### 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 (nonpharmacologic 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

Your response is too large. Try shortening some answers.

one. <u>http:// http:// http://oreg/ 2011/ 1/0120/</u>

doi: 10.2196/jmir.1923 PMID: 22209829

\* Required

Your name \* First Last

Shahrzad Yektatalab

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

Shiraz university of medical sciences, Shiraz, II

Your e-mail address \* abc@gmail.com

shahrzadyekta@yahoo.com

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

Effects of psycho-educational interventions using mobile applications and mobilebased online group discussions on anxiety and self-esteem in women with breast cancer: a 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.

BCSzone (Breast cancer support zone )

### Evaluated Version (if any)

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

V1

### Language(s) \*

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

Persian

### 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://vu.sums.ac.ir

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)"

"Breast cancer"(Patients)

### Primary Outcomes measured in trial \*

comma-separated list of primary outcomes reported in the trial

Anxiety(STAI), Self-esteem(RSES)

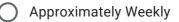
Secondary/other outcomes

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

The survey of satisfaction with the mobile-based intervention

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

Approximately Daily



- Approximately Monthly
- Approximately Yearly
- "as needed"
- Other:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
O unknown / not evaluated
0-10%
0 11-20%
O 21-30%
0 31-40%
O 41-50%
O 51-60%
O 61-70%
O 71%-80%
0 81-90%
91-100%
O 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
O no statistically significant difference between control and intervention
O potentially harmful: control was significantly better than intervention in one or more outcomes
O inconclusive: more research is needed
O 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 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? *
O 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) on ms number (yet) / not (yet) submitted to / published in JMIR
Other: 19262
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
O Other:

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					C	Clear selection

### Does your paper address subitem 1a-i? \*

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

"using mobile application and mobile-based online group discussions"

 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").

 1
 2
 3
 4
 5

 subitem not at all important
 Important</td

### 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

### "mobile-based online group discussions"

### 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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					C	Clear selection

### Does your paper address subitem 1a-iii? \*

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

### Yes, we highlight our target group as "women with breast cancer" in the title.

### 1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

## 1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

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



### Does your paper address subitem 1b-i? \* Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study "The intervention group received psycho-educational interventions through a mobile phone application and participated in nurse-assisted online mobile support sessions for a total four weeks, whereas the control group was put on a waiting list." 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) 1 2 3 4 5 subitem not at all important essential **Clear selection**

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

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

## The Intervention and level of human involvement are explained in the METHODS section of the ABSTRACT

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

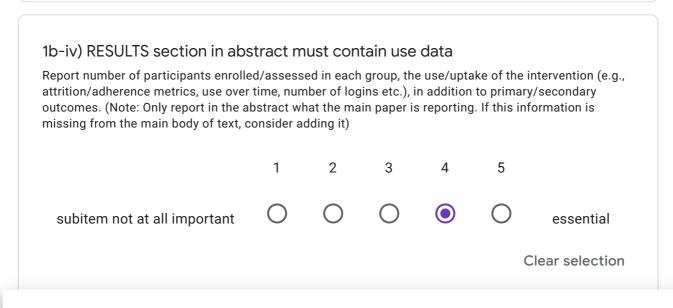
Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). 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)



### 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

The Intervention and the assessment are explained in the Abstract (Methods section)" A research assistant selected eighty-two women with non-metastatic breast cancer aged 20-60 years were from clinics during a face-to-face visit at the point of care and randomly assigned to an intervention group (n=41) and a wait-list control group (n=41) through blocked randomization."



Does your pap	er 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

### The data are explained in the Abstract (Results section)

### 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)

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
					C	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

The trial showed positive impact from the interventions.

### INTRODUCTION

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

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

### 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

We outlined the ever-increasing use of mobile technology in health care, and the digital divide considering the limited use of mobile technology among women with breast cancer.(paragraph 6 to 9,intro)

### 2a-ii) Scientific background, rationale: What is known about the (type of) system

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					C	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

### We reviewed what have done previously in Paragraph 8 to 9.

### 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

Our specific objective and hypothesis were presented in the last paragraph of Introduction.

