

# 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

\* Required

Your name \*

First Last

Oleksandr Sverdlov



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alex.sverdlov@novartis.com

**Title of your manuscript \***

Provide the (draft) title of your manuscript.

A smartphone-based intervention PEAR-004 as an adjunct to standard-of-care treatment for schizophrenia: 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.

PEAR-004



**Evaluated Version (if any)**

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

Not applicable

**Language(s) \***

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

English

**URL of your Intervention Website or App**

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

<https://peartherapeutics.com/science/product-pipeline/>

**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: It was rolled out to patients in spring 2020 due to a loosening of FDA r

**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)"

schizophrenia

**Primary Outcomes measured in trial \***

comma-separated list of primary outcomes reported in the trial

Change from baseline in total Positive and Neg



## Secondary/other outcomes

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

I) Efficacy: Change from baseline to Day 85 or last visit in: Positive PANSS score; Negative PANSS score; General Psychopathology PANSS score; Motivation and Pleasure Self-Report (MAP-SR) score; Beck Depression Inventory, Second Edition (BDI-II) score; World Health Organization Quality of Life (WHOQOL-BREF) scores in four primary domains - social relationships, psychological, physical, and environment. II) Safety: adverse events (AEs), serious adverse events (SAEs), vital signs, and the InterSePT Scale for Suicidal Thinking-Plus (ISST Plus). III) Other: Clinical Global Impression (CGI) scale; Insomnia Severity Index (ISI); Clinician Satisfaction Survey; Subject Satisfaction Survey.

## Recommended "Dose" \*

What do the instructions for users say on how often the app should be used?

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



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

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- Other: 48 out of 56 [85.7%] patients randomized to PEAR-004 completed this



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: PEAR-004 did not demonstrate effect in the primary outcome of total





**Article Preparation Status/Stage \***

At which stage in your article preparation are you currently (at the time you fill in this form)

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



**Journal \***

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

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

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

- Pilot/feasibility
- Fully powered



**Manuscript tracking number \***

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

no ms number (yet) / not (yet) submitted to / published in JMIR

Other:

**TITLE AND ABSTRACT****1a) TITLE: Identification as a randomized trial in the title****1a) Does your paper address CONSORT item 1a? \***

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

yes

Other:



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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

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

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

A "smartphone-based" intervention PEAR-004 as an adjunct to standard-of-care treatment for schizophrenia: Randomized controlled trial



### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
						<a href="#">Clear selection</a>

### 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

A smartphone-based intervention PEAR-004 as "an adjunct to standard-of-care treatment" for schizophrenia: Randomized controlled trial



**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
<a href="#">Clear selection</a>						

**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

A smartphone-based intervention PEAR-004 as an adjunct to standard-of-care treatment "for schizophrenia": Randomized controlled trial

**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)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

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

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

Abstract:

Objective: To determine whether "PEAR-004, a smartphone-based investigational digital therapeutic", improves symptoms of an acute psychotic exacerbation of schizophrenia, when added to standard treatments.

Methods: This was a 12-week multi-center, "randomized, sham-controlled, rater-blinded, parallel group proof of concept study of 112 participants with a moderate acute psychotic exacerbation in schizophrenia."



### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
<a href="#">Clear selection</a>						

### 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

This subitem was elaborated on in the Methods/Interventions section (in-text):  
"The PEAR-004 smartphone application (iOS and Android based) was designed as an illness self-management tool. Subjects could access PEAR-004 as needed to receive suggestions about coping strategies to overcome difficulties in daily life. The final PEAR-004 digital application used in this study was developed from prior versions to have ten categories of skills: Exercise, Medication, Mindfulness, Mood, Productivity, Sleep, Social activity, Stress, Thoughts, and Voices. These categories were informed directly by user research (surveys and interviews) with people with schizophrenia. Therapeutic content was available on-demand. In addition, participants were prompted to “check-in” by answering a series of questions mapped to areas of therapeutic content. Based on participant responses, PEAR-004 would suggest a therapeutic area to focus on. PEAR 004 promoted use via three daily notifications delivered at fixed times: 11am, 4pm, and 9pm."





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)

1      2      3      4      5

subitem not at all important                        essential

Clear selection

Does your paper address subitem 1b-iii?

