

CONSORT-EHEALTH Checklist V1.6.2 Report	Manuscript Number	17967
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6].		
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by		
Margrethe Røed		
Process Evaluation of an eHealth Intervention (Food4toddlers) to Improve Toddler's Diet: Randomized Controlled Trial		
TITLE		
1a-i) Identify the mode of delivery in the title		
eHealth intervention		
1a-ii) Non-web-based components or important co-interventions in title		
Process Evaluation		
1a-iii) Primary condition or target group in the title		
NA		
ABSTRACT		
1b-i) Key features/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT		
"process evaluation", "electronic health (eHealth) intervention", "website usage"		
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT		
"parent-toddler dyads", "parents in the intervention group received access to an intervention website for 6 months"		
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT		
Mentioned in the method section.		
1b-iv) RESULTS section in abstract must contain use data		
The total number of the trial and for this analysis was mentioned in the method section. The results of primary (satisfaction and usages of the website) and secondary (sub-group analyzes) is mentioned.		
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials		
The overall results of the process evaluation is mentioned (was relevant for the participants) and the secondary outcomes (differences according to education level and family composition).		
INTRODUCTION		
2a-i) Problem and the type of system/solution		
"Internet is a powerful and popular source for health information among parents"		
"Mobile health (mHealth) and eHealth interventions are gaining popularity, as such interventions have the potential to reach a large target group, can easily be adapted to new groups, are available 24/7, and can be cost-effective"		
2a-ii) Scientific background, rationale: What is known about the (type of) system		
We report results for process evaluations of similar interventions e.g. the Early Food for Future Health study and the Growing Healthy Program. In addition to describe the potential and interest of developing and evaluating the usage and satisfaction of this type of interventions.		
Does your paper address CONSORT subitem 2b?		
"The objectives of this study were to conduct a process evaluation of this eHealth intervention by examining the usage and perceived satisfaction of the intervention website among parents of toddlers and to explore whether this differed according to educational level and number of children in the household."		
METHODS		
3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio		
"Food4toddlers is a randomized controlled trial, aiming to promote healthy dietary habits among toddlers"		
3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
NA		
3b-i) Bug fixes, Downtimes, Content Changes		
NA		
4a) CONSORT: Eligibility criteria for participants		
"Eligible individuals were parents of children born between June 2016 and May 2017. The parents had to be literate in Norwegian"		
4a-i) Computer / Internet literacy		
"Eligible individuals were parents of children born between June 2016 and May 2017. The parents had to be literate in Norwegian" No other eligibility criteria was applied.		
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:		
We have stated that the parents were recruited through Facebook, and signed in on a website. Online questionnaires were used for assessment.		
4a-iii) Information giving during recruitment		
"A total of 404 parents of 12-month-old children were recruited through a Facebook advertisement, who then responded to a baseline questionnaire and were randomized into an intervention group and a control group".		
4b) CONSORT: Settings and locations where the data were collected		
Norway (Facebook)		
4b-i) Report if outcomes were (self-)assessed through online questionnaires		
The mode of delivery of the intervention was not stated in the section, however there was a link to the protocol paper listed.		
4b-ii) Report how institutional affiliations are displayed		
All procedures were reviewed and approved by the NSD (Norwegian centre for research data), and informed consent from the parents was obtained when they signed in online for participation in the study.		
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		
"The authors thank the participants. This study is funded by the University of Agder."		
5-ii) Describe the history/development process		
This paper is a process evaluation and such details are presented in the protocol paper of for the intervention (https://doi.org/10.1186/doi.s12889-019-6915-x).		
5-iii) Revisions and updating		
NA		
5-iv) Quality assurance methods		
NA		
5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used		
"The intervention group had 6 months of access to the Food4toddlers website which comprised 4 main elements: (1) lessons (n=22) on how to provide healthy food and create a healthy eating environment for the toddler, (2) recipes, (3) a discussion forum, and (4) basic information about food and beverages (called Good to know)".		
5-vi) Digital preservation		
NA. (The content will be developed on another digital platform in the future)		
5-vii) Access		

