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A randomized controlled trial of mindfulness-based stress reduction (MBSR) in Chilean health workers

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
26/03/2018

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Occupational stress (stress related to job) entails great costs for health workers, employers and patients. A recent study of French workers estimated that 5.3-33.6% of common mental disorders could be attributable to work-related stress. In the United States, it is estimated that the real cost of occupational stress amounts to 300 million dollars per year. The evidence also suggests that occupational stress may increase the prevalence of negative outcomes in patients, including a lower service satisfaction, and a higher rate of medical errors. Previous studies have shown that specific high-demanding conditions within the work context could explain the occurrence of occupational stress, including higher paperwork load, judicialization of medicine, number of "clicks" in electronic medical records, healthcare Fordism (i.e., highly standardized healthcare services), and demands for higher qualifications. One of the interventions that have shown effectiveness in the management of factors related to psychosocial risk is the Mindfulness-Based Stress Reduction program (MBSR). This study aims to analyze the effectiveness of MBSR to reduce psychological distress in health professionals and determine how it relates to psychosocial risk factors.

Who can participate?
Health care workers of UC Christus Marcoleta Health Complex who are in direct contact with patients.

What does the study involve?
Participants are randomly allocated to one of three groups: Those in the MBSR group participate in a MBSR program, as was originally developed, to complete eight weekly group sessions of 2.5 hours, which they continue to do independently at home. Those in the Stress Management Training group will participate in a 20-hour psychoeducational course on self-care and stress management. The third group will be included in a waiting list and will be offered participation on MBSR or Stress Management Training based on their personal preferences once the trial has ended. Measures of psychological distress, burnout, perceived stress, symptom distress,

interpersonal relations and social role, job satisfaction, number of sick leaves in the previous three months, mindfulness skills, job satisfaction and other quality-of-life indicators will be measured at baseline (T0), following the intervention (T1) and after six months (T2).

What are the possible benefits and risks of participating?
Potential benefits: Participants randomized to the MBSR or Stress Management Training may benefit from a significant reduction in psychological distress, burnout, perceived stress and psychosocial risk factors in the workplace. We also expect to see an improvement on participant's health, well-being and job satisfaction.
Potential risks: During Mindfulness practice, it is possible that participants may become more aware of difficult emotions, bodily and mental states such as fear, sadness, irritability, and rumination as a first step in the therapeutic process. There is also a theoretical possibility of observing adverse effects, such as major emotion dysregulation. If that occurred, the trainer in both MBSR will be responsible for referring the cases to a psychiatrist who is a member of the expert committee.

Where is the study run from?
UC Christus Marcoleta Health Complex (Lira Medical Center, Clinical Hospital, and Diagnostic Center) (Santiago, Chile)

When is the study starting and how long is it expected to run for?
August 2017 to August 2019

Who is funding the study?
Chilean Safety Association (ACHS)

Who is the main contact?
Dr Antonia Errázuriz
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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
204-2017

Study information

Scientific Title
Mindfulness based stress reduction (MBSR) for psychological distress reduction in Chilean health workers: a randomized controlled trial

Study objectives
Health workers participating in a Mindfulness Based Stress Reduction (MBSR) intervention will show lower levels of 1) psychological distress, 2) burnout, 3) perceived stress, 4) depressive symptoms, 5) psychosocial risk factors at work and 6) salivary cortisol (a stress biomarker), and an improvement in quality of life compared with (i) health workers participating in a Stress Education and Self-Management Workshop (active controls) (ii) health workers assigned to a waiting list (i.e., passive controls), as measured in the short-term (8 weeks) and long-term (6 months).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Scientific Committee of the Medical School of the Pontifical Catholic University of Chile [CEC MED UC], 11/16/2017, ref: Project ID: 170710014.

Study design
Interventional single-center three-arm parallel-group randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet: Dr. Antonia Errázuriz anerrazuriz@uc.cl

Health condition(s) or problem(s) studied
Psychological distress/occupational stress (i.e. quality of life, perceived stress, burnout, depressive symptoms).

Interventions
Participants in the trial are full-time health workers employed by the UC Christus Health Network working at the "UC Christus Marcoleta Health Complex" in Santiago, Chile. All health workers will be invited via e-mail, leaflet, brochure, and oral communication to participate in the study. Those interested will be asked to respond a questionnaire used to determine participant's eligibility based on a predefined set of inclusion/exclusion criteria (details below). Those selected to participate in the trial will be randomly assigned to one of three arms:
Arm 1. Mindfulness Based Stress Reduction (MBSR) (Experimental): The group will participate in a MBSR program, as was originally developed by Dr. Kabat-Zinn at the University of Massachusetts, consisting of eight weekly group sessions of 2.5 hours combining experiential exercises and meditation. The MBSR program will be conducted by a MBSR-certified psychologist with vast teaching experience.
Arm 2. Stress Education and Self-Management Workshop (active control): The group will participate in an educational stress management intervention consisting in eight weekly group sessions of 2.5 hours about self-care and stress management techniques for effective work development.
Arm 3. Waiting list (passive control): The group will not participate in either the MBSR program or the Stress Education and Self-Management Workshop during the trial, but will be offered the opportunity to participate in either course once the trial has ended (i.e. 6 months following the intervention).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 20/07/2020:
1. Psychological distress measured using the 12-item General Health Questionnaire (GHQ-12)
2. Perceived stress, as measured by the Perceives Stress Scale (PSS)
3. Symptoms of distress (SD), interpersonal relations (IR) and social role (SR) performance, as measured by the Outcome Questionnaire (OQ 45)

