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

maddymiller.mlm@gmail.com (not shared) Switch account

Draft saved

* Required

Your name *
First Last
Madeleine Miller

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
National Center for PTSD, Menlo Park, Californ

Your e-mail address *
abc@gmail.com
madeleine.miller@va.gov

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

A Pilot Randomized Controlled Trial of Renew: An Exposure-Based Mobile App for Symptoms of Posttraumatic Stress Disorder in Veterans
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.

Renew

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

Your answer

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: Renew is available on google play store, but users need a special code

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)"

Posttraumatic stress disorder

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

Posttraumatic Stress Disorder Checklist for D$

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

Usage data were collected to assess engagement with Renew.
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:

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:
**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.

1 2 3 4 5

- [ ] subitem not at all important
- [ ] essential

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

Yes -- "A Pilot Randomized Controlled Trial of Renew: An Exposure-Based Mobile App for Symptoms of Posttraumatic Stress Disorder in Veterans"
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").

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subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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.

Our paper does not include non-web based components in the title. A feature of our app is that participants can add "support persons" (i.e., peers, friends, family) who can send one-way messages of encouragement. This is not telephone support or support that follows a protocol, therefore we did not find it necessary to include in the title.

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

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subitem not at all important ☐ ☐ ☐ ☐ ☐ 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

Yes -- "A Pilot Randomized Controlled Trial of Renew: An Exposure-Based Mobile App for Symptoms of Posttraumatic Stress Disorder in Veterans"

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)

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subitem not at all important

essential
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.

Yes, found in the methods section of the abstract -- "Renew is a mobile mental health application that focuses on exposure therapy and incorporates a social support function designed to promote user engagement. In this randomized controlled trial, we compared the effects of Renew with support and without support from a research staff member (No Support) to Delayed Use among ninety-three veterans with clinically significant PTSD symptoms."

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)

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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.

Yes, found in the methods section of the abstract -- "In this randomized controlled trial, we compared the effects of Renew with support and without support from a research staff member (No Support)."
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)

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subitem not at all important ○ ○ ○ ○ ● essential

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

Yes, found in the methods section of the abstract -- "Participants were recruited through online advertisements. An online version of the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) was used to measure PTSD symptoms at pre-, post (6-weeks later), and 6-week follow up."

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)

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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.

Our abstract mentions use data and includes the number of participants enrolled/assessed. Tables within the manuscript contain more detailed information. "Results indicated a small effect size (d = -0.34) favoring those in the two active use conditions (n = 31; n =31) relative to the Delayed Use condition (n = 31), but the between group difference did not reach statistical significance. There were no differences between those in the Support and the No Support condition on indices of app engagement or PTSD symptom reduction."

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)

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subitem not at all important

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.

Yes, found in the results/conclusion section of the abstract -- "There were no differences between those in the Support and the No Support condition on indices of app engagement or PTSD symptom reduction. Contact with support persons is a core feature of Renew, and exploratory analyses suggest that the number of support persons users added to the app, but not the number of support messages received, was positively correlated with app engagement. Conclusions: Findings suggest Renew may hold promise as a self-management tool to reduce PTSD symptoms in veterans and that involving friends and family in mobile mental health applications may help bolster engagement."
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)

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

"Despite the growing number of mobile mental health apps, apps targeting PTSD are less common, and more evidence testing the effectiveness of apps addressing PTSD symptoms is needed...mobile apps may be useful for individuals with PTSD symptoms either alone or with coaching, but current evidence is relatively weak and limited to only a few RCTs... A key challenge with mobile mental health apps relates to sustained engagement by users...One strategy to increase app engagement is to incorporate human feedback...However, use of trained support personnel limits scalability of such interventions due to challenges associated with training, supervising, and monitoring coaches...To address these research gaps, we developed Renew, an exposure-based self-management mobile app for PTSD that includes a peer support component."
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 appropriate), 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.

