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

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and other based applications (interventions, comparators, and/or control interventions). It consists of 5 items recommended for reporting in addition to the 25 items of the CONSORT 2010 statement on randomized controlled trials and 6 items recommended for reporting in addition to the 22 items of the STROBE statement for observational studies.

Please read the CONSORT-EHEALTH checklist and guidelines in the paper or on the website http://www.consort-ehealth.com before completing this form. Go to item 2 below for separate of an attach list (in terms of ordering).

CONSORT-EHEALTH Recommendations are numbered and organized into 5 subsections (Introduction, Methods, Results, Discussion, Other). Each recommendation is followed by a letter indicating the checklist.

Items numbered 1, 2, 3, 6a, 6b, etc are original CONSORT or CONSORT-EHEALTH items. Items numbered with a decimal point (e.g. 3.1, or 6.1) are CONSORT-EHEALTH extensions.

In this CONSORT-EHEALTH form, each item is followed by a letter in parenthesis which tells you what kind of item it is: (a) for an item from the original CONSORT statement, (e) for an item from the CONSORT-EHEALTH extension, or (o) for an item from both.

PLEASE NUMBER ALL PAGES CONSECUTIVELY, IN A SUFFICIENTLY FULL FONT PLEASE USE THE SUPPLIED NUMBERING SUBMITTED CONSORT-EHEALTH CHECKLIST (V 1.6.1) WHEN REFERRING TO ITEMS (E.G. "TITLE" IS ITEM 1, "ABSTRACT" IS ITEM 2, ETC). PLEASE ALSO NUMBER YOUR PAGES, PREFERABLY WITH A FOOTER, WITH YOUR SURNAME AND THE PAGE NUMBER (E.G. "SMITH 3").

Submitted Version of the CONSORT-EHEALTH checklist (V 1.6.1)
Submitted Version of the CONSORT-EHEALTH

Does your guidance CONCISELY outline ten?
I have adequately addressed the 10 items that are required to be included in a patient leaflet. Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.
Not applicable to our study

B-1-Reg Rules, Guidelines, Current Changes
Regulatory Guidelines, Current changes, Medical Guidelines and other pertinent information. A list of all the relevant regulatory guidelines, medical guidelines and other information that is pertinent to the study. Also, a list of any current changes to the regulatory guidelines, medical guidelines and other information that is pertinent to the study. Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.

1 2 3 4 5 6 7 8 9 10
extreme not at all important — essential
Clear selection

Not applicable to our study

B-2 Ethics
Ethics information. Ethical information, Medical Ethics information, Ethics information, A list of all the relevant ethics information that is pertinent to the study. Also, a list of any current changes to the ethics information that is pertinent to the study. Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.

1 2 3 4 5 6 7 8 9 10
extreme not at all important — essential
Clear selection

Not applicable to our study

B-3 Ethics Committee
Ethics Committee, Medical Ethics Committee, Ethics information, A list of all the relevant ethics information that is pertinent to the study. Also, a list of any current changes to the ethics information that is pertinent to the study. Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.

1 2 3 4 5 6 7 8 9 10
extreme not at all important — essential
Clear selection

Does your guidance outline ten?
Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.
Not applicable to our study

B-4 Eligibility criteria for participants

Does your guidance CONCISELY outline ten?
Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.
Participants who are healthy volunteers are required to be medically assessed with suitable study eligibility per the inclusion/exclusion criteria (section 6.1 Sec 1)

1 2 3 4 5 6 7 8 9 10
extreme not at all important — essential
Clear selection

Text that is relevant does pertain from your manuscript, or alternative or other text is pertinent and relevant.
Is Table 1 Inclusion criteria - Section 6 relevant and has ethics been taken into consideration?

1 2 3 4 5 6 7 8 9 10
extreme not at all important — essential
Clear selection

B-5 Open-in, closed, early-based or, face-to-face assessments
Open-in, closed, early-based or, face-to-face assessments. Medical Assessments, Medical assessments, Medical assessments, Medical

and blinded randomization program and ensure equal allocation to both groups."

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 (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, no restrictions were applied. .

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 (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

None - the group assignment was generated electronically at point of enrollment.

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 (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

"After informed consent was obtained, study participants were randomized one-to-one using a REDCap (Research Electronic Data Capture) Cloud random number generator and allocated to the study group. All study procedures were completed remotely, and no in-person visits were required."

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 11a-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

"Participants were not blinded to the study arm, given the nature of the Waitlist Control. Statisticians performed blinded analysis of data sets that were randomly labeled as group 1 and group 2, with statistician unblinding occurring only after posttreatment month 3 data were analyzed. The study coordinator (LGC) was unblinded to individual study arm assignments and was not involved in any data analyses."

