

# 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



**kav2120@gmail.com** (not shared) [Switch account](#)



Draft saved

\* Required

Your name \*

First Last

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Primary Affiliation (short), City, Country \*

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Your e-mail address \*

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**Title of your manuscript \***

Provide the (draft) title of your manuscript.

The PTSD Family Coach App in Veteran Family Members: Pilot  
Randomized Controlled Trial

**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.

PTSD Family Coach

**Evaluated Version (if any)**

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Version 1.0

**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.

<https://apps.apple.com/us/app/ptsd-family-coach/id804318041>



URL of an image/screenshot (optional)

Your answer

Accessibility \*

Can an enduser access the intervention presently?

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

Primary Medical Indication/Disease/Condition \*

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

"PTSD (Family members of veterans with)"

Primary Outcomes measured in trial \*

comma-separated list of primary outcomes reported in the trial

caregiver burden, stress, depression, anxiety



### Secondary/other outcomes

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

beliefs about psychiatric or psychological treatment, social constraints, relationship functioning, communication danger signs

### 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: as desired



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: 42053

TITLE AND ABSTRACT

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

1a) Does your paper address CONSORT item 1a? \*

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

yes

Other:





**1a-i) Identify the mode of delivery in the title**

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

subitem not at all important

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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

"The PTSD Family Coach App"



**1a-ii) Non-web-based components or important co-interventions in title**

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

subitem not at all important

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Clear selection

**Does your paper address subitem 1a-ii?**

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

This item is not applicable



**1a-iii) Primary condition or target group in the title**

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

subitem not at all important

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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

"Veteran Family Members"

 Your answer must have a minimum of 25 characters.

**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/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT

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

subitem not at all important

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Clear selection

Does your paper address subitem 1b-i? \*

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

"PTSD Family Coach 1.0 (n=104) or a psychoeducation-only app (n=96)"



**1b-ii) Level of human involvement in the METHODS section of the ABSTRACT**

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

subitem not at all important

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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

"self-guided use of either PTSD Family Coach..."



1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

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

subitem not at all important

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Clear selection

Does your paper address subitem 1b-iii?

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

"were administered via a web survey"



### 1b-iv) RESULTS section in abstract must contain use data

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

subitem not at all important

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Clear selection

### Does your paper address subitem 1b-iv?

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

"Overall, 50.5% (101/200) of randomized participants used their allocated app. Participants found PTSD Family Coach 1.0 somewhat satisfying (mean 4.88, SD 1.11) and moderately helpful (mean 2.99, SD 0.97) to use. Linear mixed effects models revealed no significant differences in outcomes by condition for caregiver burden ( $P=.45$ ; Cohen  $d=0.1$ , 95% CI  $-0.2$  to  $0.4$ ), stress ( $P=.64$ ; Cohen  $d=0.1$ , 95% CI  $-0.4$  to  $0.6$ ), depression ( $P=.93$ ; Cohen  $d=0.0$ , 95% CI  $-0.3$  to  $0.3$ ), anxiety ( $P=.55$ ; Cohen  $d=-0.1$ , 95% CI  $-0.4$  to  $0.2$ ), beliefs about treatment ( $P=.71$ ; Cohen  $d=0.1$ , 95% CI  $-0.2$  to  $0.3$ ), partner self-efficacy ( $P=.59$ ; Cohen  $d=-0.1$ , 95% CI  $-0.4$  to  $0.2$ ), dyadic adjustment ( $P=.08$ ; Cohen  $d=-0.2$ , 95% CI  $-0.5$  to  $0.0$ ), social constraints ( $P=.05$ ; Cohen  $d=0.3$ , 95% CI  $0.0$ - $0.6$ ), or communication danger signs ( $P=.90$ ; Cohen  $d=-0.0$ , 95% CI  $-0.3$  to  $0.3$ ). Post hoc analyses collapsing across conditions revealed a significant between-group effect on stress for app users versus nonusers ( $\beta=-3.62$ ;  $t_{281}=-2.27$ ;  $P=.02$ )."



