CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS,
or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

drthimmapuram@googlemail.com Switch account
Not shared
Draft saved

* Indicates required question

Your name *
First Last

Jayaram Thimmapuram

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada

WellSpan Health

Your e-mail address *
abc@gmail.com

n@wellspan.org; drthimmapuram@yahoo.com

Title of your manuscript *
Provide the (draft) title of your manuscript.

Effect of a Web-Based Heartfulness Program on Mental Wellbeing, Biomarkers and Gene Expression Profile of Health Care Students: A Randomized study

Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Web Based Heartfulness Meditation

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Not applicable

Language(s) *
What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English

URL of your Intervention Website or App
e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

Your answer

URL of an image/screenshot (optional)

Your answer

Accessibility *
Can an enduser access the intervention presently?

- (•) access is free and open
- ( ) access only for special usergroups, not open
- ( ) access is open to everyone, but requires payment/subscription/in-app purchases
- ( ) app/intervention no longer accessible
- ( ) Other:

Primary Medical Indication/Disease/Condition *
e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Stress

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

Stress, Depression, and Anxiety scores, IL-6 an

Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Your answer

Recommended "Dose" *
What do the instructions for users say on how often the app should be used?

- (•) Approximately Daily
- ( ) Approximately Weekly
- ( ) Approximately Monthly
- ( ) Approximately Yearly
- ( ) "as needed"
- ( ) Other:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- (•) unknown / not evaluated
- ( ) 0-10%
- ( ) 11-20%
- ( ) 21-30%
- ( ) 31-40%
- ( ) 41-50%
- ( ) 51-60%
- ( ) 61-70%
- ( ) 71%-80%
- ( ) 81-90%
- ( ) 91-100%
- ( ) Other:

Overall, was the app/intervention effective? *

- (•) yes: all primary outcomes were significantly better in intervention group vs control
- ( ) partly: SOME primary outcomes were significantly better in intervention group vs control
- ( ) no statistically significant difference between control and intervention
- ( ) potentially harmful: control was significantly better than intervention in one or more outcomes
- ( ) inconclusive: more research is needed
- ( ) Other:

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- ( ) not submitted yet - in early draft status
- ( ) not submitted yet - in late draft status, just before submission
- ( ) submitted to a journal but not reviewed yet
- (•) submitted to a journal and after receiving initial reviewer comments
- ( ) submitted to a journal and accepted, but not published yet
- ( ) published
- ( ) Other:

Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ( ) not submitted yet / unclear where I will submit this
- ( ) Journal of Medical Internet Research (JMIR)
- ( ) JMIR mHealth and UHealth
- ( ) JMIR Serious Games
- ( ) JMIR Mental Health
- ( ) JMIR Public Health
- ( ) JMIR Formative Research
- ( ) Other JMIR sister journal
- (•) Other: JMIR Bioinformatics and Biotechnology

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ( ) Pilot/feasibility
- (•) Fully powered

Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ( ) no ms number (yet) / not (yet) submitted to / published in JMIR
- (•) Other: #65506

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- (•) yes
- ( ) Other:

1a-i) Identify the mode of delivery in the title
Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1a-i? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Effect of a Web-Based Heartfulness Program on Mental Wellbeing, Biomarkers and Gene Expression Profile of Health Care Students: A Randomized study

1a-ii) Non-web-based components or important co-interventions in title
Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1a-ii?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The participants met with Heartfulness trainers online via Zoom to guide with the meditation sessions.

1a-iii) Primary condition or target group in the title
Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Eligible participants were students of nursing, physiotherapy, and pharmacy at two institutions in Gujarat, India.

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1b-i? *
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The enrolled participants were randomized to the Heartfulness meditation and control groups and completed a Perceived Stress Scale (PSS) and Depression Anxiety Stress Scale (DASS-21) at baseline and after week 12. Gene expression with mRNA sequencing, DHEA-S, and Interleukin-6 (IL-6) levels were also measured at baseline and the completion of the 12 weeks.

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1b-ii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The enrolled participants were randomized to the Heartfulness meditation and control groups and completed a Perceived Stress Scale (PSS) and Depression Anxiety Stress Scale (DASS-21) at baseline and after week 12. Gene expression with mRNA sequencing, DHEA-S, and Interleukin-6 (IL-6) levels were also measured at baseline and the completion of the 12 weeks.

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT
Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

participants were recruited by the institutional research team through internal communication media.

1b-iv) RESULTS section in abstract must contain use data
Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1b-iv?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

78 participants enrolled in the study with 42 randomized to the Heartfulness group and 36 to the control group.

