# CONSORT-EHEALTH Checklist V1.6.2 Report

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## CONSORT-EHEALTH Checklist V1.6.2 Report

(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6](http://tinyurl.com/consort-ehealth-v1-6).

**Date completed**

10/21/2018 9:26:40

by

Han

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**A Mobile Game for Patients With Breast Cancer: Randomized Controlled Trial**

**TITLE**

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

We address “mobile” in our paper

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

They were interviewed every week by cell phones

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

A Mobile Game for Patients With Breast Cancer: Randomized Controlled Trial

**ABSTRACT**

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

Study participants were randomly assigned to a mobile game play group or a conventional education group in a ratio of 1:1. The patients were unblinded and followed prospectively for 3 weeks.

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

Our intervention was education through smart-phone based. So this comment was thought as slightly inappropriate.

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

The patients were unblinded and followed prospectively for 3 weeks.

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

Overall, 72 out of 76 patients completed the study after 3 weeks.

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Our trial was concluded as positive results

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**INTRODUCTION**

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

These side effects may cause poor drug compliance, prohibiting successful anticancer treatment. Poor education is one of the main determinants of poor adherence to chemotherapy. Therefore, proper education contribute to improved clinical outcomes.

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

Recent studies with health-related internet games have shown positive effects, such as improving coping strategies for health problems.

We hypothesized that mobile gaming would lead to increased drug compliance, decreased physical side effects of chemotherapy, and improved psychological status among patients.

**METHODS**

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio

A flow diagram of the study is shown in Figure 2.

3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons

We inserted sentences

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

Our study was very short term study and this address was not in the ms.

4a) CONSORT: Eligibility criteria for participants

We address the CONSORT

4a-i) Computer / Internet literacy

The exclusion criteria were as follows

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

We The patients were unblinded

4a-iii) Information giving during recruitment

Informed consent was obtained from all patients during hospitalization for chemotherapy after explaining the design, protocol

4b) CONSORT: Settings and locations where the data were collected

We explained description as follow up of cell-phone

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

The questions were assessed using a self-reported scale of 10 levels with 10 indicating

4b-ii) Report how institutional affiliations are displayed

5) CONSORT: Describe 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

A mobile game, ILOVEBREAST (CLGAMES, Seoul, Korea) was developed

5-ii) Describe the history/development process

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**RESULTS**

5-iii) Revisions and updating

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5-iv) Quality assurance methods

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Representative screenshots of the ILOVEBREAST game.

5-vi) Digital preservation

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5-vii) Access

For patients in the game group, the study mobile game (ILOVEBREAST) was installed on the participants’ smartphones

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

They were interviewed every week via cell phone until the end of the study

5-ix) Describe use parameters

They were recommended to play the game for >30 minutes a day, 3 times per week

5-x) Clarify the level of human involvement

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5-xi) Report any prompts/reminders used

They were interviewed every week via cell phone until the end of the study

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

They were interviewed every week via cell phone until the end of the study

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

The game group also showed improved compliance to medications compared with the control group (K-MAS score).

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

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

The time spent on game playing in the mobile game group was higher than that spent for self-education in the control group

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

The patients in the game group were requested to assess their level of satisfaction with ILOVEBREAST
The statistician who was independent department performed randomization
utilizing an interactive Web randomization system. We use simple randomization
utilizing an interactive Web randomization system. We use simple randomization
taken to conceal the sequence until interventions were assigned
using an interactive Web randomization system.

We explained description as follow up of cell-phone
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We use simple randomization
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We believe this fact provides an important lesson for future developers.
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Because this study was a proof-of-concept trial, the sample size calculation was done on a practical basis
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We summarized the trial protocol at "Study Procedure" section
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We didn’t use the binary outcomes
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The status who was independent department performed randomization
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The major limitation of this study is the small sample size and the short study period.
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The baseline characteristics of the study subjects are summarized in Table 1.
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Our study was divided into two groups, not blinded
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The Chi-square test
The Chi-square test

Fisher’s exact test was used for dichotomous variables
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Our study was finished after the 3-weeks follow-up of 76 female patients.
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The logistic model was used to assess the impact of the mobile game versus control intervention.
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20-i) Typical limitations in ehealth trials
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25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders
This research study was supported by a grant of Nexon 2014 and a grant from the Korea Creative Content Agency, Ministry of Culture, Sports and Tourism (2013040436).

26-i) Comment on ethics committee approval
The Chung-Ang University Hospital Institutional Review Board approved the research protocol for this study (Number C20141447)

26-ii) Outline informed consent procedures
Informed consent was obtained from all patients during hospitalization for chemotherapy after explaining the protocol, and consequences of the study.

26-iii) Safety and security procedures

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