### **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

The study design is explained in the paper (Methods section)"The present randomized controlled trial used a pretest and posttest design to investigate the impact of a mobile application-based psycho-educational intervention on anxiety and self-esteem in women with non-metastatic breast cancer presenting to breast clinics in Shiraz, Iran. "



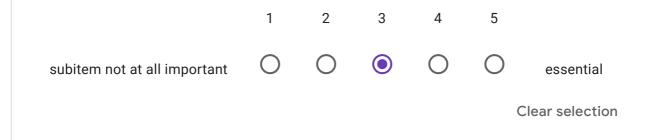
### Does your paper address CONSORT subitem 3b? \*

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

There was no important changes to the methods after trial commencement.

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

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



### Does your paper address subitem 3b-i?

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

### there was no need for bug fixes, and downtime or content changes

### 4a) Eligibility criteria for participants

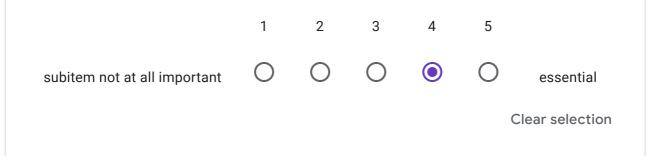
### Does your paper address CONSORT subitem 4a? \*

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

Participants' eligibility was described in Setting and sample section.

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

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



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

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

" The inclusion criteria comprised an age range of 20-60 years, willingness to participate in the study, having non-metastatic breast cancer, literacy, having access to smart mobile electronic devices connected to the internet and having the application installed on them, the ability to work with the application and social networks ..."

### 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 webbased trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	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

Information is given throughout the manuscript(Setting and sample in Methods section) " In winter 2016, a researcher's assistant randomly selected the eligible candidates who were willing to participate in the study. "

### 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.



### 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

Informed consent was obtained from our participants, as stated in the article .

### 4b) Settings and locations where the data were collected

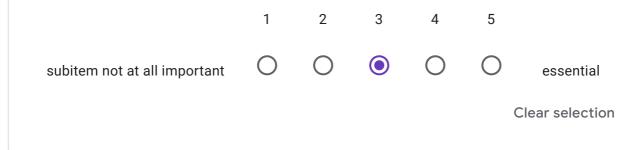
Does your paper address CONSORT subitem 4b? \*

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

Information is given throughout the manuscript(Setting and sample in Methods section)

### 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.



### 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

No online questionnaires. "Pre- and posttest data were collected using paper-based instruments. "

### 4b-ii) Report how institutional affiliations are displayed

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

	1	2	3	4	5	
subitem not at all important	0	۲	0	0	0	essential
					C	Clear selection

### 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

The information about the study included logos and contact information for all participatory clinics. The mobile app had the logo of Shiraz university of medical sciences in 'about' tab, but this was not reported in the manuscript as we do not believe this impacted the results.

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

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).  $1 \quad 2 \quad 3 \quad 4 \quad 5$ subitem not at all important O O O O O O essential Clear selection

Does your paper address subitem 5-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study										
We provided detailed information on our intervention components in the Intervention & Procedures section of the Methods.										
5-ii) Describe the history/development process Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.										
	1	2	3	4	5					
subitem not at all important	0	0	0	0	0	essential				

### 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

### We provided detailed information in "The instructional design" in Intervention section.

### 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).



### 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

### here was not an updated version used in this study

### 5-iv) Quality assurance methods Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable. 1 2 3 4 5 subitem not at all important O O O O O essential Clear selection

### Does your paper address subitem 5-iv?

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

### not applicable

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.  $1 \quad 2 \quad 3 \quad 4 \quad 5$ subitem not at all important O O O O O O essential

Your response is too large. Try shortening some answers.

Clear selection

### Does your paper address subitem 5-v?

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

The components in BCSzone are described in the manuscript, We have provided screenshots of the front page of the app in the manuscript (Multi media appendix 1). There is not a source code for this intervention.

### 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, <u>webcitation.org</u>, 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.



### 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

### There is not a URL for this intervention

#### 5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi). 1 2 3 4 5 subitem not at all important O O O O O essential

**Clear selection** 

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

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

We provided detailed information in The procedure section of the Methods section.

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 computermediated 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]. 2 3 1 4 5 subitem not at all important essential **Clear selection** 

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

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

We provided detailed information on the mode of delivery, the theory-based intervention components in the Intervention & Procedure section of the Methods section.