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials
Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 1b-v?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable. As the results were positive favoring meditation practice. Heartfulness practice was associated with decreased depression, anxiety, and stress scores and improved health measures in DHEA-S and IL-6 levels. The gene expression data point toward possible mechanisms of alleviation of symptoms of stress and depression.

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution
Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 2a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. Despite the potentially serious consequences of stress and anxiety, there are few interventions designed to combat this problem in the student population. Educators need to develop an active awareness of mental well-being and should consider incorporating relevant instruction and interventions during the process of training healthcare professionals

2a-ii) Scientific background, rationale: What is known about the (type of) system
Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

subitem not at all important 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 (•) essential
Clear selection

Does your paper address subitem 2a-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Health care students have a high degree of stress and burnout due to the number of hours spent on learning each week, the large body of clinical knowledge to master, and the challenges of balancing work and home life .

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. The current study investigated whether using an online Heartfulness meditation program with certified trainers is associated with improvements in mental well-being in healthcare professional students. The current study also measured changes in the gene expression profile, DHEA-S, and IL-6 levels

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

A total of 78 eligible and willing participants enrolled in the study. Computer randomization was performed with 42 participants randomized to the intervention arm and 36 to the control arm.

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as we did not make any changes after trial commencement

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

There were no changes to the methods or downtimes or content changes

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The eligibility criteria included participants to be aged 18 or above, able to read and understand English language and willing to participate in the study. All instructions were in English language and no translation was used for the questionnaires or the consent forms. Participants with any physical or mental conditions that would prevent them from sitting down for the duration of meditation were excluded. Those participants who were able to provide data and blood samples both at baseline and at the follow up after 12 weeks were included in the study. Those who failed to attend the final follow up session for data collection and blood sample collection were excluded from the analysis.

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

All research participation was voluntary following an informed electronic consent. The eligibility criteria included participants to be aged 18 or above, able to read and understand English language and willing to participate in the study. All instructions were in English language and no translation was used for the questionnaires or the consent forms.
The intervention was virtual during the study period. The participants met with Heartfulness trainers online via Zoom to guide with the meditation sessions.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Participants were recruited by the institutional research team through internal communication media.The intervention was virtual during the study period. The participants met with Heartfulness trainers online via Zoom to guide with the meditation sessions.

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

An introductory overview of the program was offered on a virtual Zoom platform and follow-up announcements in the colleges. All research participation was voluntary following an informed electronic consent.

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Eligible participants were students of nursing, physiotherapy, and pharmacy at two institutions in Gujarat, India.

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Those participants who were able to provide data and blood samples both at baseline and at the follow up after 12 weeks were included in the study. Those who failed to attend the final follow up session for data collection and blood sample collection were excluded from the analysis. All participants were requested to fill out the Perceived Stress Scale and Depression Anxiety and Stress Scale-21 forms at baseline before the start of the intervention.

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable. Institutional affiliations may not be required to be displayed.

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The participants met with Heartfulness trainers online via Zoom to guide them with the meditation sessions.

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as there was no development process of the application involved

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as there is no version number applicable and there were no major changes during the evaluation process

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Independent t-test and Fisher's exact test were utilized for baseline comparisons . Levene's test was performed to assess the homogeneity of variance. One way ANOVA was used for assessing group differences. The level of significance was set at $p<0.0125$, (0.05/4) following the Bonferroni correction, to account for multiple comparisons and potential Type I errors. Paired t-test analysis was conducted to evaluate within group changes. The final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 25.0.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as there is no source code involved

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as this was a guided program offered by trainers via zoom

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The participants met with Heartfulness trainers online via Zoom to guide with the meditation sessions. The participants did not have to pay for the services

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The participants met with Heartfulness trainers online via Zoom to guide with the meditation sessions.

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

All participants in the Heartfulness meditation group were invited for an online orientation session via zoom on the aspects of the study and the structure of the meditation protocol. Participants were also briefed about expectations during meditation sessions and were offered the contact details of trainers for scheduling meditation sessions.
During the online guided meditation sessions, participants were walked through relaxation instructions by the trainers and were asked to gently place their attention on the source of light within their hearts. They were asked to simply tune into their hearts and be open to any experience they may have as opposed to trying to visualize the light. Participants were advised to gently redirect their attention toward their heart if their attention drifted. The guided meditation sessions with the trainers were offered daily and lasted approximately 30 minutes. A total of 84 sessions were offered over a 12-week period.