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

This subitem was elaborated on in the Study Design section (in-text):

"Eligible subjects were equally randomized on day 1 to receive either PEAR-004 (investigational digital therapeutic) or sham (control) for a period of 12 weeks. Subjects in both groups continued to receive their clinician-directed standard-of-care for schizophrenia, including pharmacotherapy. Subjects returned to the clinic for outpatient visits at week 4 (day 29), week 8 (day 57), and week 12 (day 85). At each visit, standard assessments including efficacy and safety were performed according to the assessment schedule. A final follow-up visit was performed at week 16 (day 115)."



### 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)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
<a href="#">Clear selection</a>						

### 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

Abstract:

Methods: This was a 12-week multi-center, randomized, sham-controlled, rater-blinded, parallel group proof of concept study of "112 participants with a moderate acute psychotic exacerbation in schizophrenia."

Results: "...Application engagement was good, and patient and clinical investigator satisfaction was high."



### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
<a href="#">Clear selection</a>						

### 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

Abstract:

Results: "Total PANSS scores slightly decreased from baseline over the study period in both groups; the treatment difference at Day 85 between PEAR-004 and sham was 2.7 points, in favor of the sham (2 sided p=0.0931). Secondary scales found no benefit except for transient improvement in depressive symptoms with PEAR-004. Application engagement was good, and patient and clinical investigator satisfaction was high. No safety concerns were seen."

### 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)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
<a href="#">Clear selection</a>						

### 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

Introduction, 4th paragraph:

"PEAR-004 is being developed as a prescription digital therapeutic delivered via smartphone for subjects who are under the care of a qualified healthcare professional. It is intended to deliver multimodal evidence-based neurobehavioral mechanisms of action, which include cognitive restructuring, illness self-management training, and social skills training."



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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



**Does your paper address subitem 2a-ii? \***

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

Introduction, 4th paragraph:

"...Preliminary evidence has shown that subjects with psychotic disorders can actively engage with software similar to PEAR 004, which suggests that PEAR-004 may improve both positive and depressive symptoms in subjects with schizophrenia [13, 14] and serious mental illness [15]. Our current paper reports the results of a randomized, sham-controlled study of PEAR-004 in schizophrenia."

Choice of the comparator: See Methods/Interventions section:

"...The sham control arm was chosen to account for nonspecific effects of engagement with a smartphone. The sham application did not deliver any active coping skills (ingredients of a psychosocial intervention). It appeared similar to the PEAR 004 application in its initial screen and randomization to sham or PEAR-004 was conducted at the time of application download unbeknownst to participants to maintain blinding."

**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

**Methods/Study Objectives:**

The primary objective was to compare the effect of PEAR-004 versus sham as assessed by change from baseline to day 85 in total Positive and Negative Syndrome Scale (PANSS) score. It was hypothesized that the PEAR-004 group would exhibit greater reduction in total PANSS compared with the sham group. In addition, retention to assigned study treatment (dropout rate), patient engagement data, secondary efficacy outcomes, clinician outcome assessments, and safety and tolerability data were analyzed.

**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

**Methods/Study Design:**

"The study was a multi-center, randomized, sham-controlled, rater-blinded, parallel group proof of concept trial of participants with schizophrenia (trial registration: ClinicalTrials.gov NCT03751280). Eligible subjects were equally randomized on day 1 to receive either PEAR-004 (investigational digital therapeutic) or sham (control) for a period of 12 weeks."

**3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons****Does your paper address CONSORT subitem 3b? \***

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

Not applicable.





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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
						Clear selection

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

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

Methods/Interventions:

"...A single version of PEAR-004 or sham was utilized for the duration of the clinical study, for all randomized subjects."

### 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

Methods/Study Participants:

"...The investigators ensured that all subjects being considered for the study met the eligibility criteria at screening. The inclusion criteria are described in Textboxes 1 and 2. "

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
						Clear selection

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

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

Textbox 1 - Inclusion criteria:

"5. Capable of using a mobile device (compatible with PEAR-004) and using common applications, in the judgement of the Investigator."



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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

#### Does your paper address subitem 4a-ii? \*

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

##### Introduction/Study Sites:

"Potentially eligible subjects were enrolled by six investigational study sites in the USA." The site details are provided in the manuscript.

##### Introduction/Study Participants:

"The investigators ensured that all subjects being considered for the study met the eligibility criteria at screening. The inclusion criteria are described in Textboxes 1 and 2."