### 5-ix) Describe use parameters

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					C	Clear selection

### Does your paper address subitem 5-ix?

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

Participants were told that they could use the app anytime, anywhere.Information is given throughout the manuscript(the procedure in Methods section)

### 5-x) Clarify the level of human involvement

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

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
					C	Clear selection

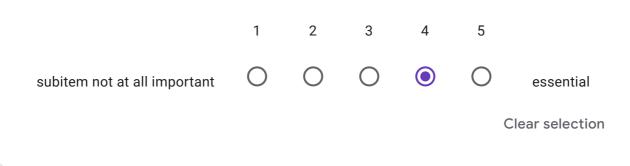
### Does your paper address subitem 5-x?

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

"A psychiatric nurse followed up the patients and their participation and provided them with support, advice and guidance for about 60 minutes per weekend, if needed, through the same WhatsApp online group chat. As the only reminder, the patients were reminded by the psychiatric nurse to use the app during the weekly sessions."

### 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).



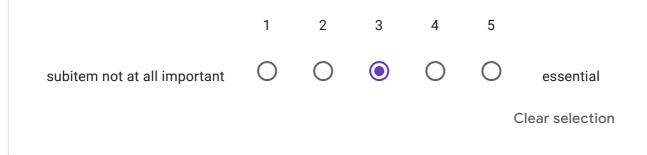
### Does your paper address subitem 5-xi? \*

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

There were no prompts to use BCSzone app."As the only reminder, the patients were reminded by the psychiatric nurse to use the app during the weekly sessions."

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

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



### 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

Information is given throughout the manuscript (see the Intervention section)

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

We defined our outcomes as "The data collection tools comprised the STAI, the RSES and demographic information questionnaires.... At the end of the treatment, the intervention group completed a self-designed survey of satisfaction with the mobile-based intervention. "

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].



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

Online questionnaires were not used. The data were collected via a paper-based instruments.

(logins, logfile analysis, etc.). Use/add reported in any ehealth trial.						
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection
Does your paper address sub	oitem 6a	a-ii?				
Copy and paste relevant sections fror	m manuso	cript text				
				of app us		
were supposed to use the app 6a-iii) Describe whether, how was obtained Describe whether, how, and when qua emails, feedback forms, interviews, fo	v, and w	4 weeks /hen qua	s of the alitative	interven feedbad	tion. ck from	
6a-iii) Describe whether, how was obtained Describe whether, how, and when qua	v, and w	4 weeks /hen qua	s of the alitative	interven feedbad	tion. ck from	
6a-iii) Describe whether, how was obtained Describe whether, how, and when qua	v, and w litative fe ocus grou	4 weeks /hen qua edback fro ps).	s of the alitative	feedbac	tion. ck from obtained (	
6a-iii) Describe whether, how was obtained Describe whether, how, and when qua emails, feedback forms, interviews, fo	v, and w litative fe ocus grou	4 weeks /hen qua edback fro ps).	s of the alitative	feedbac	tion. ck from obtained 5	é.g., through
6a-iii) Describe whether, how was obtained Describe whether, how, and when qua emails, feedback forms, interviews, fo	v, and w litative fe ocus grou 1 0	4 weeks when qua edback fro ps). 2 O	s of the alitative	feedbac	tion. ck from obtained 5	(e.g., through essential

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

Does your paper address CC Copy and paste relevant sections from indicate direct quotes from your man information not in the ms, or briefly e No changes were made to tria	n the mar uscript), c xplain wh	nuscript (ir or elaborat y the item	nclude quo e on this if is not app	tem by pro licable/rel	viding add evant for y	litional			
<b>7a) How sample size was de</b> NPT: When applicable, details of whe addressed			ustering by	/ care prov	ides or ce	nters was			
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.									
	1	2	3	4	5				
subitem not at all important	0	0	0	0	۲	essential			
					C	Clear selection			

### 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

The sample size calculation was described as "The minimum sample size was calculated as 25 per group in Number Cruncher Statistical System based on the data obtained by Aghabarari [35], a mean anxiety difference score of 3±2.08, an effect size of 0.79, a significance level of 0.05 and a test power of 80%. The ultimate sample size was calculated as 41 in each group considering the drop-out effect."