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subitem not at all important       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

*PTSD affects a significant minority (8%) of the general US population and a larger proportion of certain groups, including veterans. An estimated 14% of Veterans returning from Iraq and Afghanistan meet diagnostic criteria PTSD [3] and an additional 7.6% experience clinically significant symptoms of PTSD that warrant clinical intervention but do not meet diagnostic criteria ...Trauma-focused psychotherapy (i.e., therapy that addresses traumatic memories and trauma-related appraisals and includes exposure and/or cognitive restructuring as a primary therapeutic component) is recommended as the first line treatment for veterans with PTSD ...delivering trauma-focused PTSD interventions via mobile apps could increase the reach of effective care with minimal resources relative to delivery via face-to-face psychotherapy. However, despite the growing number of mobile mental health apps, apps targeting PTSD are less common, and more evidence testing the effectiveness of apps addressing PTSD symptoms is needed...A key challenge with mobile mental health apps relates to sustained engagement by users ...use of trained support personnel limits scalability of such interventions due to challenges associated with training, supervising, and monitoring coaches. Thus, another unanswered question is whether support from a friend or family member can be used to increase user engagement or improve outcomes...To address these research gaps, we developed Renew, an exposure-based self-management mobile app for PTSD that includes a peer support component...the current randomized controlled trial aimed to assess the preliminary effectiveness of Renew, and examine the impact of the support component among veterans reporting clinically significant PTSD symptoms. 
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

"We hypothesized that veterans using Renew for six weeks would show greater reductions in PTSD symptoms relative to waitlist, and that those who were assigned to receive support from project staff would show greater app engagement and greater reductions in PTSD than those who were not provided with a support person. We also explored relationships between indices of support (number of peer support persons added and number of support messages received from peer supporters) and indices of app engagement."

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

Yes, found in the procedures section of the methods, "Consented participants then completed baseline surveys online before scheduling a second phone call for randomization and condition assignment, following a parallel study design. Participants and researchers were unblinded. Randomization was done by study RAs using block randomization allocating participants to the three groups using a 1:1:1 ratio."

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

There were no changes to the methods to report.

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].

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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

Yes, found in the procedures section of the methods, "After trial commencement, a bug was detected that caused the app to crash when the Approach feature was opened. This was reported by n=11 participants before it was corrected halfway through the study period."

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

"Participants were recruited through Facebook advertisements. Interested participants completed an online screening to assess veteran status, criterion A trauma exposure, and PTSD symptom severity. Participants were 93 veterans who reported significant PTSD symptoms – a score of 31 or greater [32] on the PTSD Checklist for DSM-5 [33] – and access to an Android phone."

4a-i) Computer / Internet literacy

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

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

Computer/Internet literacy was not included in the eligibility criteria, however, participants were guided through downloading the Renew app from the google play store and all participants already owned Android smartphones. All participants received an in-depth orientation to using the Renew app over the phone with a study research assistant. "During the second phone call, participants in either of the two active treatment conditions received a 30-min app orientation."
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.

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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 through Facebook advertisements" indicating that participants were recruited online from an open access website. There were no face-to-face interactions in this study. The highest degree of study team members getting to know participants was during consent and the phone interview. "Eligible participants who provided their contact information were then sent the informed consent information sheet and completed the informed consent process with a study research assistant by phone (see Appendix A)...After the 6-week app-use phase, participants completed a post-use online survey and a brief telephone interview."

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.

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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

Written consent is included in appendix A. "Eligible participants who provided their contact information were then sent the informed consent information sheet and completed the informed consent process with a study research assistant by phone (see Appendix A)."

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

Participants were recruited through online advertisements and could participate in the study from any location.

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.

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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

Study outcomes were self-assessments through online questionnaires. "After the 6-week app-use phase, participants completed a post-use online survey."

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)

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

Institutional affiliation was not displayed on the study advertisement for recruitment. However, if someone clicked on the advertisement for more information they would see the study PI's name and affiliation.

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).

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

"Renew was developed by Vertical Inc. and is owned by the VA."

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.
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

"The feasibility and acceptability of Renew was recently demonstrated in a small study of 18 adults who had experienced a traumatic event [31]. Qualitative data from this study suggested that users who were motivated to work independently to manage their PTSD felt the app would be helpful in reducing symptoms."

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).

