

Brief digital mindfulness and compassion training for healthcare professionals

Submission date 08/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/11/2023	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/01/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Several studies show that intense work schedules make healthcare professionals particularly vulnerable to emotional exhaustion and burnout. Self-compassion and mindfulness have often been found to be negatively correlated with burn-out, suggesting these behaviors may prevent burn-out and promote well-being. Scalable, digital app-based methods may have potential to enhance self-compassion and mindfulness in health-care professionals. In this study, we designed and implemented a scalable, digital app-based, brief mindfulness and compassion training program "WellMind" for healthcare professionals to investigate if this digital training may enhance self-compassion and mindfulness.

Who can participate?

Healthcare professionals aged 18-65 years can participate in this study.

What does the study involve?

The WellMind group participants received the digital app intervention and had periodic email contact from our research team during intervention, at about once every two weeks frequency, to ensure compliance and help troubleshoot any issues faced by the participants. The no-contact control group had no interaction with the study research team nor any digital training resource provided to them between their pre and post assessment time points.

What are the possible benefits and risks of participating?

Possible benefits are improvement in mental health and risks of participating are minimal with some risk of loss of confidentiality although privacy and confidentiality is prioritized throughout the study.

Where is the study run from?

University of California San Diego (USA)

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

January 2021 to December 2022.

Who is funding the study?
Sanford Institute for Empathy and Compassion (USA)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Brief digital mindfulness and compassion training drives behavioral and neural plasticity in healthcare professionals

Acronym
WellMind

Study objectives
The WellMind program will enhance mindfulness and compassion in healthcare professionals.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 29/01/2021, University of California San Diego Institutional Review Board (9500 Gilman Drive, San Diego, 92037, United States of America; +1 858-246-4777; hrpp@ucsd.edu), ref: 180140

Study design

Interventional cluster randomized

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

University/medical school/dental school

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Mindfulness and compassion in healthcare professionals

Interventions

Participants were cluster randomized by their study batch to the WellMind or control group. This was done because individuals within each study batch (but not across batches) knew each other professionally and could reveal components of the study intervention to each other.

The WellMind group participants received the digital app intervention and had periodic email contact from our research team during intervention, at about once every two weeks frequency, to ensure compliance and help troubleshoot any issues faced by the participants.

The no-contact control group had no interaction with the study research team nor any digital training resource provided to them between their pre and post assessment time points.

Digital WellMind intervention. The WellMind digital intervention was deployed on the BrainE© platform implemented in Unity and available on both iOS and Android phone devices. This digital program is HIPAA-compliant and secured by password-protection, and each user interacts via an alphanumeric study ID that is not linked to any personal health information. Participants accessed the app in their own free time and engaged in breath-focused mindfulness training with each session of 5-10 minutes duration for up to 60 sessions. The training was delivered in a game-like format and was performance-adaptive. Specifically, individuals were requested to close their eyes, pay attention to their breathing and tap the mobile screen after a specific number of breaths. The app monitored consistency of tap responses. If the user was distracted based on low consistency of breath monitoring taps, a gentle chime reminded the user to let go

of the distraction and revert their attention back to mindful breathing. Initially, at level 1, participants tapped the screen after each breath. If they were able to do this consistently for three repeats of level 1 of 1 minute duration each, they graduated to level 2 and tracked two breaths at a time for 2 minutes, and so on. Thus, in the performance-adaptive task, the level reflected the number of minutes spent at that level and the number of breaths the participant was requested to repeatedly monitor. The max achievable level was level 10, i.e. monitoring 10 breaths at a time for up to 10 minutes. When the user graduated to the max level, they stayed at this level until end of all assigned sessions, i.e. 60 sessions. Also within the game-like format, when the participant opened their eyes at the end of a level, a peaceful nature scene would slowly unveil as a form of training reward.

Overall, this digital meditative practice is considered closed-loop because of its performance-adaptive feature. Consistent attention to breathing is emphasized over say other types of breathing techniques like deep breathing. The moment-to-moment performance tracking further allows quantification of the attentive focus during each session that is not possible with traditional non-digital meditation.

Finally, the training also introduced standard compassion cultivation instructions as audio and text prompts prior to the start of each session's breath practice. Prompts were updated every 6 sessions, with a total of 10 prompts gradually increasing in complexity over 60 sessions. These prompts were designed per guidance from the Compassion Cultivation Training program, and included (i) settling the mind, (ii) compassion for a loved one, (iii) compassion for oneself, (iv) loving kindness for oneself, (v) embracing common humanity, (vi) embracing common humanity continued, (vii) cultivating compassion for oneself and others, (viii) cultivating compassion for others continued, (ix) active compassion, and (x) integrated compassion cultivation practice. Participants received in-app notifications, once a day, reminding them to complete their training.

Intervention Type

Behavioural

Primary outcome measure

At baseline (T1), post-intervention completion (T2) (or 3 month no-contact period for the control group), and at follow-up (T3) (6 months following baseline) self-report scales measured:

1. Self-compassion: 12-item self-compassion scale,
2. Mindfulness: 14-item mindful attention awareness scale (MAAS).

Secondary outcome measures

1. Maslach Burnout Inventory (MBI) at T1 and T2.
2. Objective neurophysiological assessment of interoceptive attention to breathing at T1 and T2.

Overall study start date

29/01/2021

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Participants must be healthy adults and affiliated with the UC San Diego School of Medicine

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

40; 2 clusters; 20 per arm

Total final enrolment

43

Key exclusion criteria

1. Current clinical diagnosis or illness
2. Use of psychotropic medications

Date of first enrolment

01/02/2021

Date of final enrolment

01/10/2022

Locations**Countries of recruitment**

United States of America

Study participating centre

University of California San Diego

9500 Gilman Drive, Mail Code 0875

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Sponsor information**Organisation**

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Sponsor type

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Funder(s)**Funder type**

University/education

Funder Name

T. Denny Sanford Institute for Empathy and Compassion

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2024

Individual participant data (IPD) sharing plan

The datasets analyzed in the current study will be stored in the publicly available DataDryad.org repository.

doi:10.5061/dryad.0zpc8672x

Please note that datadryad.org keeps this dataset URL private until the manuscript has been accepted. The data will be freely available for download post-publication of the research.

Consent was obtained from participants for de-identified data sharing. The data does not have any personal health information for participants. The dataset is de-identified and there are no ethical or legal restrictions.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Protocol file		14/11/2023	No	No
Statistical Analysis Plan		14/11/2023	No	No
Results article	22/01/2024	23/01/2024	Yes	No