## 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

### Not applicable.

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

### random allocation sequence is explained in the Setting and sample section

# 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

details of randomization is given throughout the manuscript (see Methods section and Figure1)

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

details of random allocation sequence is given throughout the manuscript (see Methods section and Figure1)

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

details of random allocation sequence is given throughout the manuscript (see Methods section and Figure1)

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

CO										
			<b>9</b> -							
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).										
	1	2	3	4	5					
subitem not at all important	0	0	0	0	۲	essential				
					C	Clear selection				
Does your paper address sub	pitem 11	a-i? *								
Copy and paste relevant sections from indicate direct quotes from your many information not in the ms, or briefly es	uscript), c	or elaborat	e on this i	tem by pro	oviding add	litional				
"unblinded randomized controlled trial"										
11a-ii) Discuss e.g., whether p			ew whic	h interv	ention w	vas the				
	Darticip I which can create	ants kne one was e biases ar	s the "co nd certain	omparat expectation	o <b>r"</b> ons - discu	ss e.g., whether				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention	Darticip I which can create	ants kne one was e biases ar	s the "co nd certain	omparat expectation	o <b>r"</b> ons - discu	ss e.g., whether				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention	Darticip I which can create was the "	ants kne one was e biases ar interventio	s the "co nd certain on of intere	omparat expectation est" and w	C <b>OR"</b> ons - discu hich one w	ss e.g., whether				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention "comparator".	Darticip I which can create was the "	ants kne one was e biases ar interventio	s the "co nd certain on of intere	omparat expectation est" and w	or" ons - discu chich one w 5	ss e.g., whether /as the				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention "comparator".	Darticip I which can create was the " 1	ants kne one was e biases ar interventio 2	s the "co nd certain on of intere	omparat expectation est" and w	or" ons - discu chich one w 5	ss e.g., whether vas the essential				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention "comparator". subitem not at all important	Darticipa I which can create was the " 1 0 Ditem 11 m the mar uscript), c	ants kne one was e biases ar interventio 2 Q a-ii? nuscript (in pr elaborat	s the "co nd certain on of intero 3 O	expectation est" and w 4 () otes in quot tem by pro-	or" ons - discu chich one w 5 0 0 0 0 0 0 0 0 0 0 0 0 0	ss e.g., whether vas the essential Clear selection rks "like this" to litional				
11a-ii) Discuss e.g., whether p "intervention of interest" and Informed consent procedures (4a-ii) of participants knew which intervention "comparator". subitem not at all important Does your paper address sub Copy and paste relevant sections from indicate direct quotes from your man	Darticipa I which can create was the " 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	ants kne one was e biases ar interventio 2 Q a-ii? nuscript (in or elaborat y the item	s the "co nd certain on of intere 3 O	expectation est" and w 4 () otes in quo tem by pro- licable/re	or" ons - discu hich one w 5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	ss e.g., whether vas the essential Clear selection				

### 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

### Not applicable

### 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

Information is given throughout the manuscript(Statistical analyses in Methods section) "The demographic variables were expressed using descriptive statistics, including mean, standard deviation and frequency. Depending on the type of data, one-way ANOVA, the Fisher's exact test, the independent t-test, the paired t-test and the chi-squared test were used to perform inferential analysis. .... The Kolmogorov–Smirnov test was also used to investigate the data normality. P<.05 was set as the level of statistical significance. "

### 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]).

	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection

### Does your paper address subitem 12a-i? \*

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

"In addition, no missing values were reported in the main outcomes. .... According to Figure 1, randomization and attrition data were organized according to the Consolidated Standards of Reporting Trials (CONSORT) statement, and two patients in the control group and three in the intervention group dropped out owing to their failure to complete the intervention (n=2), unwillingness to continue with the study (n=1) and failing to follow-up (n=2). "

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

### Does your paper address CONSORT subitem 12b? \*

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

### No adjusted analyses were done



### Does your paper address subitem X26-i?

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

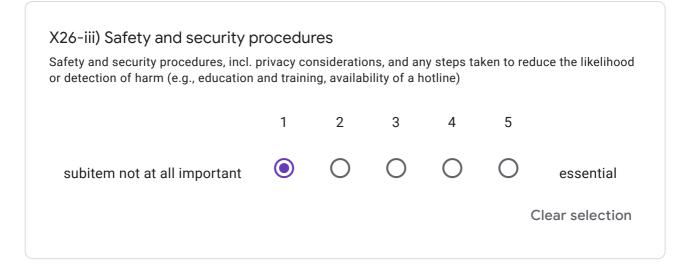
"This study was approved by the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran (IR.SUMS.REC.1395.20) and registered in the Iranian Registry of Clinical Trials (IRCT20150721232279N2) [36]. Written informed consent was obtained from all the study participants, and their voluntary participation in the entire process of the study and confidentiality of their information were ensured."