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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

A bug was identified that caused the Approach feature to crash. This was corrected halfway through the trial and is addressed in the manuscript. "After trial commencement, a bug was detected that caused the app to crash when the Approach feature was opened. This was reported by n=11 participants before it was corrected halfway through the study period."
5-iv) Quality assurance methods

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

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subitem not at all important  ○  ○  ○  ○  ○  essential

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

This is not applicable to our study.

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.

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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.

Yes, our manuscript contains screenshots of Renew's main features.

---

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.

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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.

Our manuscript contains screenshots of Renew's main features. Webcite is currently not accepting archival requests.
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).

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.

"During the second phone call, participants in either of the two active treatment conditions were guided through downloading Renew and given a special code to allow them access to Renew's content. Study RAs provided participants with a 30-minute in-depth orientation to the app...Participants were compensated with Amazon gift cards in the amount of $100 after study completion."
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].

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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.

"Renew is a self-management app for symptoms of posttraumatic stress disorder... Renew was developed by Vertical Inc. and is owned by the VA... Users earn points for completing activities in the app and can achieve new levels that unlock features and activities. Crisis resources are listed within the app. Renew includes two primary exposure components that are each presented with a rationale, detailed instructions, and examples, and are preceded and followed by a 0-100 subjective unit of distress (SUDS) rating. Process guides users through imaginal exposure (i.e., approaching trauma memories in imagination) using a series of writing prompts. Users may use their phone keyboard or the talk-to-text function, with the goal of describing their worst traumatic event for at least 20 minutes. Approach guides users through in vivo exposure by identifying situations they have been avoiding due to their trauma and building a hierarchy of situations for them to approach. Psychoeducation is provided through Learn, which includes information about common reactions to trauma, the development of PTSD symptoms, the role of avoidance in maintaining symptoms, and the science behind exposure therapy techniques. The Self-Care section allows users to identify and schedule self-care activities that promote relaxation, physical activity, and social engagement. Support allows users to invite trusted friends or family members to be part of their support team in Renew. Support persons are invited to download "Renew Support" (available on Apple and Android smartphones) which provides psychoeducation about PTSD symptoms and information on how to support someone who is working on managing PTSD symptoms. Support team members receive notifications when the primary user earns points or achieves a new level, and they are instructed to send an encouraging message through the app’s one-way message system. Motivate allows users to personalize the app by selecting quotes, videos, and images (options are provided, and users may also add their own, e.g., a photo of their family) that motivate them to work on managing their PTSD symptoms. In Progress, users can complete a 5-item "symptom tracker" assessing coping self-efficacy, depression, and PTSD symptoms (users are also prompted to complete this assessment every 2 weeks) and view the results of these assessments, as well as the SUDS data from Process and Approach over time in a graph view (see Figures 1-4)."
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.

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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.

Yes, participants "were invited to use the app as much as they wanted for 6-weeks."

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).

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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.

Yes, our manuscript clearly explains the level of human involvement in each of the treatment conditions.

"Participants were randomized to Renew Alone, Renew with Staff Support, or Waitlist.
Renew Alone
Participants received a 30-minute orientation to Renew and were invited to use the app as much as they wanted for 6-weeks. Participants were allowed, but not instructed, to invite peer support persons who could send one-way messages of encouragement through the Renew app.
Renew with Study Staff Support
Participants received a 30-minute orientation to Renew and were instructed to add a study research assistant (RA) to their support team. Participants were allowed to invite additional peer support persons as they wished. Support team members are notified when the participant levels up or earns points. The assigned study RA responded to all notifications with reinforcing messages (i.e., "Great job staying focused on recovery!") or when the participant had not earned points or gained a level in 7 or more days (i.e., "Hey, it’s been a while since you’ve used Renew. Do you have time to focus on recovery today?"). Participants were instructed to use the app as much as much as they wanted for 6-weeks. Waitlist
Participants were informed that an RA would reach out to them in 6-weeks to schedule the app orientation session with them and that they could elect to receive study staff support or not."

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)

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subitem not at all important

5 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.

Yes, participants in the staff support condition were guaranteed to receive reminders as indicated in item 5-x. Participants had the ability to turn on daily notifications for Renew. "Users can turn on daily notifications to receive reminders to use Renew."

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.