#### 4a-iii) Information giving during recruitment

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
						Clear selection

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

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

Introduction/Randomization:

"...Trained site staff assisted subjects with all treatment onboarding activities. The subjects were required to use their own personal mobile phone for the study. If a subject did not have their own phone, one was provided to them for use during the study."

#### 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

Your answer

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



**Does your paper address subitem 4b-i? \***

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

**Assessments:**

Clinical data were acquired during in-clinic visits. These included: demographics and baseline characteristics, efficacy assessments (PANSS, MAP-SR, BDI-II, WHOQOL-BREF), safety assessments (AEs, SAEs, vital signs, ISST-Plus), and other assessments (CGI, ISI, Clinician Satisfaction Survey, and Subject Satisfaction Survey).

Data on patient engagement with the assigned app was collected throughout the study. The cross-platform engagement metrics (for individuals in both PEAR-004 and sham groups) included time using app, number of days when the app was active, total number of sessions and number of sessions per day.

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential



**Does your paper address subitem 4b-ii?**

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

Not applicable.

**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).

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	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

Both interventions (PEAR-004 and sham) were provided by Pear Therapeutics, Inc. This study was funded by Novartis Institutes for Biomedical Research, Cambridge, MA, USA. This information is disclosed in the 'Acknowledgements' section.

### 5-ii) Describe the history/development process

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

1      2      3      4      5

subitem not at all important                        essential

Clear selection





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

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

Introduction, 4th paragraph:

"...Preliminary evidence has shown that subjects with psychotic disorders can actively engage with software similar to PEAR-004, which suggests that PEAR-004 may improve both positive and depressive symptoms in subjects with schizophrenia [13, 14] and serious mental illness [15]. "

### 5-iii) Revisions and updating

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						



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

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

#### Methods/Interventions:

"...A single version of PEAR-004 or sham was utilized for the duration of the clinical study, for all randomized subjects."

"...Therapeutic content was available on-demand. In addition, participants were prompted to "check-in" by answering a series of questions mapped to areas of therapeutic content.

Based on participant responses, PEAR-004 would suggest a therapeutic area to focus on.

PEAR 004 promoted use via three daily notifications delivered at fixed times: 11 am, 4pm, and 9pm."

### 5-iv) Quality assurance methods

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential



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

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

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.

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
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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

The source code is proprietary and cannot be shared as an open source.



### 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.

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
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### Does your paper address subitem 5-vi?

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

For details on the PEAR-004 product one can refer to the Pear Therapeutics website:  
<https://peartherapeutics.com/science/product-pipeline/>



### 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).

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	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

#### Methods/Interventions:

"On Day 1, eligible subjects gained access to either PEAR-004 or sham according to their randomization assignment. A single application containing both PEAR-004 and sham was downloaded from the iOS or Android-based app store to the subject's mobile device, and then the assigned application was unlocked using a prescription access code provided by Pear Therapeutics. Study site staff received training on how to download PEAR-004 or sham to the assigned subject's phone as part of site initiation activities."



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

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
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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

#### Methods/Interventions:

PEAR-004: "The PEAR-004 smartphone application (iOS and Android based) was designed as an illness self-management tool. Subjects could access PEAR-004 as needed to receive suggestions about coping strategies to overcome difficulties in daily life. The final PEAR-004 digital application used in this study was developed from prior versions to have ten categories of skills: Exercise, Medication, Mindfulness, Mood, Productivity, Sleep, Social activity, Stress, Thoughts, and Voices. These categories were informed directly by user research (surveys and interviews) with people with schizophrenia. Therapeutic content was available on-demand. In addition, participants were prompted to "check-in" by answering a series of questions mapped to areas of therapeutic content. Based on participant responses, PEAR-004 would suggest a therapeutic area to focus on. PEAR 004 promoted use via three daily notifications delivered at fixed times: 11am, 4pm, and 9pm."

Sham: "In the sham control group, the sham application was downloaded to the subject's phone, but did not deliver the active therapeutic content of PEAR-004. Similar to PEAR-004, the sham application delivered three daily notifications prompting the subject to open the sham app, and then displayed a prescription timer (timer clock countdown until the next prescription dose) for the remaining duration of app availability. The sham control arm was chosen to account for nonspecific effects of engagement with a smartphone. The sham application did not deliver any active coping skills (ingredients of a psychosocial intervention). It appeared similar to the PEAR 004 application in its initial screen and randomization to sham or PEAR-004 was conducted at the time of application download unbeknownst to participants to maintain blinding."