### 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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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

"Approximately half of the randomized participants never used their allocated app, and participants in the PTSD Family Coach 1.0 condition only opened the app approximately 4 times over 4 weeks, suggesting limitations to this app version's feasibility. PTSD Family Coach 1.0 users reported moderately favorable impressions of the app, suggesting preliminary acceptability. Regarding efficacy, no significant difference was found between PTSD Family Coach 1.0 users and psychoeducation app users across any outcome of interest. Post hoc analyses suggested that app use regardless of treatment condition was associated with reduced stress. Further research that improves app feasibility and establishes efficacy in targeting the domains most relevant to CSOs is warranted."





## INTRODUCTION

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

#### 2a-i) Problem and the type of system/solution

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

subitem not at all important

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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

Your answer



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.

subitem not at all important

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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

"Posttraumatic stress disorder (PTSD) related to military service has negative impacts not only on service members and veterans but also on their families"

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

"This study was designed to gather preliminary evidence for the feasibility, acceptability, and efficacy of PTSD Family Coach 1.0, the first iteration of a mobile app-based health support tool for family member CSOs of veterans with PTSD."

"Given that the app was developed based on CSOs' articulated needs, it was hypothesized that participants would use PTSD Family Coach 1.0 and find it satisfying and helpful. Given that a needs assessment highlighted several CSO concerns above and beyond traditional psychoeducation [31], in which CSOs can access via the internet even if they do not use a mobile app [19-21], preliminary efficacy was assessed by testing the hypothesis that the full version of PTSD Family Coach 1.0, including stress management and self-assessment features, would outperform a psychoeducation-only version of the app in reducing caregiver burden, stress, depression and anxiety, and improving beliefs about accessing psychiatric or psychological treatment and social constraints as a function of coexisting with PTSD, self-efficacy, relationship functioning, and communication danger signs."

## 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

Your answer



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

"Those who were screened completed the baseline survey and provided an email address to receive randomization information and instructions for downloading their allocated app."

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].

subitem not at all important

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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

Not applicable

 Your answer must have a minimum of 25 characters.

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? \*

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

"The study inclusion criteria were as follows: (1) age  $\geq 18$  years, (2) iPhone ownership, (3) cohabitation with a veteran with a diagnosis of PTSD, and (4) a Perceived Stress Scale (PSS) score  $> 14$ , indicating moderate or higher stress [35]."



#### 4a-i) Computer / Internet literacy

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

subitem not at all important

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Clear selection

#### Does your paper address subitem 4a-i?

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

This item is not applicable



**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.

subitem not at all important

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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

"Prospective participants were recruited via Facebook and Google advertisements targeting those who were interested in veteran-related issues that directed them to the baseline Qualtrics survey where they accessed an electronic consent form."

"Those who consented were directed to a brief screener questionnaire, which included an assessment of age, PSS, and three yes or no questions as follows: (1) Do you own an iPhone or iPad? (2) Are you currently living with a Veteran? and (3) Has the Veteran that you are living with been diagnosed with PTSD? Those who were screened completed the baseline survey and provided an email address to receive randomization information and instructions for downloading their allocated app."

"After 4 weeks, participants were e-mailed a link to the posttreatment survey."

**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.

subitem not at all important

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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

"advertisements targeting those who were interested in veteran-related issues"

"Qualtrics survey where they accessed an electronic consent form. Those who consented were directed to a brief screener questionnaire, which included an assessment of age, PSS, and three yes or no questions as follows: (1) Do you own an iPhone or iPad? (2) Are you currently living with a Veteran? and (3) Has the Veteran that you are living with been diagnosed with PTSD? Those who were screened completed the baseline survey and provided an email address to receive randomization information and instructions for downloading their allocated app"

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

"data, such as the number of times each participant opened their app, were collected"

"Caregiver burden, stress, depression, anxiety, beliefs about treatment, CSO self-efficacy, and relationship functioning assessed using measures of dyadic adjustment, social constraints, and communication danger signs were administered via a web survey at baseline and after treatment"



**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.

subitem not at all important

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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