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essential ☐

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

Renew was a standalone intervention. Staff members providing support were not trained on a particular protocol. Messages of encouragement were developed before the study began and sent to participants in the Renew with Staff Support condition when they earned points, leveled up, or had not used the app in 7 or more days.

"Renew with Study Staff Support

Participants received a 30-minute orientation to Renew and were instructed to add a study research assistant (RA) to their support team. Participants were allowed to invite additional peer support persons as they wished. Support team members are notified when the participant levels up or earns points. The assigned study RA responded to all notifications with reinforcing messages (i.e., "Great job staying focused on recovery!") or when the participant had not earned points or gained a level in 7 or more days (i.e., "Hey, it's been a while since you've used Renew. Do you have time to focus on recovery today?"). Participants were instructed to use the app as much as they wanted for 6-weeks."
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

Yes – "Consented participants then completed baseline surveys online before scheduling a second phone call for randomization and condition assignment...After, the 6-week app-use phase, participants completed a post-use online survey."

Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)

The PCL-5 [33] is a 20-item self-report measure of PTSD symptoms as defined by the Diagnostic and Statistical Manual of Mental Disorders [34]. The PCL-5 has been shown to have high internal consistency [Cronbach's alpha .91–.95; 35] and strong test–retest reliability [36, 37].

Renew Usage Data

A research dashboard collected information on app usage, including button-presses, activities completed, length of time users engaged with each app section, and number of characters entered into free text fields of the app. No identifying information was included in the app usage data.

To measure user engagement with the Renew app, the following variables were included in our analyses: time spent using the app, time spent completing exposure activities, and the number of points a user gained for completing activities in the app. All time variables were measured in minutes, but are presented in minutes in this paper for ease of interpretation. “Exposure activities” included both in vivo and written exposure tasks (activities in the Approach and Process sections of the Renew app). Users gained points for completing activities in the app, with users gaining more points for completing exposure activities than for non-exposure activities. The number of points a user gained over the six-week period serves as a non-temporal metric of engagement, and is a proxy for the number and type of activities users completed over the app-use period. All usage variables reported in this paper describe app usage during the six-week active use period for all participants, regardless of study condition."
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].

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Does your paper address subitem 6a-i?
Copy and paste relevant sections from manuscript text

Our paper followed CHERRIES items to describe how the questionnaires were designed/deployed. We also state that the questionnaire was tested in an online format. "The PCL-5 was delivered as an online survey. The psychometric properties of the PCL-5 has been previously tested when used in an online format [37]."

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.

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| subitem not at all important | | | | | essential |

Clear selection
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

"A research dashboard collected information on app usage, including button-presses, activities completed, length of time users engaged with each app section, and number of characters entered into free text fields of the app...To measure user engagement with the Renew app, the following variables were included in our analyses: time spent using the app, time spent completing exposure activities, and the number of points a user gained for completing activities in the app. All time variables were measured in seconds, but are presented in minutes in this paper for ease of interpretation."

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).

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Does your paper address subitem 6a-iii?
Copy and paste relevant sections from manuscript text

"After the 6-week app-use phase, participants completed a post-use online survey and a brief telephone interview. Interviews were audio recorded and transcribed by study RAs."

6b) Any changes to trial outcomes after the trial commenced, with reasons
7a) How sample size was determined
NPT: When applicable, details of whether and how the clustering by care provider or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size
Describe whether and how expected attrition was taken into account when calculating the sample size.

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subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 7a-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

We anticipated about 30% drop out. This was a pilot study and we were not trying to power it to test for statistical significance. We planned to use ITT analyses.

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 (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 did not conduct interim analyses or end our trial early.

8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *
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

"Randomization was done by a study RA using an online random block generator allocating participants to the three groups using a 1:1:1 ratio."

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

"Randomization was done by a study RA using an online random block generator allocating participants to the three groups using a 1:1:1 ratio."

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
Consented participants then completed baseline surveys online before scheduling a second phone call for randomization and condition assignment, following a parallel study design. Randomization was done by a study RA using an online random block generator allocating participants to the three groups using a 1:1:1 ratio. The study RA was unaware of the participants' condition until randomization allocation. Participants and researchers were unblinded to study condition.