### 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. 1 2 3 4 5 subitem not at all important O O O O O O O essential Clear selection

### Does your paper address subitem X26-ii?

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

"Written informed consent was obtained from all the study participants, and their voluntary participation in the entire process of the study and confidentiality of their information were ensured. All the participants were allowed adequate time to carefully review the consent forms and ask relevant questions before signing them. At the end of the study, all the patients in the wait-list control group also received the psycho-educational intervention."



### 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

In the patients information was explained that using theBCSz one app is not harmful."In the recruitment step, the patients were briefed on the study objectives and procedure through face-to-face communication and provided with a brochure in the reception of the breast clinics and examination rooms. The researchers also responded to the enquiries and concerns of the participants. .......... Written informed consent was obtained from all the study participants, and their voluntary participation in the entire process of the study and confidentiality of their information were ensured. "

# 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

See table 1 and 2 as well as figure 1.

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

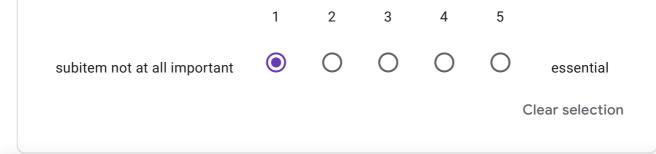
Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) \*

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

see figure 1 (flowchart)

#### 13b-i) Attrition diagram

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



#### Does your paper address subitem 13b-i?

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

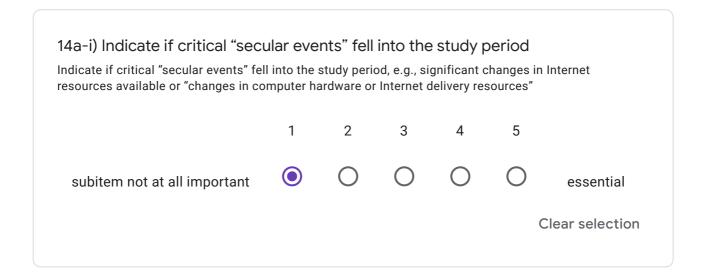
Loss and exclusion was presented in the flowchart (Figure 1)

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

Does your paper address CONSORT subitem 14a? \*

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

"This trial was conducted between October 2016 and February 2017. Recruitment and base-line assessments were first performed for three months, the intervention for four weeks and the post-intervention assessments for one week after the intervention."



#### 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

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

#### Does your paper address CONSORT subitem 14b? \*

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

#### Not applicable.

## 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

#### see T able 1

#### 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.

	1	2	3	4	5	
subitem not at all important	0	0	0	۲		essential Clear selection

Does your paper address sub Copy and paste relevant sections from indicate direct quotes from your man information not in the ms, or briefly e	n the mar uscript), c	nuscript (ir or elaborat	e on this it	tem by pro	viding add	litional
see table 1						
16) For each group, number analysis and whether the an	•	•				
16-i) Report multiple "denom Report multiple "denominators" and p study participation [and use] threshol used more than y weeks, N participar points of interest (in absolute and rel intervention.	orovide de ds" [1], e. nts "used"	finitions: F g., N expos the interve	Report N's sed, N con ention/cor	(and effec sented, N mparator a	t sizes) "a used more t specific	e than x times, N pre-defined time
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection

#### Does your paper address subitem 16-i? \*

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

#### see respective tables and text

16-ii) Primary analysis should Primary analysis should be intent-to-to-to-to-to-to-to-to-to-to-to-to-to	treat, seco	ondary ana	lyses coul			only "users", with
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection

Does your paper address subitem 16-ii?

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

We applied ITT for the primary outcome analysis, which was mentioned in the statistical analysis section and results section.

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

Mean, standard deviation, 95% confidence interval, p-value are given for each outcome in the manuscript.

## 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).

	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection

#### Does your paper address subitem 17a-i?

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

#### Not applicable

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

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

#### Information is given throughout the manuscript(Results section)

#### 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).

	1	2	3	4	5	
subitem not at all important	۲	0	0	0	0	essential
					C	Clear selection

#### Does your paper address subitem 18-i?

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

#### Not applicable

## 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

Except for privacy concerns, this trial did not have any other important harms to consider . "The present study included only the psychiatric nurse and study participants in a private WhatsApp group and the messages were end-to-end encrypted to ensure privacy in sharing identifiable health data. "

19-i) Include privacy breache	s, techr	nical pro	blems			
Include privacy breaches, technical p but also incidents such as perceived unexpected/unintended incidents. "U	or real pri	vacy bread	hes [1], te	chnical pr	oblems, ar	nd other
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	lear selection

#### Does your paper address subitem 19-i?

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

There were no privacy breaches of technical problems.