""Caregiver burden, stress, depression, anxiety, beliefs about treatment, CSO self-efficacy, and relationship functioning assessed using measures of dyadic adjustment, social constraints, and communication danger signs were administered via a web survey at baseline and after treatment""



#### 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)

subitem not at all important

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#### 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

Your answer

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).

subitem not at all important

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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

Your answer



### 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.

subitem not at all important

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### 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

Your answer



### 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).

subitem not at all important

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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

Your answer



#### 5-iv) Quality assurance methods

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

subitem not at all important

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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

Your answer



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.

subitem not at all important

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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

Your answer





### 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](http://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.

subitem not at all important

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essential

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

Your answer



### 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).

subitem not at all important

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### Does your paper address subitem 5-vii? \*

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

"The participants were enrolled in 2014. At that time, downloading a prototype app for research on an iPhone involved a specialized multistep process. Once participants had identified the app in the app store, they were required to open Settings on their device, select Device Management, and "Trust" a nonverified developer (ie, the research app platform) to install the app on their device. Upon first opening the app, participants were required to enter a unique six-character study invite code. Thereafter, participants were able to access the app freely at any time."



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].

subitem not at all important

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**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

**"PTSD Family Coach 1.0**

Participants randomized to the full version of PTSD Family Coach 1.0 had access to all features of the app for 4 weeks and could use it as much or as little as they wished. Features of PTSD Family Coach 1.0 included the following: (1) psychoeducation on PTSD, self-care, relationship functioning, and military and veteran-specific issues (Learn); (2) 24 unique stress management tools, including mindfulness exercises, social skills resources, and cognitive-behavioral strategies (Manage Stress); (3) a self-assessment tool (ie, the PSS) so that users could track their stress levels over time (Self-Assessment); and (4) resources for connecting to other military families and caregivers, finding professional help, contacting crisis services, and reaching out to existing social support (Get Support). Screenshots of PTSD Family Coach 1.0 can be found in Figure 1.

**Psychoeducation Comparison**

Participants randomized to the psychoeducation app had access only to the psychoeducation and support resources (ie, Learn and Get Support) from PTSD Family Coach 1.0 (see Figure 1, panels b and d) and could use these resources as much or as little as they wished."

**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.

subitem not at all important

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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

Your answer

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).

subitem not at all important

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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

Your answer



### 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).

subitem not at all important

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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

No prompts or reminders were used



**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).

subitem not at all important

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**Does your paper address subitem 5-xii? \***

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

"Those who were screened completed the baseline survey and provided an email address to receive randomization information and instructions for downloading their allocated app."

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



## Does your paper address CONSORT subitem 6a? \*

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

### "Outcomes of Interest

#### Caregiver Burden

Participants' perceptions of caregiver burden were measured using the Montgomery Borgatta Caregiver Burden Scale [39], a 16-item self-report measure. Items are scored on a 5-point Likert scale ranging from 1 (not at all) to 5 (a great deal). Scores range from 16 to 80, with higher scores reflecting a greater caregiver burden. The Montgomery Borgatta Caregiver Burden Scale has been shown to have good internal consistency ( $\alpha=.86$ ).

#### Perceptions of Stress

Participants' perceptions of stress were measured using the PSS [40]. The PSS is a 10-item self-report measure of respondents' perception of stress in their lives. Items are scored on a 5-point Likert scale for frequency, ranging from 0 (never) to 4 (very often). Scores ranged from 0 to 40, with higher scores reflecting greater perceived stress. The PSS has been shown to have acceptable internal consistency ( $\alpha=.78$ ) [40].

#### Depression Symptoms

Participants' depression symptoms were measured using the 8-item version of the Patient Health Questionnaire (PHQ)-8. This version is identical to the PHQ-9 [41] but does not include the item on suicidal ideation and was developed for instances in which study staff were not able to provide immediate crisis intervention if participants endorsed suicidal thoughts or feelings [42], as was the case in this study. Items are rated on a 4-point Likert scale for frequency, ranging from 0 (not at all) to 3 (nearly every day). Scores ranged from 0 to 24, with higher scores reflecting more severe depressive symptoms. The PHQ-8 has been shown to have good internal consistency ( $\alpha=.89$ ) [43].