### 5-ix) Describe use parameters

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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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

Multimedia Appendix 1/Exploring the study implementation aspects:

"In this study, the directions for use and product onboarding were not explicitly stated in protocol or site operating manual. The reference guide, which was intended to be reviewed with and provided to patients, stated directions for product use in a very general manner, e.g. "...PEAR-004 works best when you use it regularly and consistently... To get the most out of your time with PEAR-004, you should try to use it every day...". The decision to not suggest a specific amount (number of times a day) or type (engaging with a specific feature) of use was so that we could generate the natural proof-of-concept data to understand which patterns of engagement were associated with clinical change."





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

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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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

Multimedia Appendix 1/Exploring the study implementation aspects:

"...Throughout the study, the sites performed phone call appointment reminders to participants at weeks 2, 6, and 10. The goal was to triage any issues preventing participants from using product as much as they wanted, but not to encourage or direct future use."



### 5-xi) Report any prompts/reminders used

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
						Clear selection



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

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

**Methods/Interventions:**

PEAR-004: "...Therapeutic content was available on-demand. In addition, participants were prompted to "check-in" by answering a series of questions mapped to areas of therapeutic content. Based on participant responses, PEAR-004 would suggest a therapeutic area to focus on. PEAR 004 promoted use via three daily notifications delivered at fixed times:

11am, 4pm, and 9pm."

Sham: "...Similar to PEAR-004, the sham application delivered three daily notifications prompting the subject to open the sham app, and then displayed a prescription timer (timer clock countdown until the next prescription dose) for the remaining duration of app availability."

**Multimedia Appendix 1/Exploring the study implementation aspects:**

"...Throughout the study, the sites performed phone call appointment reminders to participants at weeks 2, 6, and 10. The goal was to triage any issues preventing participants from using product as much as they wanted, but not to encourage or direct future use."



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

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
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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

Study participants were expected to maintain their physician prescribed pharmacotherapy during the study at least 2 weeks prior to randomization, as specified in the exclusion criteria.

Methods/Study Design:

"...Subjects in both groups continued to receive their clinician-directed standard-of-care for schizophrenia, including pharmacotherapy. "

**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

Primary (efficacy): Change from baseline in total Positive and Negative Syndrome Scale (PANSS) score at Day 85 or last visit

Secondary (efficacy): Change from baseline to Day 85 or last visit in: Positive PANSS score; Negative PANSS score; General Psychopathology PANSS score; Motivation and Pleasure Self-Report (MAP-SR) score; Beck Depression Inventory, Second Edition (BDI-II) score; World Health Organization Quality of Life (WHOQOL-BREF) scores in four primary domains - social relationships, psychological, physical, and environment.

Secondary (safety): adverse events (AEs), serious adverse events (SAEs), vital signs, and the InterSePT Scale for Suicidal Thinking-Plus (ISST Plus).

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

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

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subitem not at all important                        essential



Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Not applicable.

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

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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### Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

#### Methods/Assessments/Engagement with App:

"Data on patient engagement with the assigned app was collected throughout the study. The cross-platform engagement metrics (for individuals in both PEAR-004 and sham groups) included time using app, number of days when the app was active, total number of sessions and number of sessions per day. For subjects in the PEAR-004 group, additional metrics were derived, such as number of skills practiced; number of skills repeated (practiced at least 2 times); number of skills mastered (practiced at least 3 times); and number of skills practiced in each of the ten categories of the PEAR 004 app (Exercise, Medication, Mindfulness, Mood, Productive, Sleep, Social, Stress, Thoughts, and Voices)."

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

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Methods/Assessments/Other Assessments:

"...Patient reported outcomes included the Insomnia Severity Index (ISI) [24] and Subject Satisfaction Survey assessing the subject's experience with PEAR-004 or sham."

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

Does your paper address CONSORT subitem 6b? \*

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

No changes were made.

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

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





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

Describe whether and how expected attrition was taken into account when calculating the sample size.

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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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

Methods/Statistical Methods/Sample Size and Power:

"The required sample size (n=102) was calculated to address the primary objective of treatment comparison at week 12 with respect to change in PANSS total score. To account for potential dropouts, a total of n=112 subjects were enrolled and randomized into the study."

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

Methods/Randomization:

"Randomization was implemented by means of interactive response technology (IRT) using permuted blocks of size 4, with targeted allocation ratio 1:1."

