CONSORT-EHEALTH Checklist V1.6.2 Report	Manuscript Number	11462
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6].		
Date completed		
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by		
Helen Fu		
Influence of Patient Characteristics and Psychological Needs on Diabetes Mobile App Usability in Adults With Type 1 or Type 2 Diabetes: Crossover Randomized Trial		
TITLE		
1a-i) Identify the mode of delivery in the title		
Background: in Abstract, proof page 1		
1a-ii) Non-web-based components or important co-interventions in title		
This is not applicable because this study only involved mobile app testing.		
1a-iii) Primary condition or target group in the title		
proof page 3		
ABSTRACT		
1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT		
Abstract Methods: proof page 1		
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT		
Abstract method proof page 1		
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT		
Proof page 1		
1b-iv) RESULTS section in abstract must contain use data		
Results proof page 1		
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials		
Proof page 1		
INTRODUCTION		
2a-i) Problem and the type of system/solution		
proof page 2		
2a-ii) Scientific background, rationale: What is known about the (type of) system		
proof page 1		
Does your paper address CONSORT subitem 2b?		
proof page 2		
METHODS		
3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio		
proof page 3		
3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
no		
3b-i) Bug fixes, Downtimes, Content Changes		

4a) CONSORT: Eligibility criteria for participants		
proof page 3		
4a-i) Computer / Internet literacy		
We verified mobile phone use proficiency by screening for app use and did not include typical mobile phone usage for calls, texting, emailing, or taking pictures.		
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:		
Procedures section		
4a-iii) Information giving during recruitment		
proof page 3		
4b) CONSORT: Settings and locations where the data were collected		
7. Individual study sessions were held in a private room.		
4b-i) Report if outcomes were (self-)assessed through online questionnaires		
proof page 3		
4b-ii) Report how institutional affiliations are displayed		
Proof page 3		
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		
Proof page 3		
5-ii) Describe the history/development process		
proof page 4		
5-iii) Revisions and updating		
The same 2017 version of both apps were used during the study period		
5-iv) Quality assurance methods		
proof page 3		
5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used		
proof page 3		
5-vi) Digital preservation		
OnTrack and mySugr are publicly available in the app store		
5-vii) Access		
proof page 3		
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework		
Theoretical Framework section proof page 2		
5-ix) Describe use parameters		
proof page 3 - procedure		
5-x) Clarify the level of human involvement		
proof page 3 - procedure		
5-xi) Report any prompts/reminders used		
proof page 4 -		
5-xii) Describe any co-interventions (incl. training/support)		

Proof page 3 and 4		
6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		
Measurements section in the paper Proof page 4		
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed		
not applicable		
6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored		
Proof page 3		
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained		
Proof page 3		
6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons		
7. Individual study sessions were held in a private room.		
7a) CONSORT: How sample size was determined		
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size		
Proof page 4		
7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines		
Measurements section in the paper Proof page 4		
8a) CONSORT: Method used to generate the random allocation sequence		
Proof page 3		
8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)		
Proof page 3		
9) CONSORT: 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		
Proof page 3		
10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
Proof page 3		
11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
11a-i) Specify who was blinded, and who wasn't		
Proof page 3		
11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"		
Proof page 3		
11b) CONSORT: If relevant, description of the similarity of interventions		
Not applicable		
12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes		
Proof page 4		
12a-i) Imputation techniques to deal with attrition / missing values		
The only missing data was an HbA1c level from one participant.		
12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses		
Proof page 4		
RESULTS		
13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		

Proof page 4		
13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons		
There were no losses. The only missing data was an HbA1c level from one participant.		
13b-i) Attrition diagram		
not applicable, we did not have attrition		
14a) CONSORT: Dates defining the periods of recruitment and follow-up		
Proof page 3 and 4		
14a-i) Indicate if critical "secular events" fell into the study period		
not applicable		
14b) CONSORT: Why the trial ended or was stopped (early)		
The trial did not ended or stop early.		
15) CONSORT: A table showing baseline demographic and clinical characteristics for each group		
Proof page 4 and 5		
15-i) Report demographics associated with digital divide issues		
In Table 1. Device brand, n (%) and Mobile phone comfort level, n (%)		
16a) CONSORT: 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		
Proof page 1		
16-ii) Primary analysis should be intent-to-treat		
All participants were analyzed.		
17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		
Proof page 3-6		
17a-i) Presentation of process outcomes such as metrics of use and intensity of use		
This was not applicable in this study.		
17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
not applicable. We did not have binary outcomes		
18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
Proof page 6		
18-i) Subgroup analysis of comparing only users		
Proof page 6		
19) CONSORT: All important harms or unintended effects in each group		
Proof page 9, Fatigue with the 2-hour testing session ..		
19-i) Include privacy breaches, technical problems		
Proof page 3		
19-ii) Include qualitative feedback from participants or observations from staff/researchers		
Proof page 9		
DISCUSSION		
20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses		

20-i) Typical limitations in ehealth trials		
Proof page 9		
21) CONSORT: Generalisability (external validity, applicability) of the trial findings		
21-i) Generalizability to other populations		
Proof page 9		
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting		
Proof page 9		
22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)		
Discussion sectionProof page 8 and 9		
22-ii) Highlight unanswered new questions, suggest future research		
Proof page 9		
Other information		
23) CONSORT: Registration number and name of trial registry		
While this study uses a randomized controlled design (i.e., crossover design), participants did not receive a health-related intervention and does not involve a health-related outcome. Rather, the research is a “simulated experiment” to assess app usability and user satisfaction with using apps that contained fake/simulated data. Therefore, this study is not a clinical trial and is exempt from clinical trial registration.		
24) CONSORT: Where the full trial protocol can be accessed, if available		
Our study used a protocol. It is available upon request.		
25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders		
Acknowledgement Proof page 9		
X26-i) Comment on ethics committee approval		
Proof page 3		
x26-ii) Outline informed consent procedures		
Proof page 3		
X26-iii) Safety and security procedures		
Proof page 3		
X27-i) State the relation of the study team towards the system being evaluated		
Proof page 9		