Mindful Prevention of Psychopathology in healthcare workers during the COVID-19 crisis

Published: 11-06-2020
Last updated: 09-04-2024

We want to examine whether a semi-acute mindfulness based stress reduction (MBSR) intervention, specifically tailored to fit the needs of the health care workers and crisis situation, in addition to support as usual (SAU) can prevent incident/...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49279

Source
ToetsingOnline

Brief title
Covid-19 MindPreP

Condition

- Psychiatric disorders NEC

Synonym
psychopathology; psychiatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID, Healthcare workers, Mindfulness, Prevention

Outcome measures

Primary outcome

Primary outcome will be changes from baseline (pre-MBSR) to 4 and 7-months on depression, anxiety and somatoform symptoms measured with the Patient Health Questionnaire SADS (PHQ-SADS).

Secondary outcome

Secondary measures of psychopathology will be the change of post-traumatic stress symptoms (PDS), insomnia (ISI) and substance abuse (AUDIT-C, SCID). In addition, we will measure positive changes in post-traumatic growth (PTG-R), positive mental health (MHC-SF) and general health (EQ-5D-5L). As possible mediators we will measure perseverative thinking (PTQ), mindfulness skills (FFMQ-SF) and self-compassion (SCS). After 7 months of follow-up, a structured psychiatric interview (SCID) will determine whether (and which) or not psychiatric disorders are present. At that time point, the costs arising from any psychosocial problems of the participants (TIC-P) will also be measured. In addition, at baseline we will collect demographic data as well as data on negative life events (part of NLEQ).

Study description

Background summary

Frontline health care workers are exposed to extreme acute stress during this COVID-19 pandemic. Data recently collected in China show that this might lead

to substantial burden of psychopathology in these health care workers, which might represent both new (incident) and deteriorating (prevalent) cases. This is in line with findings from previous (health care) crises.

Study objective

We want to examine whether a semi-acute mindfulness based stress reduction (MBSR) intervention, specifically tailored to fit the needs of the health care workers and crisis situation, in addition to support as usual (SAU) can prevent incident/prevalent psychopathology. Our hypothesis is that it can diminish depression, anxiety, stress, post-traumatic stress symptoms, insomnia and substance abuse and improve post-traumatic growth and positive mental health.

Study design

A randomized, single-blind, controlled trial with a SAU (including access to a YouTube channel offering daily mindfulness exercises) control group and a MBSR + SAU intervention group.

Intervention

The intervention is a adapted MBSR program. The training consists of eight 1.5 hour sessions twice per week. The sessions will be held via interactive videostreaming and will be recorded. This will enable those who could not attend (e.g. because of an evening-shift) to catch up with the program. In addition, SAU will consist of the possibility we provide to join the daily guided mindfulness exercise (30 min) on a live YouTube channel, amongst the other interventions already available in the hospital (e.g. buddy system, psychological debriefing).

Study burden and risks

The health care workers will follow the 4 week MBSR program with biweekly 1.5 hour sessions and are encouraged to practice MBSR inbetween. Furthermore, they will be asked to fill in online questionnaires before and directly after the intervention (1 month post-baseline), and at 4 and 7 months (3 and 6 months after the end of the intervention) which will take approximately 30-60 minute each. Time investment for the group receiving SAU this is 5 hours and for the group receiving SAU+MBSR is 17 hours across 7 months. MBSR is not known to cause any serious effects and no risks are associated with the intervention.

Contacts

Public

Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthcare workers working/reallocated on/to COVID-19 wards

Exclusion criteria

Impossibility to obtain a valid informed consent
Insufficient comprehension of the Dutch language
Inability to access the interactive videostream

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2020
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	11-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73793.091.20