**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

Methods/Randomization:

"Randomization was implemented by means of interactive response technology (IRT) using permuted blocks of size 4, with targeted allocation ratio 1:1."

**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

Methods/Randomization:

"Randomization was implemented by means of interactive response technology (IRT) using permuted blocks of size 4, with targeted allocation ratio 1:1."

**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

**Methods/Randomization:**

"An investigator or delegate at a given study site logged on to the IRT system after confirming that the subject fulfilled all the inclusion/exclusion criteria. The IRT assigned the subject to a treatment arm, which was used by the site staff to request a "prescription access code" in a separate Study Portal. Trained site staff assisted subjects with all treatment onboarding activities. The subjects were required to use their own personal mobile phone for the study. If a subject did not have their own phone, one was provided to them for use during the study. Additional information on the prescription access code and distribution of study treatment was given in the site operational manuals provided to the sites. If the subject failed to be treated for any reason, the IRT was updated that the subject was not treated. The treatment arm assignment was recorded in the case report form. "

**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).

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
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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

This was a rater-blinded study. Raters remained blinded to study treatment throughout the study. The identity of the treatments was concealed by limiting rater access to the randomization list, subject-specific phone, and web portal. Raters were independent of other aspects of study conduct, and subjects were instructed not to provide specific details about the content they were viewing on their phone to the rater. All unblinded personnel otherwise kept randomization lists and data or information that could unblind the rater confidential and secured until clinical database lock.



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

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

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subitem not at all important                        essential

Clear selection

Does your paper address subitem 11a-ii?

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

Methods/Interventions:

"...A single application containing both PEAR-004 and sham was downloaded from the iOS or Android-based app store to the subject's mobile device, and then the assigned application was unlocked using a prescription access code provided by Pear Therapeutics. "

**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

**Methods/Interventions:**

"...The sham application did not deliver any active coping skills (ingredients of a psychosocial intervention). It appeared similar to the PEAR 004 application in its initial screen and randomization to sham or PEAR-004 was conducted at the time of application download unbeknownst to participants to maintain blinding."

**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

#### Methods/Statistical Methods:

"The primary efficacy endpoint, change in total PANSS score from baseline to day 85 or last visit, was analyzed using the mixed-effects model for repeated measures (MMRM) [25], applied on the intention-to-treat (ITT) set which included all subjects to whom study treatment was assigned by randomization and who had a baseline observation and at least one post-randomization observation for the analysis endpoint."

The secondary efficacy endpoints were analyzed similarly to the primary endpoint (MMRM on change from baseline values, using the ITT set).

### 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]).

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						





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

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

The primary MMRM model implicitly imputed missing data under a missing at random (MAR) assumption. Therefore, no explicit imputation of missing data was done for the primary analysis approach.

**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

Not applicable.

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

## X26-i) Comment on ethics committee approval

1      2      3      4      5

subitem not at all important                  essential

Clear selection

## Does your paper address subitem X26-i?

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

## Methods/Ethics and Informed Consent:

"The study protocol and the amendment were reviewed by the Institutional Review Board (IRB) for each center. The study was conducted according to ICH E6 Guideline for Good Clinical Practice that have their origin in the Declaration of Helsinki."



### x26-ii) Outline informed consent procedures

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
<a href="#">Clear selection</a>						

### 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

#### Methods/Ethics and Informed Consent:

"...Informed consent was obtained from each subject in writing at screening before any study specific procedure was performed. The study was explained to the subject by the investigator or designee, who answered any questions, and written information was also provided."



### 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)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

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

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

Methods/Assessments/Safety:

"Safety assessments consisted of collecting all adverse events (AEs), serious adverse events (SAEs), vital signs, and the InterSePT Scale for Suicidal Thinking-Plus (ISST Plus) [21, 22]."

## 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

See Figure 1 - Study participant flowchart—CONSORT diagram

**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 - Study participant flowchart—CONSORT diagram



### 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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

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

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

See Figure 2 - Kaplan-Meier plot of time to dropout

### 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

**Results/Study Sample:**

"From December 10, 2018 to September 26, 2019, a total of 112 subjects with schizophrenia were enrolled and randomized into the study."

**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"

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

**Does your paper address subitem 14a-i?**

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

Not applicable.



**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 study was successfully completed as planned.

**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 Table 1 - Subject demographics and baseline characteristics





**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
<a href="#">Clear selection</a>						

**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

See Table 1 - Subject demographics and baseline characteristics.

