CONSORT-EHEALTH Checklist V1.6.2 Report	Manuscript Number	37314
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6].		
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by		
Mohammad Habibur Rahman Sarker		
A CKD awareness campaign and mHealth education to improve knowledge, quality of life, and motivation for a healthy lifestyle among CKD patients in Bangladesh: A randomized controlled trial.		
TITLE		
1a-i) Identify the mode of delivery in the title		
A CKD awareness campaign and mHealth education to improve knowledge, quality of life, and motivation for a healthy lifestyle among CKD patients in Bangladesh: A randomized controlled trial.		
1a-ii) Non-web-based components or important co-interventions in title		
1a-iii) Primary condition or target group in the title		
Chronic Kidney Diseases patients		
ABSTRACT		
1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT		
Adults individual with CKD (stages 1-3) were enrolled in November 2020 and randomly assigned to one of two groups: intervention or control. The intervention group received health education through a CKD awareness campaign and mHealth technologies, whereas the control group received standard treatment, and was observed for 6 months		
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT		
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT		
1b-iv) RESULTS section in abstract must contain use data		
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials		
INTRODUCTION		
2a-i) Problem and the type of system/solution		
Yes, we did not face any problem		
2a-ii) Scientific background, rationale: What is known about the (type of) system		
Yes. CKD education in the early stages could be an integral part of patient management and reduction of the related risk factors, slowing down the progression of the disease, and the need for such education is greater in rural and peri-urban areas		
Does your paper address CONSORT subitem 2b?		
Yes. the present study aims to evaluate the outcome of a health education intervention designed to enhance knowledge, health-related QOL, and motivation about healthy lifestyle among rural and peri-urban adults suffering from CKD (stage 1-3).		
METHODS		
3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio		
This study was a community-based, single-centered, prospective, open-label, two-arm (1:1), randomized control trial.		
3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
No, we did not made any changes after trial commencement.		
3b-i) Bug fixes, Downtimes, Content Changes		
4a) CONSORT: Eligibility criteria for participants		
Yes, inclusion and exclusion criteria was used to select the participants.		
4a-i) Computer / Internet literacy		
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:		
Yes (mobile based) health education was provided.		
4a-iii) Information giving during recruitment		
4b) CONSORT: Settings and locations where the data were collected		
Mirjzapur subdistrict, Tangail, Bangladesh		
4b-i) Report if outcomes were (self-)assessed through online questionnaires		
Health education was provided through mHealth		
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		
5-ii) Describe the history/development process		
5-iii) Revisions and updating		
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		
5-vi) Digital preservation		
5-vii) Access		
Not applicable as the participants did not need access to platform or internet.		
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework		
Health education for CKD patients		
5-ix) Describe use parameters		
5-x) Clarify the level of human involvement		
5-xi) Report any prompts/reminders used		
Yes, we have called all the participants.		
5-xii) Describe any co-interventions (incl. training/support)		
Yes, training was provided to the community health workers		
6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		
Yes, primary and secondary outcomes were well defined.		
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		
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained		

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons		
Mirjzapur subdistrict, Tangail, Bangladesh		
7a) CONSORT: How sample size was determined		
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size		
7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines		
Yes, primary and secondary outcomes were well defined.		
8a) CONSORT: Method used to generate the random allocation sequence		
Permuted block randomization technique was performed using a block size of six based on a computer-generated random number sequence.		
8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)		
Permuted block randomization technique was performed using a block size of six based on a computer-generated random number sequence.		
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		
Allocation was concealed in identical sealed envelopes that were only opened when the study patient was ready for enrolment under the supervision of the principal investigator		
10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
An experienced statistician, not involved in the study in any way, prepared the randomization table and listed study patients' numbers with corresponding intervention allocations for CKD patients in sequentially numbered sealed envelopes according to the randomization schedule to correspond to the serial number of the CKD patients		
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		
This study was a parallel-group (1:1) randomized controlled trial in the Mirzapur sub-district of Bangladesh that compared two groups of CKD patients. Adults individual with CKD (stages 1-3) were enrolled in November 2020 and randomly assigned to one of two groups: intervention or control		
11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"		
11b) CONSORT: If relevant, description of the similarity of interventions		
It was not a placebo control trial.		
12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes		
For the baseline assessment, continuous variables were compared by t-test or Man-Whitney U test, and categorical variables were compared by the chi-square (X2) test. Multiple comparisons were performed by two-way repeated measure ANOVA test for the evaluation of the outcome variables such as CKD knowledge questionnaire and physical measurements and QOL at baseline, three months, and six months.		
12a-i) Imputation techniques to deal with attrition / missing values		
Intention treat analysis were performed.		
12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses		
Not applicable as we did not perform any sub group analysis.		
RESULTS		
13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		
Yes, intention to treat analysis was performed		
13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons		
A total enrolled of 126 patients (control group, n=63, intervention group, n=63) were enrolled in the study. Of them, five patients were withdrawn from further participation during the follow-up period. Among them, four were from the intervention group and one from the control group. Two patients in the intervention group did not participate in the health campaign, and the other two did not continue their health education. The only patient in the control group, on the other hand, left the area after enrolment into the study".		
13b-i) Attrition diagram		
14a) CONSORT: Dates defining the periods of recruitment and follow-up		
The total study duration was one year; during that one year, the intervention duration was six months, starting from mid-November 2020 and completed in May 2021		
14a-i) Indicate if critical "secular events" fell into the study period		
14b) CONSORT: Why the trial ended or was stopped (early)		
Not applicable as it was not stopped (early).		
15) CONSORT: A table showing baseline demographic and clinical characteristics for each group		
Yes, baseline characteristics was provided.		
15-i) Report demographics associated with digital divide issues		
Yes. Age, gender, education was provided in demographics characteristics was provided.		
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		
Yes, clearly defined the denominators.		
16-ii) Primary analysis should be intent-to-treat		
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)		
Yes. Estimated effect size and its precision.		
17a-i) Presentation of process outcomes such as metrics of use and intensity of use		
17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
For binary outcomes, presentation of both absolute and relative effect sizes was measured		
18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
Repeated measure ANOVA and Generalized Estimating Equation (GEE) was performed		
18-i) Subgroup analysis of comparing only users		
19) CONSORT: All important harms or unintended effects in each group		
No any important harm was observed.		
19-i) Include privacy breaches, technical problems		
19-ii) Include qualitative feedback from participants or observations from staff/researchers		
DISCUSSION		
20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses		
20-i) Typical limitations in ehealth trials		
Data contamination by neighbors and family members was very plausible		
21) CONSORT: Generalisability (external validity, applicability) of the trial findings		
21-i) Generalizability to other populations		
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting		
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)		
Health education through a nephrologist facilitated health campaign and CHWs conducted mHealth education improved the patient knowledge status when compared with usual patient care		
22-ii) Highlight unanswered new questions, suggest future research		

Other information		
23) CONSORT: Registration number and name of trial registry		
ClinicalTrials.gov NCT04094831.		
24) CONSORT: Where the full trial protocol can be accessed, if available		
JMIR Res Protoc. 2021 Nov 19;10(11):e30191.doi: 10.2196/30191		
25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders		
Japan's Grants-in-Aid for Scientific Research Program		
X26-i) Comment on ethics committee approval		
x26-ii) Outline informed consent procedures		
X26-iii) Safety and security procedures		
X27-i) State the relation of the study team towards the system being evaluated		