological work environment promotion and prevention in private companies

Interventions

The intervention is three-fold:

1. 2-hour obligatory introductory sessions for all employees and managers within four small and medium-sized private companies

2. A 10-week workplace-adapted MBSR-programme for self-selected employees and managers within the respective companies

3. A 2-hour workshop for selected managers and employee representatives on further implementation of mindfulness in the companies following the MBSR-programme A certified MBSR teacher carries out both the two-hour introductory sessions and the workplaceadapted MBSR-programme. The workplace-adapted MBSR-programme is delivered in a live online format with one weekly 1.5-hour session. The workshop is led by an organizational psychologist, a scientific assistant and a certified MBSR teacher and delivered in a live online format.

Intervention Type

Behavioural

Primary outcome measure

Perceived stress level measured using Cohen's Perceived Stress Scale-10 (PSS-10) at baseline, post-intervention and at 12 months follow-up

Secondary outcome measures

Utilizing mixed methods, both quantitative and qualitative methods are used to evaluate the feasibility and impact of the intervention.

Quantitative evaluation:

1. Self-reported symptoms of depression and anxiety measured using Hopkins Symptom Check List-5 (SCL-5) at baseline, post-intervention and at 12 months follow-up

2. Self-reported well-being measured using Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) at baseline, post-intervention and at 12 months follow-up

3. Self-reported resilience measured using Brief Resilience Scale (BRS) at baseline, postintervention and at 12 months follow-up

4. Self-reported mindfulness practice measured using questions related to mindfulness practice at post-intervention and 12 months follow-up

5. Self-reported sleep measured using 6 items of the Karolinska Sleep Questionnaire at baseline, post-intervention and at 12 months follow-up

6. Social capital in the workplace measured using a questionnaire developed by the Danish National Institute of Occupational Health at baseline, post-intervention and at 12 months followup

7. Negative acts in the workplace measured using Negative Act Questionnaire-short (NAQ-S) at baseline, post-intervention and at 12 months follow-up

8. Self-reported dispositional mindfulness measured using Five Facet Mindfulness Questionnaire-15 (FFMQ-15) at baseline, post-intervention and at 12 months follow-up

9. Organizational conditions relating to the psychological work environment, such as social support and work-life balance, measured using questions from a questionnaire on psychological work environment developed by the Danish National Institute of Occupational Health at baseline, post-intervention and at 12 months follow-up

Qualitative evaluation:

 Data on participants' knowledge of mindfulness, perceived stress and stress management, organizational conditions for psychological work environment and knowledge of facilitators and barriers to implementation, collected using semi-structured focus group interviews with both employees and managers in each company at baseline and post-intervention
 Team psychological safety measured using the 7-item scale developed by Amy Edmundson at baseline, post-intervention and at 12 months follow-up

Overall study start date

01/01/2020

Completion date

01/02/2022

Eligibility

Key inclusion criteria

1. For companies to enroll in this trial, they have to be a small or medium-sized private company (10-250 employees and managers)

2. All employees and managers within the enrolled companies are eligible for inclusion

Participant type(s) Other

Age group All

Sex Both

Target number of participants

According to power calculations, a number of 150 participants are required to detect a mean change of 1.5 point on the PSS-score

Total final enrolment 250

Key exclusion criteria Companies with more than 250 employees

Date of first enrolment 28/02/2020

Date of final enrolment 04/12/2020

Locations

Countries of recruitment Denmark

Study participating centre Aarhus University

Danish Center for Mindfulness Hack Kampmanns Plads 1-3 4th floor Aarhus Denmark 8000

Study participating centre Southern University of Denmark Campusvej 55 Odense Denmark 5230

Sponsor information

Organisation Aarhus University

Sponsor details

Nordre Ringgade 1 Aarhus Denmark 8000 +45 (0)87150000 mindfulness@clin.au.dk

Sponsor type University/education

Website http://www.au.dk/en/

ROR https://ror.org/01aj84f44

Funder(s)

Funder type

Funder Name

The Velliv Association

Results and Publications

Publication and dissemination plan

 Planned publications in high-impact peer-reviewed journals
 Planned dissemination at international conferences regarding mental health and psychological work environment

Intention to publish date

01/02/2023

Individual participant data (IPD) sharing plan

Anonymized data will be available upon reasonable request from the Principal Investigator, Associate Professor Lise Juul (lise.juul@clin.au.dk). The quantitative data will be available for researchers following the publication of the results of the trial until 01/03/2025. The quantitative data can be used for replication of the analyses performed. Participants provided consent by completing baseline questionnaires, this being the standard protocol in Denmark when performing non-biological research. The qualitative data will not be made freely available but we encourage interested researchers to contact us, should questions arise.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	In Danish	01/09/2019	05/09/2022	No	No
Results article		06/12/2022	16/03/2023	Yes	No
<u>Results article</u>		07/03/2023	16/03/2023	Yes	No