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

All participants in the Heartfulness meditation group were invited for an online orientation session via zoom on the aspects of the study and the structure of the meditation protocol. Participants were also briefed about expectations during meditation sessions and were offered the contact details of trainers for scheduling meditation sessions.
During the online guided meditation sessions, participants were walked through relaxation instructions by the trainers and were asked to gently place their attention on the source of light within their hearts. They were asked to simply tune into their hearts and be open to any experience they may have as opposed to trying to visualize the light. Participants were advised to gently redirect their attention toward their heart if their attention drifted. The guided meditation sessions with the trainers were offered daily and lasted approximately 30 minutes. A total of 84 sessions were offered over a 12-week period.

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

All participants in the Heartfulness meditation group were invited for an online orientation session via zoom on the aspects of the study and the structure of the meditation protocol. Participants were also briefed about expectations during meditation sessions and were offered the contact details of trainers for scheduling meditation sessions.

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No other interventions such as educational sessions were included during the study.

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The enrolled participants were randomized to the Heartfulness meditation and control groups and completed a Perceived Stress Scale (PSS) and Depression Anxiety Stress Scale (DASS-21) at baseline and after week 12. Gene expression with mRNA sequencing, DHEA-S, and Interleukin-6 (IL-6) levels were also measured at baseline and the completion of the 12 weeks.

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Not applicable as the questionnaires were filled out by participants in person.

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

The number of sessions attended by the participants was logged by the volunteer trainers.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

No qualitative feedback was obtained except for the questionnaires

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No changes to the trial outcomes were made

Text Value specify one was determined
Text Value specify one the number of whether and how the clustering by care provider or service was addressed

5.6.3 Describe whether and how supported attrition was taken into account when calculating the sample size
Text Value describe whether and how supported attrition was taken into account when calculating the sample size

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 7a?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Based on the significance level (α = 0.05), an estimated effect size (d = 0.45), and power (80%), the sample size estimated was 150 participants in each group. Considering 20% attrition, a larger number of participants were recruited. A total of 18 eligible and willing participants were recruited from the community and were randomized to the two groups (intervention and control) by the coordinator and put into the study pool.

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b ?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

No interim analysis was performed

8a) Method used to generate the random allocation sequence
NFT: When applicable, how units (provider) were allocated to each trial group

Does your paper address CONSORT subitem 8a?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Computer randomization was performed with 40 participants randomized to the intervention and 40 to the control arm.

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

A total of 18 eligible and willing participants enrolled in the study. Computer randomization was performed with 40 participants randomized to the intervention and 40 to the control arm.

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

No concealment was done after computer randomization

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Investigators generated the computerized randomization

11a) If blind, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
NFT: Whether or not administering co-interventions were blinded to group assignment

Does your paper address CONSORT subitem 11a?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

The nurse and interviewer only. The Nonsteroidal anti-inflammatory drugs (NSAIDs) & 5-alpha-reductase inhibitors were blinded.

11a(i) Distance (e.g., whether participants knew which intervention was received, whether those assessing outcomes were blinded to participants' received intervention procedures (such as cover-between and sham operations)
NFT: Whether or not participants were blinded to the intervention due to "mechanism of intervention" and which arm was the "comparator"

Does your paper address CONSORT subitem 11a(i)?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Not applicable/were blinded

11a(ii) If relevant description of the similarity of interventions
NFT: Whether or not the "comparator" was described as a placebo, a similarity of placebo or other intervention to a similar method/intervention

Does your paper address CONSORT subitem 11a(ii)?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

No placebo or sham intervention was used

12a) Statistical methods used to compare groups for primary and secondary outcomes
NFT: When applicable, details of whether and how the clustering by care provider or service was addressed

Does your paper address CONSORT subitem 12a?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Descriptive statistics were utilized to summarize participant demographics and work-related characteristics. Independent t-tests and Fisher's exact tests were employed to assess baseline variables between the two groups. Generalized estimating equations (GEE) models were used for pioneering group differences. The level of significance was set at 0.05 (two-tailed). Intention-to-treat analysis was performed using the last observation carried forward approach. Linear mixed-effects models were constructed to evaluate whether the intervention had a significant effect on the primary outcome (Pain Catastrophizing Scale [PCS]) at follow-ups. IBM-SPSS software, IBM Corp/Armonk, Chicago, USA, version 23.0.

A subgroup of different experiences analysis (sensitivity) was carried out. Data pertinent to participants who had completed the intervention (n = 35) and those who had completed at least 1 of the 3 assessed differential experiences were considered to be significant and further used for analysis. Participants who had completed the intervention (n = 35) were further categorized into the intervention experienced and the non-experienced after the intervention. Participants who had completed at least 1 of the 3 differential experiences (pain control, pain control for medication and 12 months) were taken to gain insights on the improvement experienced by participants. Data were analyzed using the Mann-Whitney U test for continuous and Chi-square for dichotomous variables.