#### Anxiety Symptoms

Participants' anxiety symptoms were measured using the Generalized Anxiety Disorder-7 (GAD-7) [43]. The GAD-7 is a 7-item self-report measure of physiological and psychological indicators of generalized anxiety. Items are rated on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). Scores ranged from 0 to 21, with higher scores reflecting more severe anxiety symptoms. The GAD-7 has been shown to have excellent internal consistency ( $\alpha=.92$ ) [43].

#### Beliefs About Treatment

Participants' views on psychological and psychiatric treatment for mental health problems were assessed using the Beliefs about Psychotherapy and Medications Scale [44]. This is a 14-item self-report measure, with items rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Scores range from 14 to 70, with higher scores reflecting more favorable views of mental health treatment. The medication subscale demonstrated acceptable internal consistency ( $\alpha=.71$ ), and the psychotherapy subscale has demonstrated good internal consistency ( $\alpha=.82$ ) [44].

#### Social Constraints

Participants' perceptions of constraints on their relationship were assessed using the Social Constraints Scale (SCS) [45]. The SCS is a 5-item self-report measure, with items rated on a 5-point Likert scale for frequency ranging from 1 (almost never) to 5 (almost always).





Scores ranged from 5 to 25, with higher scores reflecting greater perceived constraints on social functioning. The SCS has been shown to have good internal consistency ( $\alpha=.81$ ).

#### Self-efficacy

Participants' perceptions of self-efficacy were assessed using 3 items from the Partner Self-Efficacy scale (PSE) [15]. The items assessed the degree to which control CSOs felt that they had over their loved ones' emotional difficulties and were rated on a 5-point Likert scale of control, ranging from 0 (no control/ability) to 4 (total control/ability). PSE scores ranged from 0 to 12, with higher scores reflecting greater perceived self-efficacy. The PSE has been shown to have questionable internal consistency ( $\alpha=.54$ ) [15].

#### Relationship Functioning

Participants' perceptions of overall relationship functioning with veterans were assessed using the Dyadic Adjustment Scale (DAS) [46]. DAS is a 47-item self-report measure with subscales for consensus, cohesion, and satisfaction. Items 1 to 3 were scored on a 6-point Likert scale ranging from 1 (always agree) to 6 (always disagree). Items 4 to 6 were scored on a 6-point Likert scale ranging from 1 (never) to 6 (more often than once per day). Item 7 was scored on a 7-point Likert scale ranging from 1 (extremely unhappy) to 7 (perfect). Scores ranged from 7 to 43, with higher scores reflecting more effective relationship functioning. The DAS has demonstrated excellent internal consistency ( $\alpha=.96$ ) [46].

#### Communication Danger Signs

Perceived communication problems between participants and veterans were assessed using the Communication Danger Signs scale (CDS) [47]. The CDS is an 8-item self-report measure with items rated on a 3-point Likert scale ranging from 1 (almost never) to 3 (frequently). Scores ranged from 8 to 24, with higher scores reflecting more problematic communication patterns. The CDS has demonstrated acceptable internal consistency ( $\alpha=.73$ ) [47]."



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].

subitem not at all important

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer



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.

subitem not at all important

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essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Your answer



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).

subitem not at all important

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

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

Does your paper address CONSORT subitem 6b? \*

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

This item is not applicable to our study



**7a) How sample size was determined**

NPT: When applicable, details of whether and how the clustering by care provides 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.

subitem not at all important

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**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

Your answer

**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

This item is not applicable to our study

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

"200 individuals were randomized (1:1) into the PTSD Family Coach (n=104) and psychoeducation app conditions (n=96)."

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

Blocking was not used in the present study



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

Does your paper address CONSORT subitem 9? \*

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

randomization was 1:1 for every eligible participant

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

Does your paper address CONSORT subitem 10? \*

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

randomization was 1:1 for every eligible participant

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



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

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

subitem not at all important

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### Does your paper address subitem 11a-i? \*

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

Participants were not blinded to study condition





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

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

subitem not at all important

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Does your paper address subitem 11a-ii?