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 11a-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 unblinded due to the obvious nature of the ER group versus Usual Care.

"Although the WLC group did not receive any study intervention, participants were informed at the outset that they would be offered the ER treatment class after study completion at 3 months."

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

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

Our comparator was a waitlist group which instructed patients to resume usual care.

"The study used a Waitlist Control (WLC) group because the ER class online delivery is a new approach that has not been previously tested [46, 47]. During the screening phone call, participants randomized to the WLC were advised to continue any ongoing clinical care."

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

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

"For primary analyses, we employed a between-within mixed design using PROC GLIMMIX in SAS9.4® to assess the effect of treatment, time and treatment × time effects, where time represented the within-subjects factor and treatment was specified as a between-subjects factor. Within subjects' dependency was modeled by specifying participant as a random effect with a heterogenous compound symmetry covariance structure. Similar analyses were used to examine the treatment effect for all secondary and tertiary outcomes at each post-treatment month. Intention-to-treat (ITT) analysis was used to investigate the causal effect of the treatment. All statistical significances were applied at the two-sided 0.05 level with Tukey-Kramer adjustment for multiple testing. Cohen's d effect sizes for the between-subjects' factor was calculated from the between-subjects' F statistic adjusting for sample size. Responder analyses were conducted by calculating the proportion of participants with 15% (mild), 30% (moderate), and 50% (substantial) improvement from baseline for pain-related outcomes. All data processing and statistical analyses were performed on the SAS9.4® (SAS Base and SAS/STAT) platform."

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/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 12a-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

"Intention-to-treat (ITT) analysis was used to investigate the causal effect of the treatment."

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 (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 additional subgroup or adjusted analyses were conducted.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem X26-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

"Research procedures were approved by the Stanford Institutional Review Board (IRB)."

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem X26-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

"After informed consent was obtained, study participants were randomized..."

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem X26-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

The consent form offers details risks and benefits, security procedures, and privacy considerations (it is included in the submission).

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

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

"One hundred and four participants were enrolled and randomized, and 101 participants completed baseline surveys (ER=50, WLC= 51). A total of 49 participants received the Empowered Relief intervention, of whom 2 were lost to follow-up due to feeling unwell or being too busy to complete follow-up surveys. A final sample of 94 participants provided complete follow-up data. Nearly 94% (47/50) of participants in ER group and 86% (44/51) of participants in WLC group completed their 3-month follow-up surveys (end of study)."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

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 49 participants received the Empowered Relief intervention, of whom 2 were lost to follow-up due to feeling unwell or being too busy to complete follow-up surveys."

We have no additional data on participants lost to follow-up.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (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 had minimal attrition in the study, and no data on participants lost to follow-up beyond the intervention, and the two who did not complete baseline measures.

"A total of 49 participants received the Empowered Relief intervention, of whom 2 were lost to follow-up due to feeling unwell or being too busy to complete follow-up surveys. A final sample of 94 participants provided complete follow-up data."

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

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

"This study was conducted between August 2020 and February 2021."

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 14a-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

Not applicable to the current study.

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

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 to the study.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

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, this is presented in tabular form in the manuscript (Tables 3 and 4).

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 15-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

None of the demographic data were predictive.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions

Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 16-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

"A total of 49 participants received the Empowered Relief intervention, of whom 2 were lost to follow-up due to feeling unwell or being too busy to complete follow-up surveys. A final sample of 94 participants provided complete follow-up data. Nearly 94% (47/50) of participants in ER group and 86% (44/51) of participants in WLC group completed their 3-month follow-up surveys (end of study). "

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 16-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

"Intention-to-treat (ITT) analysis was used to investigate the causal effect of the treatment."

17a) 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 subitem 17a? *

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

"Pain Catastrophizing
We observed a significant treatment effect (P=.005) on pain catastrophizing; on average, the ER group had lower PCS scores compared to the WLC group (Cohen d=0.50). Separately, we observed a time effect; average PCS significantly decreased over time for both study groups (time effect, P<.001). Most importantly, the decrease was greater for ER versus WLC (group X time effect, P<.001). At post-treatment 3-months, clinically meaningful reductions in PCS were found for ER but not for WLC (ER: PCS, -8.72, 42.25% reduction; WLC: PCS -2.25, 11.13% reduction). Figure 3 displays the average PCS at 3-months by study arm, and Table 5 displays the between-group comparisons for PCS at baseline and post-treatment months. ER was superior to WLC (difference=-6.05; P<.01; 95% CI -9.92 to -2.18) at 3-months post-treatment.