12a(i) Imputation techniques to deal with attrition / missing values
Imputation techniques to deal with attrition / missing values. Not all participants will use the intervention/experience the outcome but should be included in the analysis. Specify how participants who did not use the application or dropped out from the trial (participants who do not have any usage data) will be included in the statistical analysis. Simple and complex imputation techniques such as LOCF may also be problematic [28].

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT subitem 12a(i)?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

No participants did not complete the intervention/sample collections and thus ITT not the final forms were excluded from the analysis

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

This was reported in the supplementary section.

IOG RQ-RB Approval and Ethical Considerations Documentation (e.g. ratification by ethics committee or CONSORT item)

IOG-2 Contract or ethics committee approval

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 23?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Ethics approval for the Ethics Board (Protocol number: 1706011) participants were recruited by the institutional research team through internal communication media.

IOG-3 Outline informed consent procedures
Outline informed consent procedures (e.g., if consent was obtained offline or online Explain individual consent procedures, if consent was obtained offline or online. IOG RQ-RB item 3 Items to be included in informed consent documents)

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 23?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Ethics approval for the Ethics Board (Protocol number: 1706011) participants were recruited by the institutional research team through internal communication media.

IOG-4 Safety and security procedures
Safety and security procedures (e.g. encryption, pseudonymisation, and steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 23?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

For any questions related to the study, the investigators were available throughout the study duration.

RESULTS

15a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
NFT: Number of units randomized to each trial group, number of units in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 15a?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Out of the 18 home-geriatric sessions, 03 participants attended 100% of the sessions, 6 of 12 sessions (50%) of the sessions and the rest of them attended a lower 4 sessions.

15b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT item 15b?(To. Preferably, this is shown in a CONSORT flow diagram)
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

CONSORT Flow diagram should be presented here in Online Jpt.

16.1 Attrition diagram
Attrition diagram (e.g. an attrition diagram (e.g. proportion of participants still engaging in a study like intervention/component in each group) plot over time, similar to a Kaplan-Meier survival curve or other figure or table demonstrating usage/engagement

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 15b?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Recruitment period was between February 17, 2022, to March 25, 2022. The study was conducted in the Geriatric Medicine Department of Hospitals in Karachi, Pakistan. The study was conducted from April 2022 to July 2022.

16b) 2 Indicate if a linear "secular trend" for the study period
Indicate if a linear "secular trend" for the study period, i.e. significant changes in relevant secondary variables or Changes in computer hardware or internet delivery capacity

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 16b?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Not applicable as there were no internet delivery interface changes required during the study period.

16c) Why the trial ended or was stopped (early)

Does your paper address CONSORT item 16c?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Study was not stopped early

17b A table showing baseline demographic and clinical characteristics for each group
NFT: When applicable, a description of care providers (case volume, qualifications, training, etc.) and centers (volume, setting)

Does your paper address CONSORT item 17b?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Table 1 shows demographics and characteristics

17d A Report demographics associated with digital divide issues
A sub-analysis is a secondary exercise to report demographics associated with digital divide issues. Such a table could be based on the Table 1 in Richardson et al (2017) Computer-Internet Adoption Survey of the participants. If Possible.

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 17d?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Table one includes gender, age and baseline details.

18/19 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assignment

Does your paper address CONSORT item 18/19?

18.0 Report multiple "denominators" and provide definitions
Report multiple "denominators" and provide definitions, for example 1) Intent-to-treat (ITT) cohort, 2) Intent-to-treat (ITT) cohort and Intensity (IT) (e.g. 4 or more sessions), 3) Intent-to-treat (ITT) cohort and Intensity (IT) and Survey, 4) Intent-to-treat (ITT) cohort and Intensity (IT) and Survey and Intervention or specify the sufficient number of sessions to be considered "engaged" (e.g. 4 or more sessions) and Survey and Intervention.

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 18/19?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Intent-to-treat analysis was performed

19.2 For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT item 19?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Number of participants, utilization of the mediation practices and the effect sizes have been mentioned.

19.3 Primary analysis should be intention-to-treat
Primary analysis should be intention-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample anymore.

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 19?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Intent-to-treat analysis was performed

19.4 Presentation of process outcomes such as metrics of user and intensity of use

In addition to primary/secondary clinical outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose response) and their association with the outcome is critical to understand the "active ingredient" of the intervention (what aspects of the intervention are being used by participants and which are most beneficial). Process outcomes could be as simple as a "login" or more complex such as the number of "modules" completed, or a "session" is defined (e.g., minimum after site time [21] Impact under two hrs).