All primary outcomes will be measured at baseline (T0), at week 8 immediately after the intervention (T1) and 6 months after baseline (T2) in all participants.

Previous primary outcome measure:
1. Psychological distress measured using the 12-item General Health Questionnaire (GHQ-12)
2. Burnout, as measured by the Maslach Burnout Inventory (MBI)
3. Perceived stress, as measured by the Perceives Stress Scale (PSS)
4. Symptoms of distress (SD), interpersonal relations (IR) and social role (SR) performance, as measured by the Outcome Questionnaire (OQ 45)
5. Circadian excursions of salivary cortisol concentrations, as measured by LC/MS-MS. Salivary samples for cortisol measurements will be collected at 3 time points/day (at awakening, 30 min after awakening and at bedtime or around 10 pm) prior to intervention (1 day = 3 measurements /person) and post intervention (1 day = 3 measurements/ person). Saliva samples will be collected using a Salivette Cortisol (Sarsted, Germany) device.
All primary outcomes except cortisol concentration will be measured at baseline (T0), at week 8 immediately after the intervention (T1) and 6 months after baseline (T2) in all participants.

Cortisol concentration will only be measured at T0 and T1 and only in participants receiving MBSR or passive controls
Updated 10/08/2018: Cortisol concentration will only be measured at T0 and T1

Secondary outcome measures
Current secondary outcome measures as of 20/07/2020:
1. Job satisfaction, as measured by the Job Satisfaction Scale (JSS)
2. Number of sick leaves in the previous three months
3. Mindfulness skills, as measured by the Five Facet Mindfulness Questionnaire (FFMQ)
4. Other quality-of-life indicators (e.g. comorbidity, sleep quality)
5. Circadian excursions of salivary cortisol concentrations, as measured by LC/MS-MS. Salivary samples for cortisol measurements will be collected at 3 time points/day (at awakening, 30 min after awakening and at bedtime or around 10 pm) prior to intervention (1 day = 3 measurements /person) and post intervention (1 day = 3 measurements/ person). Saliva samples will be collected using a Salivette Cortisol (Sarsted, Germany) device.

All secondary outcomes will be measured at T0, T1, and T2 in all participants, bar cortisol concentration, which will only be measured at T0 and T1.

Previous secondary outcome measures:
1. Job satisfaction, as measured by the Job Satisfaction Scale (JSS)
2. Number of sick leaves in the previous three months
3. Mindfulness skills, as measured by the Five Facet Mindfulness Questionnaire (FFMQ)
4. Other quality-of-life indicators (e.g. comorbidity, sleep quality)
All secondary outcomes will be measured at T0, T1, and T2 in all participants.

Overall study start date
01/08/2017

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Health worker at UC Christus Marcoleta Health Complex
2. Has direct patient contact
3. Gives consent

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
150

Total final enrolment
105

Key exclusion criteria
1. Working under a fixed-term contract
2. Not in direct contact with patient
3. Reporting severe depression symptoms (OQ-45 score >= 47)
4. Reporting suicidal ideation (OQ-45 item 8 "almost always")
5. Reporting problematic alcohol consumption (OQ-45 item 11 "almost always")
6. Not available to attend to all 8 sessions of an MBSR course/Stress Education and Self-Management Workshop

Date of first enrolment
20/03/2018

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Chile

Study participating centre
UC Christus Marcoleta Health Complex
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Sponsor information

Organisation
Pontifical Catholic University of Chile (Pontificia Universidad Catolica de Chile)

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Funder(s)

Funder type
Charity

Funder Name
Chilean Safety Association (ACHS)

Results and Publications

Publication and dissemination plan
A synthesis of the study will appear on the website of the Department of Psychiatry of the School of Medicine of the Catholic University.
A synthesis of the study will appear in the UC Health Magazine available in digital and printed formats.
Based on the study results, the final report will include didactic material describing the intervention, its characteristics and the expected results.
The results of the study will be published in a peer-reviewed scientific journal.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The raw data is available in two publicly available repositories: Dataverse and Mendeley Data.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		13/08/2020	13/08/2020	No	No
Results article	results	01/11/2020	24/11/2020	Yes	No
Dataset		26/05/2020	28/10/2022	No	No
Dataset		11/08/2020	28/10/2022	No	No