#### 19-ii) Include qualitative feedback from participants or observations from

#### staff/researchers

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

	1	2	3	4	5	
subitem not at all important	0	0	0	٢	0	essential
					C	Clear selection

#### Does your paper address subitem 19-ii?

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

Information is given throughout the manuscript (see Results section and Table 3)

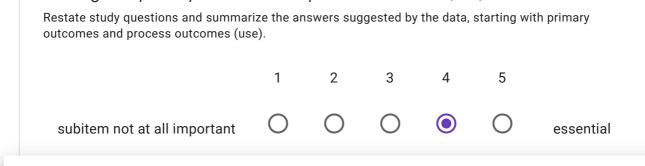
#### DISCUSSION

#### 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)



#### 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

#### see Results section

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

	1	2	3	4	5		
subitem not at all important	0	0	0	۲	0	essential	
					C	Clear selection	

#### Does your paper address subitem 22-ii?

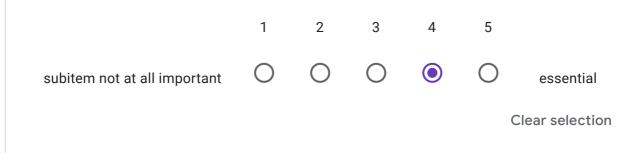
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Further studies are recommended that be conducted in this context using longer follow-ups."

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.



#### 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

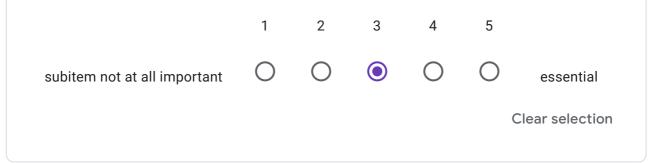
#### Information is given throughout the manuscript( study limitation)

#### 21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

#### 21-i) Generalizability to other populations

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



#### Does your paper address subitem 21-i?

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

#### the next steps would introduce the BCSzone App to more breast cancer patients

### 21-ii) Discuss if there were elements in the RCT that would be different in a

#### routine application setting

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

	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	Clear selection

#### Does your paper address subitem 21-ii?

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

Information is given throughout the manuscript(Practical implications)

#### 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 Registration: Iranian Registry of Clinical Trials IRCT20150721232279N2; (Archived by Website at https://en.irct.ir/trial/19882)

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

Does your paper address CONSORT subitem 24?\*

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

the study protocol is not accessible

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

"The authors would like to express their gratitude to the authorities of Shiraz University of Medical Sciences for approving and financially supporting this study as part of a dissertation thesis (Grant No. 94-01-08-10534). "

X27) Conflicts of Interest (not a CONSORT item)

study team towards the system being identical with the developers/sponso				-		
	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					C	Clear selection
Does your paper address sub						
Copy and paste relevant sections fror indicate direct quotes from your man information not in the ms, or briefly e	uscript), d	or elaborat	e on this i	tem by pro	viding add	litional
No conflicts of interest were o	declare	d.				
About the CONSORT EHEAL	_TH che	ecklist				
As a result of using this chec	klist, di	d you m	ake cha	nges in	your ma	nuscript? *
As a result of using this chec O yes, major changes	klist, di	d you m	ake cha	nges in	your ma	nuscript? *
-	klist, di	d you m	ake cha	nges in	your ma	nuscript? *
	klist, di	d you m	ake cha	nges in	your ma	nuscript? *
<ul> <li>yes, major changes</li> <li>yes, minor changes</li> </ul>		- 				

making changes in your manuscript *	ugh the checklist INCLUDING
5 days	
As a result of using this checklist, do you thir	וk your manuscript has improved? *
• yes	
O no	
O Other:	
<ul> <li>Would you like to become involved in the CC</li> <li>This would involve for example becoming involved in part</li> <li>"Explanation and Elaboration" document</li> <li>yes</li> <li>no</li> </ul>	•
O Other:	
	Clear selection
Any other comments or questions on CONS	ORT EHEALTH
Your answer	
STOP - Save this form as PDF before you cli	
	mend to generate a PDF of this page (on a

#### Final step: Click submit !

Click submit so we have your answers in our database!

Submit

Never submit passwords through Google Forms.

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