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 19.4?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Not applicable as all the participants attended to the intervention and who provided data were included.

20.1 For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT item 20.1?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Effect sizes are reported

20 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT item 20?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

The analysis was performed according to pre-specified objectives

19.5 Subgroup analysis of competing only users
A subgroup analysis of competing only users is not uncommon in health trials, but if conducted, should be pre-specified. Such a "competing only users" analysis could no longer be unbiased (except from a randomized sample frame).

1 2 3 4 5 6 7
subtitle=not at all important ○ ○ ○ ○ ○ ○ ○ subtitle=essential
Clear selection

Does your paper address CONSORT item 19?
Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value Copy and paste relevant sections from the manuscript Click brackets symbol to open/close the text box. Text Value

Not applicable as all the participants attended to the intervention and who provided data were included.

19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No unintended or harmful effects were reported

19-i) Include privacy breaches, technical problems
Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2]

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 19-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No privacy breaches have been reported

19-ii) Include qualitative feedback from participants or observations from staff/researchers
Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 19-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

While explicit qualitative feedback was not collected. The researchers felt the study was received well by the participants.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)
Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 22-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The current study shows an improvement in mental well-being with Heartfulness meditation offered with guidance by certified trainers. Stress, anxiety, and depression levels showed a decrease with 12 weeks of practice. DHEA-S levels showed a significant increase in the meditation group at the end of the study compared to the baseline scores. IL-6 levels decreased in both the groups. Gene expression profiling with mRNA sequencing showed significant changes in immune response, nervous system homeostasis, neuroinflammatory protective effect and reduction of oxidative stress. The study findings support positive effect of meditative practices on wellbeing.

22-ii) Highlight unanswered new questions, suggest future research
Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 22-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Further research with a longer follow up period for up to a year or more is recommended to evaluate the long-term effects of Heartfulness meditation for mental well-being and changes in the biomarkers.

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials
Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 20-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The control group was a no-treatment group, with no alternative activity offered. Many factors influence inflammatory markers and therefore it is difficult to assess the exclusive effect of meditation practices. Participants who were unable to attend the study site on the day of completion could not be included in the analysis. There could also be many unknown sources of bias, including diet and health conditions along with personal life factors of participants. Also, the long-term follow up data on the lasting effects of Heartfulness meditation are lacking in this study

21) Generalizability (external validity, applicability) of the trial findings
NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations
Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 21-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

To our knowledge, this is the first study in health care professional students including nursing, physiotherapy, and pharmacy assessing mental well-being, biomarkers, and gene expression. The participants had no formal meditation experience and were novice meditations indicating that this practice could be of practical utility in a real life set up.

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting
Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem 21-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

To our knowledge, this is the first study in health care professional students including nursing, physiotherapy, and pharmacy assessing mental well-being, biomarkers, and gene expression. The participants had no formal meditation experience and were novice meditations indicating that this practice could be of practical utility in a real life set up.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The study was registered with trial number, ISRCTN28360715 (date of registration: April 6, 2022).

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *
Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The study was registered with trial number, ISRCTN28360715 (date of registration: April 6, 2022).

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We express our profound gratitude to GIPCL for funding the study. The funders had no role in design or analysis or outcomes of the study.

X27) Conflicts of interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated
In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	◉	essential

Clear selection

Does your paper address subitem X27-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The authors declare no financial conflicts of interest

About the CONSORT EHEALTH checklist

As a result of using this checklist, did you make changes in your manuscript? *

- ○ yes, major changes
- ◉ yes, minor changes
- ○ no

What were the most important changes you made as a result of using this checklist?

Your answer

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

Work has been progressing slowly over a few weeks

As a result of using this checklist, do you think your manuscript has improved? *

- ◉ yes
- ○ no
- ○ Other:

Would you like to become involved in the CONSORT EHEALTH group?
This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- ○ yes
- ○ no
- ◉ Other: Currently my clinical duties at the hospital take up a lot of time. Unfort

Clear selection

Any other comments or questions on CONSORT EHEALTH

None. Thank you for the opportunity

STOP - Save this form as PDF before you click submit
To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.

When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.

Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!

Final step: Click submit !
Click submit so we have your answers in our database!

Submit Clear form

Never submit passwords through Google Forms.

This content is neither created nor endorsed by Google. Report Abuse - Terms of Service - Privacy Policy

Google Forms