All of the procedures were conducted by trained study RAs. "Randomization was done by study RAs..."
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).

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| subitem not at all important | | | | | essential |

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 and researchers were unblinded."

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”.

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| subitem not at all important | | | | | essential |
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 in either treatment group were not blinded to their treatment condition. Participants in the Renew with Staff Support condition were not made aware these was the group of interest.

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

This is not applicable to our study.

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

This is not applicable to our study.
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

"Hypothesis 1 was tested using a standard linear mixed effects model [38, 39], specifically a random intercept piecewise growth model to characterize the two distinct longitudinal 6-week segments from baseline to post-treatment and from post-treatment to follow-up. The analysis was conducted following the intention to treat principle and implemented using the MIXED procedure in SAS [version 9.4; SAS 40]. The primary outcome of interest was the 6-week change (slope) in PCL-5 from baseline to post-treatment. Post-hoc tests examined whether within-group slopes were significant. For analyses of indices of support, the variables of interest were characterized by skew distributions where non-parametric tests are more appropriate: for the secondary hypothesis comparing indices of support between the two active use conditions, the Mann-Whitney-Wilcoxon test and AUC effect size [41] for the exploratory analysis of associations with indices of support, the Spearman's rank correlation coefficient."

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  ☐ ☐ ☐ ☐ ☑ 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

"The analysis was conducted following the intention to treat principle and implemented using the MIXED procedure in SAS [version 9.4; SAS 40]."
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

"As an exploratory analysis, we examined whether support, operationalized by the number support messages, was associated with higher app engagement, during the active use period for all three conditions combined. As shown in Table 3, none of the associations were significant or met the criterion for moderate effect size rating (Spearman's rho of 0.3 or above)."

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

X26-i) Comment on ethics committee approval

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

"This study was approved by the Stanford 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.

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subitem not at all important  ○  ○  ○  ○  ● essential

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.

"Eligible participants who provided their contact information were then sent the informed consent information sheet and completed the informed consent process with a study research assistant by phone (see Appendix A)."

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)

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subitem not at all important  ○  ○  ○  ○  ● 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.

"Crisis resources – such as 911, the national sexual assault hotline, the national domestic violence hotline, the national suicide crisis hotline, the suicide prevention lifeline, the Veterans text crisis line, and the Veterans Combat Call Center – are listed within the app."

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.

Yes, our CONSORT diagram displays the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for primary outcomes.

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

Yes, this information is available in our CONSORT diagram. One participant withdrew from the study. n = 14 participants were lost to follow-up and could not be reached.

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.

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

Tables 2 and 4 show usage data throughout the study duration (i.e. time in app, time spent on exposure activities, number of points earned, number of support persons added, number of support messages received). This data was not collected past study completion.

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

"The timeline for participant recruitment to follow up was from 7/18/20 - 2/3/21."

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”

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subitem not at all important ○ ○ ○ ○ ● essential

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

There were no critical "secular events" during our study timeframe to report.

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. The trial did not end early. The trial came to an end when the intended study period was complete.
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, Table 1 contains participant demographics.

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.

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

Our paper addresses age, gender, race, ethnicity, education, military status, employment, and relationship status. We did not assess technical literacy, however, all participants were provided an in-depth orientation to using the app.

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.

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subitem not at all important ○ ○ ○ ○ ○ 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

This is not applicable, we did not look at subgroups in our analyses.

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).

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subitem not at all important ○ ○ ○ ○ ○ 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

Yes, primary analyses were intent to treat.
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.

"The linear mixed effects model estimates showed a larger PCL-5 decrease during the 6-week treatment period for the combined Active Use group compared to the Delayed Use group (-5.71 vs -1.94; Figure 6). This difference was not statistically significant (p = 0.26), but there was a small effect size, d = -0.34 [42]. Using the model estimates, the within-group PCL-5 change from baseline to post-treatment was significant for the combined Active Use participants (-5.71, 95%CI = -9.44, -1.98, p = .003), but not for the Delayed Use group. During the usage period from 6-12 weeks for the Delayed Use group, the within-group PCL-5 change was also significant (-10.1, 95%CI = -15.8, -4.4, p<.001). "

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).

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).