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

Participants were not blinded to study condition

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

"Interventions

PTSD Family Coach 1.0

Participants randomized to the full version of PTSD Family Coach 1.0 had access to all features of the app for 4 weeks and could use it as much or as little as they wished. Features of PTSD Family Coach 1.0 included the following: (1) psychoeducation on PTSD, self-care, relationship functioning, and military and veteran-specific issues (Learn); (2) 24 unique stress management tools, including mindfulness exercises, social skills resources, and cognitive-behavioral strategies (Manage Stress); (3) a self-assessment tool (ie, the PSS) so that users could track their stress levels over time (Self-Assessment); and (4) resources for connecting to other military families and caregivers, finding professional help, contacting crisis services, and reaching out to existing social support (Get Support). Screenshots of PTSD Family Coach 1.0 can be found in Figure 1.

Psychoeducation Comparison

Participants randomized to the psychoeducation app had access only to the psychoeducation and support resources (ie, Learn and Get Support) from PTSD Family Coach 1.0 (see Figure 1, panels b and d) and could use these resources as much or as little as they wished."

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

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



Does your paper address CONSORT subitem 12a? \*

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

"Data Analyses

All data analyses were conducted in R using the lme4 package [48]. Data inspection and visualization revealed that all variables met the assumptions of normality. Observed scores for all variables of interest were plotted for individuals by time point, and observed variance-covariance and correlation matrices were generated. Ordinary least squares residuals were plotted to determine whether they appeared to have any remaining time trend that would need to be addressed before analyses [49]. No changes were needed.

Descriptive and summary statistics were used to assess feasibility, and 2-tailed t tests were used to assess differences in acceptability metrics by condition. For all efficacy analyses, maximum likelihood estimation methods were used to make use of all available data for each participant [50]. Intent-to-treat analyses were performed using linear mixed effects models [51]. As this was a pilot project, additional exploratory post hoc analyses were conducted to better understand how mobile app uptake might impact the outcomes of interest. These analyses explored outcomes by app use versus nonuse as well as by group randomization."



### 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

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### 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

"linear mixed modeling approaches, which are robust to high rates of attrition, such as those observed in this project, were therefore used to maximize data quality"

Imputation was not used

### 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 this was a pilot project, additional exploratory post hoc analyses were conducted to better understand how mobile app uptake might impact the outcomes of interest. These analyses explored outcomes by app use versus nonuse as well as by group randomization."

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

X26-i) Comment on ethics committee approval

subitem not at all important

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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

"The VA Medical Center and Affiliated University Institutional Review Board approved all study procedures (eProtocol #28147), and all participants provided electronic consent. "

x26-ii) Outline informed consent procedures

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

subitem not at all important

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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

"The VA Medical Center and Affiliated University Institutional Review Board approved all study procedures (eProtocol #28147), and all participants provided electronic consent. "



### X26-iii) Safety and security procedures

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

subitem not at all important

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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

Your answer

## 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

"Demographic characteristics of the participants are presented in Table 1. The flow of the study is presented in Figure 2. Of the 665 individuals assessed for eligibility, 465 (69.9%) did not consent, completed the initial assessment, or met the study inclusion criteria. Of those remaining, 200 individuals were randomized (1:1) into the PTSD Family Coach (n=104) and psychoeducation app conditions (n=96)."

"Of the 200 randomized individuals, 101 (50.5%) used their allocated app at least once over 4 weeks of the study. There were no significant differences between the proportion of app users in each condition (PTSD Family Coach, n=54, 51.9%; psychoeducation, n=47, 49%; N=200;  $\chi^2=0.2$ ;  $P=.62$ ) or the average number of times the app was opened overall ( $t=163.94$ ;  $P=-1.03$ ;  $P=.31$ ): PTSD Family Coach, mean 3.77 (SD 4.22), psychoeducation, mean 3.10 (SD 4.21). Similarly, there was no significant difference in app use each week by condition (Figure 3). PTSD Family Coach 1.0 users opened their apps an average of 2.38 times in the first week (SD 2.86), with a reduction in use for weeks 2 (mean 0.45, SD 1.13), 3 (mean 0.14, SD 0.46) and 4 (mean 0.22, SD 0.92)."