The ER group effect size as 0.89, with combined results showing a large effect size and moderate clinical importance. As much as 62% (31/50) of ER and 23.5% (12/51) of WLC participants achieved a 30% or more reduction in PCS. For ER, 46% (23/50) achieved over 50% or more in PCS reduction, while for WLC, 11.8% (6/51) reached that threshold. Secondary Outcomes

See Results section for the other outcomes. The file was too large to include all the outcomes here.

17a-i) Presentation of process outcomes such as metrics of use 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, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 17a-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 intervention was Zoom-delivered and participants were encouraged to use the skills they learned daily.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

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 to this manuscript.

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

Does your paper address CONSORT subitem 18? *

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 to this project.

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

subitem not at all important	1	2	3	4	5	essential

Clear selection

Does your paper address subitem 18-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

In the limitations section, we include:

"First, given the participant population was on average of higher socioeconomic status, as evidenced by their average education and income levels, the results may not generalize to populations of different demographics. No data was available on medical diagnoses, current prescriptions or OTC medication use, or concurrent treatments for either study group."

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 harmful effects resulted from the class.

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].

subitem not at all important	1	2	3	4	5	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 or technical problems were observed / 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.

subitem not at all important	1	2	3	4	5	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

The study design was not designed to include qualitative data.

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

"ER demonstrated high feasibility as indexed by high enrollment rate and excellent engagement; 94% of participants in the ER group attended the class and completed all surveys through the 3-month duration of the study. The enrollment rate was 53.1% (104/196), which is five times higher than what we observe in other studies [36, 66] and stand as an index of both the inclusivity of the study protocol (few exclusionary criteria; all types of chronic pain) and the convenience of a single-session pain treatment study. Importantly, participants reported high overall satisfaction with the class (>86%, Mr 8.28–8.77), the usefulness of presented information, and the likelihood to use the skills and information learned. Also, participants reported high satisfaction with operating the Zoom-platform (92% satisfaction), in addition to high satisfaction engaging with class material, other attendees, and the class instructor. Importantly, of the nine participants who indicated they had never used Zoom-platform during screening, none requested additional or individual training with the platform. These metrics indicate superior feasibility, accessibility, and engagement with the Zoom-delivered Empowered Relief intervention."

"Although a growing body of research exists on the efficacy of ER for chronic and acute pain management [32, 35, 36] (Ziadni et al, unpublished data), the use of Zoom as a platform to deliver behavioral medicine for chronic pain—particularly single-session treatment—remains novel and understudied. In addition, the extant literature on digital behavioral health research has reported participant treatment engagement rates ranging from 20% to 60% [32, 73-75]. Strikingly, the current trial evidenced a 94% (47/50) engagement rate in the treatment arm. These results also highlight the public interest in the online delivery of behavioral medicine interventions as a home-based chronic pain treatment modality. Combined with high participant engagement data and high satisfaction with utilizing Zoom-platform, these data extend prior work [17-24] supporting the utility, user satisfaction, and efficacy of videoconference-delivered interventions for chronic pain."

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

"Replication studies are indicated with participants with more demographic variability, over a longer follow-up period."

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

"Several findings should be qualified within a number of limitations. First, given the participant population was on average of higher socioeconomic status, as evidenced by their average education and income levels, the results may not generalize to populations of different demographics. No data was available on medical diagnoses, current prescriptions or OTC medication use, or concurrent treatments for either study group. Correction for multiple comparisons was not applied, and risk for false-positive findings exists. Also, all data were self-report, and we did not control for receipt of medical care. Although in the light of COVID-19 restrictions, participants were likely receiving their care via online delivery as well. In addition, the pain intensity measure used was a 5-point NRS scale, as opposed to the 11-point NRS [76] typically used in research, limiting variability and may have obscured treatment effects and clinically meaningful findings. Finally, participants were unblinded to study group assignment. However, given ER is low-risk and low burden, placebo effects are less concerning. Replication studies are indicated with participants with more demographic variability over a longer follow-up period. Finally, future studies should characterize pain diagnoses and pain types."

21) Generalisability (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

"First, given the participant population was on average of higher socioeconomic status, as evidenced by their average education and income levels, the results may not generalize to populations of different demographics."

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

None - the study was optimized to be delivered online and all study procedures completed online with no in-person contact needed. Staff involvement was minimal.

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

Registered on CT.gov: NCT 04546685

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

Registered on CT.gov though this is not a full protocol. Protocol is under review elsewhere (Trials journal) since October of 2020.

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

Not applicable to this 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

No conflicts of interest to disclose.

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?

Included more details that has been omitted.

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

6 hours to complete the checklist.

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:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Helpful process, but time consuming

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

Never submit passwords through Google Forms.

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

Your response is too large. Try shortening some answers.

Google Forms