**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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

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

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

See Table 3 and Table 4 - the analyses of primary and secondary efficacy outcomes contain the group sample sizes at different study visits.



**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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

**Does your paper address subitem 16-ii?**

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

Methods/Statistical Methods/Statistical Analyses:

"The primary efficacy endpoint, change in total PANSS score from baseline to day 85 or last visit, was analyzed using the mixed-effects model for repeated measures (MMRM) [25], applied on the intention-to-treat (ITT) set which included all subjects to whom study treatment was assigned by randomization and who had a baseline observation and at least one post-randomization observation for the analysis endpoint."

**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

See Table 3 and Table 4 - the analyses of primary and secondary efficacy outcomes contain estimated values of treatment mean (SE) and mean difference (SE), with 90% confidence intervals and 2-sided p-values.

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



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

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

See Table 2 - Engagement metrics for PEAR-004 and sham groups.

**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

A more in-depth analysis of engagement data is given in Multimedia Appendix 1.

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
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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

A more in-depth analysis of engagement data is given in Multimedia Appendix 1.



### 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

Adverse events are summarized by treatment group - see Multimedia Appendix 2.

#### 19-i) Include privacy breaches, technical problems

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

1      2      3      4      5

subitem not at all important                  essential

#### 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

Not applicable.



### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

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

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

Multimedia Appendix 4 presents a summary of clinician and patient satisfaction surveys.

### DISCUSSION





**22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence**

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



**Does your paper address subitem 22-i? \***

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

**Discussion/Principal Results:**

"The primary objective of this study was to determine whether PEAR-004, a software-based intervention delivered via smartphone, can further reduce symptoms of schizophrenia as measured by the PANSS in subjects, almost all of whom currently on antipsychotic pharmacotherapy. No benefit was seen. Secondary outcomes suggested brief transient improvement in depressive symptoms only. No safety concerns were seen."

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



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

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

#### Discussion/Principal Results:

"...Lack of efficacy in this study was not due to lack of engagement, which was demonstrated to be adequate, or lack of satisfaction. ...The current study provided many valuable insights that may be useful in future development programs of digital therapeutics."

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

#### 20-i) Typical limitations in ehealth trials

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



**Does your paper address subitem 20-i? \***

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

Discussion/Strengths and Limitations:

"...As regards limitations, there was some heterogeneity in study implementation aspects by different study sites. From post-study interviews with coordinators at all six sites, we found that there were differences among the sites' onboarding processes and directions on product use at baseline and throughout the study."

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

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

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection



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

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

#### Discussion/Principal Results:

"To our knowledge this study is the largest RCT to date with a sham control group in schizophrenia. Lack of benefit when compared to sham may reflect the nonspecific aspects of benefit seen with digital interventions. It is notable that all subjects improved, and if a wait list control had been used rather than sham, we might have interpreted the results as suggesting mild benefit with the intervention. Natural history of recovery from an acute psychotic exacerbation also is relevant for improvement seen with 12 weeks of follow-up. The inclusion criteria of a moderate psychotic state (PANSS  $\geq 60$ ) might have allowed for lower levels of symptomatology, often associated with sham or placebo response."

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

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

1      2      3      4      5

subitem not at all important                        essential

Clear selection



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

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

Discussion/Principal Results:

"Lack of efficacy in this study was not due to lack of engagement, which was demonstrated to be adequate, or lack of satisfaction. Despite lack of definable clinical benefit, patients reported that PEAR-004 app was engaging, interactive and helped them feel better."

### 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: ClinicalTrials.gov NCT03751280;  
<https://clinicaltrials.gov/ct2/show/NCT03751280>



**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 full trial protocol is available from the corresponding author upon request.

**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

Acknowledgements:

"Both interventions (PEAR-004 and sham) were provided by Pear Therapeutics, Inc. This study was funded by Novartis Institutes for Biomedical Research, Cambridge, MA, USA."

**X27) Conflicts of Interest (not a CONSORT item)**

**X27-i) State the relation of the study team towards the system being evaluated**

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
						Clear selection

**Does your paper address subitem X27-i?**

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

**Acknowledgements**

"Both interventions (PEAR-004 and sham) were provided by Pear Therapeutics, Inc. This study was funded by Novartis Institutes for Biomedical Research, Cambridge, MA, USA."

**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?

Ethics and Informed Consent section was added.

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

2 hours



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

yes

no

Other:

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

yes

no

Other:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer



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