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subitem not at all important 〇 〇 〇 〇 〇 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

Yes, we looked at time spent in the app and time spent in exposure activities as metrics of use and intensity of use. This information is presented in tables 2 and 3.

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

This is not applicable to our study, we do not have binary outcomes.

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

Yes, our manuscript specifies which analyses are exploratory. "As an exploratory analysis, we examined whether support, operationalized by the number support messages, was associated with higher app engagement, during the active use period for all three conditions combined."
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 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

We did not compute sub-group analyses.

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

There were no reported harms or unintended effects of Renew.
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].

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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

"After trial commencement, a bug was detected that caused the app to crash when the Approach feature was opened."

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.

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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.

This data was collected but is not presented in this manuscript. Qualitative findings are being reported in a secondary paper.

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).

subitem not at all important

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essential
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

Yes, the manuscript addresses this information. Tables 2 and 3 summarize usage data. "The goals of this pilot were to examine the effects of Renew on symptoms of PTSD and to evaluate the impact of the staff support component on app engagement and PTSD symptom change. Results provide partial support for the preliminary efficacy of Renew. Veterans with clinically significant symptoms of PTSD who used Renew reported reductions in PTSD symptoms over a six-week period. In contrast, veterans in the Delayed Use condition reported no reductions in PTSD symptoms over the same six-week period. The between group difference did not reach statistical significance, but it was associated with a small effect size favoring those in the Active Use conditions. The preliminary efficacy of Renew was also evidenced by the reduction in PTSD symptoms among the Delayed Use group after the six-week waitlist period elapsed and they were granted access to Renew...Contrary to hypothesis, we did not see greater app engagement or PTSD symptom change among those in the Support condition, who were assigned a study staff person as one of their support team members relative to those in the No Support condition. "

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

Highlight unanswered new questions, suggest future research.

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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

Yes, our discussion highlights areas to continue exploring in future studies. "The pattern of PTSD symptom change indicates some continued improvement during the follow-up period. This finding is consistent with a study of PTSD Coach showing that PTSD symptoms continued to decline over a three-month use period and, to a lesser degree, a subsequent three-month follow-up [12]. Thus, it seems warranted to examine the impact of Renew over a longer use period in future studies...It is relevant to mention that this study did not follow a tested model of incorporating peer support, such as Schueller's (2017) Efficiency Model of Support, which limits our ability to interpret the effectiveness of peer support. In future studies of Renew, this model, or another tested protocol for incorporating support, should be followed to allow for stronger testing on the Support function... Veterans in this study were instructed to use the app as much as they wanted for six weeks and were oriented to and encouraged to try all components of Renew. Although those in the Support condition received messages in response to their use of Renew, there was no synchronous coaching provided (e.g., coaching phone calls). While this allows us to better approximate what the effect of Renew may be in routine use, it is possible that additional scaffolding to support app engagement would have resulted in greater clinical benefit. Future studies could explore the impact of Renew with coaching or as an adjunct to more traditional care (e.g., including a therapist as a Support team member)."

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.

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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.

Yes, these are addressed in the limitations section. "We relied on survey assessments, which is not the gold standard. Finally, there was low overall engagement with Renew. It is relevant to note that were no use requirements, in an attempt to look at the natural use of Renew."

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

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.

"Participants were veterans who responded to social media advertisements about a mobile app study. Findings may not generalize to other populations, including civilians or patients in VA mental health clinics."
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.

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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

"Veterans in this study were instructed to use the app as much as they wanted for six weeks and were oriented to and encouraged to try all components of Renew. Although those in the Support condition received messages in response to their use of Renew, there was no synchronous coaching provided (e.g., coaching phone calls)...this allows us to better approximate what the effect of Renew may be in routine use."

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

Clinical Trials NCT04155736
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.

Our clinical trials reference number can be used to access the trial protocol.

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.

Yes, found on our title page, "This material is the result of work supported with resources and the use of facilities at the VA Palo Alto Health Care System. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors."

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.

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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 state they had no conflicts of interest to declare.

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?

Our methods section is more detailed as a result of using this checklist (i.e., explains randomization)
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

The checklist and changes to our manuscript took roughly five hours.

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

Your answer
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