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

"Of the 200 randomized individuals, 101 (50.5%) used their allocated app at least once over 4 weeks of the study. There were no significant differences between the proportion of app users in each condition (PTSD Family Coach, n=54, 51.9%; psychoeducation, n=47, 49%; N=200;  $\chi^2=0.2$ ;  $P=.62$ ) or the average number of times the app was opened overall ( $t=163.94$ ;  $P=-1.03$ ;  $P=.31$ ): PTSD Family Coach, mean 3.77 (SD 4.22), psychoeducation, mean 3.10 (SD 4.21). Similarly, there was no significant difference in app use each week by condition (Figure 3). PTSD Family Coach 1.0 users opened their apps an average of 2.38 times in the first week (SD 2.86), with a reduction in use for weeks 2 (mean 0.45, SD 1.13), 3 (mean 0.14, SD 0.46) and 4 (mean 0.22, SD 0.92)."

Figure 2 also includes study flow highlighting where participants did not engage with the intervention or complete an assessment

### 13b-i) Attrition diagram

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

subitem not at all important

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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

Figure 2 is an attrition diagram

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 app was built and data were collected in 2014."



**14a-i) Indicate if critical “secular events” fell into the study period**

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

subitem not at all important

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**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

Your answer

**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

The present trial was not ended or stopped early

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

The required table is presented as Table 1 in the manuscript



**15-i) Report demographics associated with digital divide issues**

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

subitem not at all important

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essential

**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

All described demographics with the exception of internet literacy are presented in Table 1

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



### 16-i) Report multiple “denominators” and provide definitions

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

subitem not at all important

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essential

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

denominator N's, and effect sizes are reported in Table 2 and Table 3



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

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

subitem not at all important

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**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

primary analyses were intent-to-treat

**17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)**



Does your paper address CONSORT subitem 17a? \*

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

Effect sizes and 95% CIs are reported in tables 2 and 3

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

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

subitem not at all important

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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

Your answer

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

Does your paper address CONSORT subitem 17b? \*

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

Not applicable to this present study

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

Primary outcomes in Table 2 and secondary outcomes in Table 3 are labeled and differentiated



### 18-i) Subgroup analysis of comparing only users

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

subitem not at all important

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### 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

Your answer

### 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

Harms and unintended effects did not occur

19-i) Include privacy breaches, technical problems

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

subitem not at all important

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essential

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

Your answer



19-ii) Include qualitative feedback from participants or observations from staff/researchers

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

subitem not at all important

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essential

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

Your answer

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

"This study tested the feasibility, acceptability, and potential efficacy of a mobile app-based mental health resource for CSOs living with veterans with PTSD. Approximately half of the randomized participants never opened the app, and participants in the PTSD Family Coach 1.0 condition only opened the app approximately 4 times over 4 weeks, suggesting limitations to this version's feasibility. In terms of acceptability, PTSD Family Coach 1.0 users reported moderately favorable impressions of the app regarding satisfaction and perceived helpfulness. For potential efficacy, findings suggested no differences between participants randomized to PTSD Family Coach 1.0 versus the psychoeducation app on any outcome of interest. Post hoc analyses of participants who did and did not download and open their allocated app yielded a significant between-groups effect for perceived stress, such that app users had moderately greater reductions (ie, Cohen  $d=-0.6$ ) in perceived stress scores from baseline to posttreatment compared with nonusers."