<p>"Participants in the intervention group were given access to the Food4toddlers website for 6 months". More details are presented in the protocol paper of for the intervention (https://doi.org/10.1186/doi s12889-019-6915-x).</p> <p>5-viii) Mode of delivery, features/functionality/components of the intervention and comparator, and the theoretical framework These issues are presented in the protocol paper of for the intervention (https://doi.org/10.1186/doi s12889-019-6915-x).</p> <p>5-ix) Describe use parameters The duration of the intervention is listed (6 months) in the Intervention development section along with the content.</p> <p>5-</p> <p>5-x) Clarify the level of human involvement The duration of the intervention is listed (6 months) and no tailoring except for push notifications were available.</p> <p>5-xi) Report any prompts/reminders used "Initially, the web page was limited to information relevant for the child's age at baseline and gradually expanded in 20 steps as the child got older."</p> <p>5-xii) Describe any co-interventions (incl. training/support) NA</p> <p>6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed Stated in the Data and Measurements and statistics section.</p> <p>6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed All questions used are validated and reliability tested. Stated in the "Measures and outcomes" section.</p> <p>6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored This is the main results of this article. See the results section.</p> <p>6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained NA</p> <p>6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons Norway (Facebook)</p> <p>7a) CONSORT: How sample size was determined 7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size This issues was stated in the protocol paper of the study.</p> <p>7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines Stated in the Data and Measurements and statistics section.</p> <p>8a) CONSORT: Method used to generate the random allocation sequence This issues was stated in the protocol paper of the study. https://doi.org/10.1186/s12889-019-6915-x</p> <p>8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size) "The parents had to be literate in Norwegian. Of the 404 recruited parents, 298 (73.8%) filled in more than half of the baseline questionnaire which was the minimum requirement to be randomized into either the control or intervention group (n=148)."</p> <p>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 This issues were stated in the protocol paper of the study. https://doi.org/10.1186/s12889-019-6915-x</p> <p>10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions This issues were stated in the protocol paper of the study. https://doi.org/10.1186/s12889-019-6915-x</p> <p>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 NA</p> <p>11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator" NA</p> <p>11b) CONSORT: If relevant, description of the similarity of interventions NA</p> <p>12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes "Means with standard deviations for continuous variables and frequencies and percentages for categorical variables were reported. The chi-square tests were used to test potential differences in the perceived value of the intervention between the 2 education groups and according to the number of children in the household. Independent sample t tests were used to test potential group differences for continuous variables."</p> <p>12a-i) Imputation techniques to deal with attrition / missing values Listed in the result section.</p> <p>12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses We listed subgroup analyses.</p>		
RESULTS		
<p>13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome NA (We use only data from the intervention group, but the numbers are listed in the method section).</p> <p>13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons "In the intervention group, 93/148 (62.8%) participants answered at least parts of the questionnaire at follow-up 1. However, only 83/148 (56.1%) participants answered the last questions in the questionnaire that concerned the website use".</p> <p>13b-i) Attrition diagram See table 2</p> <p>14a) CONSORT: Dates defining the periods of recruitment and follow-up This is listed in the study design section.</p> <p>14a-i) Indicate if critical "secular events" fell into the study period NA</p> <p>14b) CONSORT: Why the trial ended or was stopped (early) NA</p> <p>15) CONSORT: A table showing baseline demographic and clinical characteristics for each group See table 1</p> <p>15-i) Report demographics associated with digital divide issues See table 1</p> <p>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 The the result section.</p> <p>16-ii) Primary analysis should be intent-to-treat See table 2: "One participant got access to the intervention but decided to quit. Two did not get access to the intervention mistakenly. These 3 are included in the reported numbers."</p> <p>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) "Statistical significance was set to the P≤.05 level".</p> <p>17a-i) Presentation of process outcomes such as metrics of use and intensity of use</p>		

See the result section.		
17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
NA		
18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
NA		
18-i) Subgroup analysis of comparing only users		
NA		
19) CONSORT: All important harms or unintended effects in each group		
NA		
19-i) Include privacy breaches, technical problems		
Not listed in this paper. See the protocol paper. https://doi.org/10.1186/s12889-019-6915-x		
19-ii) Include qualitative feedback from participants or observations from staff/researchers		
NA		
DISCUSSION		
20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses		
20-i) Typical limitations in ehealth trials		
See the strengths and limitation section.		
21) CONSORT: Generalisability (external validity, applicability) of the trial findings		
21-i) Generalizability to other populations		
We highlight the biased sample of this intervention (highly educated mothers).		
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting		
NA		
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)		
"More than 86.5% (128/148) of parents in the intervention group visited the website and most of them found the website useful, especially the modules and the recipes. The website content, texts, and interface were highly valued by most parents, which may have influenced parental engagement on the website. Besides, most parents in the intervention group found the content applicable to their child's age."		
22-ii) Highlight unanswered new questions, suggest future research		
IN the conclusion section: "Developing eHealth interventions and may inform future interventions to take particular care in matching intervention content to different educational and socioeconomic groups' needs."		
Other information		
23) CONSORT: Registration number and name of trial registry		
"The study was approved by the Norwegian Centre for Research Data on June 08, 2016 (reference number 48643)."		
24) CONSORT: Where the full trial protocol can be accessed, if available		
https://doi.org/10.1186/s12889-019-6915-x		
25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders		
"This study is funded by the University of Agder. The financial contributor was not involved in designing the study, collection, analyses, and interpretation of data or in writing the manuscript."		
X26-i) Comment on ethics committee approval		
"The study was approved by the Norwegian Centre for Research Data on June 08, 2016 (reference number 48643)."		
x26-ii) Outline informed consent procedures		
Informed consent from parents was obtained when they signed in online for participation.		
X26-iii) Safety and security procedures		
This issues were stated in the protocol paper of the study. https://doi.org/10.1186/s12889-019-6915-x		
X27-i) State the relation of the study team towards the system being evaluated		
This study is funded by the University of Agder. The financial contributor was not involved in designing the study, collection, analyses, and interpretation of data or in writing the manuscript.		