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

Highlight unanswered new questions, suggest future research.

subitem not at all important

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essential

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

Your answer

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.

subitem not at all important

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essential



**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

**"Limitations**

This study has several limitations. The app was built and data were collected in 2014. Given the rapid rate of change in technological platforms [57], this dates and limits the applicability of the study findings to current efforts to develop and pilot-test app-based interventions. The attrition rates in both randomized conditions were high. This may be attributable to a less directive methodological approach to study recruitment and retention [58]. Approximately half of those randomized to a condition accessed their allocated app, and approximately 40% of all participants did not complete the posttreatment survey. High rates of attrition and low levels of intervention engagement are common problems in internet-based intervention studies [59,60], and this problem likely extends to mobile app interventions as well. In epidemiological-level work, internet-based projects that use some offline enrollment initiatives outperform those that are completely virtual [58]. For evidence-based interventions to be developed for mobile apps such that they are widely available and scalable, however, it will be crucial to use research methods that allow participants to find and use these tools with minimal to no face-to-face support. Subsequent studies may benefit from using larger incentives [61], more user-friendly training tools (eg, a training video or an interactive step-by-step guide to download the app), or more readily available access to troubleshooting technology. Therefore, linear mixed modeling approaches, which are robust to high rates of attrition, such as those observed in this project, were therefore used to maximize data quality [62]. However, future work should prioritize app training and retention efforts to ensure that those who enroll are more likely to receive their allocated interventions.

The demographic features of the sample were narrow, such that it was composed primarily of White female spouses of male veterans. Thus, cohabitating CSOs other than White female spouses were not adequately represented in this study, and the extent to which these findings generalize across demographic factors such as gender, race, ethnicity, and family role for families of veterans living with PTSD. At the time the study procedures were conducted, granular descriptive use data, such as which tools participants accessed or returned the most, were not available. The absence of significant differences between PTSD Family Coach 1.0 users and psychoeducation-only users may point to CSO reliance on psychoeducation tools in both conditions. However, information on how users navigated the app could potentially shed light on whether CSOs gravitated to psychoeducation over more active tools, such as skill-building or self-assessment, and these anonymized data were collected for the updated version of the app, PTSD Family Coach 2.0. It is possible that constraints on app content and design diminished PTSD Family Coach 1.0's usefulness for CSOs, and the lack of descriptive data on how CSOs used various tools limits the conclusions that can be drawn about these potential constraints. For example, it is possible that the coping skills CSOs were encouraged to practice in the Manage Stress section required further tailoring to address CSOs' articulated needs (eg, managing reactions to veterans' PTSD symptoms). Across its various features, PTSD Family Coach 1.0 was heavy in text, which may have made the tools less accessible or more difficult to navigate.





Updates to PTSD Family Coach 2.0 included revisions to how tools were labeled, and how much text-based content users would need to navigate on each screen. Future work would benefit from more granular data about which tools are used, and it may prove beneficial to build in opportunities for CSOs to provide immediate feedback on each accessed tool (eg, 3 yes or no questions after a tool has been accessed to determine whether CSOs found the tool helpful, appealing, and easy to understand). PTSD Family Coach 1.0 was available for research use only on iOS devices, limiting inclusion to only those with iPhones. Some demographic and personality differences between iOS and Android users have been identified in prior work, suggesting that apps available only to iOS users may limit the generalizability of the findings [63,64]. PTSD Family Coach 2.0 is available on Android platforms and should be tested by both types of smartphone users. Minimal training on downloading the mobile app and now obsolete security barriers appear to have resulted in more-than-typical issues with accessing both app versions. Study procedures should be replicated with the more user-friendly functionality of being able to download the app directly from the app store on a user's phone. Finally, the study was conducted in 2014. Smartphone ownership in the United States has increased by 30% from 2014 to 2021, and mobile technologies are undergoing nearly constant changes and updates [65]. As such, future projects examining PTSD Family Coach 2.0 are likely to include more generalizable samples with more experience using smartphone technologies."

## 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

subitem not at all important

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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

Your answer



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.

subitem not at all important

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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

Your answer

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

trial number is NCT02486705

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

<https://clinicaltrials.gov/ct2/show/NCT02486705>

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

"This work did not receive funding support."

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.

subitem not at all important

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**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

Your answer

**About the CONSORT EHEALTH checklist**

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

- yes, major changes
- yes, minor changes
- no

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

Your answer

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

It took approximately two 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:

Any other comments or questions on CONSORT EHEALTH

Your answer

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