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.

* Required

Your name *

First Last

Lenneke van Genugten

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Erasmus Medical Ceente

Your e-mail address *

abc@gmail.com

I.vangenugten@erasmus

Title of your manuscript *

Provide the (draft) title of your manuscript.

Evaluating the effects of an online computer-tailored weight management intervention for overweight adults on anthropometric and behavioural outcome measures: results of a randomised controlled trial.
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
onot submitted yet - in early draft status
O not submitted yet - in late draft status, just before submission
C 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
Opublished
Other:
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) Other: 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 in JMIR) no ms number (yet) / not (yet) submitted to / published in JMIR
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

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.
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subitem not at all important C C C essential
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 "online computer-tailored"
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").
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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 "computer-tailored"
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 "computer-tailored" 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
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 "computer-tailored" 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

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"The first module of the tailored intervention was visited by almost all participants, but only 15% completed all four modules of the tailored intervention, while 46% completed the three modules of the general information intervention. The tailored intervention was considered more personally relevant (TI 3.20 vs GI 2.83, P=.001), containing more new information (TI 3.11 vs GI 2.73, P=.003) and having longer texts (TI 3.20 vs GI 3.07, P=.01) but was appreciated equally to the generic information

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)

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subitem not at all important	0	0	0	0	0	essentia

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

"The online computer-tailored weight management intervention for adults being overweight resulted in prevention of weight gain and changes in dietary intake in the desired direction, but the intervention was not more effective in preventing weight gain than generic information. A possible reason for the absence of intervention effects is sub-optimal use of the intervention and the self-regulation components. Further research is therefore needed to gain more insight in how the intervention and exposure to its contents can be improved."

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)

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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
yes "Prevention of weight gain is particularly important among people being overweight (BMI 25-30 kg/m2), since they are most at risk of becoming obese." "Therefore, we developed a computer-tailored intervention aiming to prevent weight gain among adults being overweight" "The aim of this study was to establish the efficacy of an online, computer-tailored weight management intervention (GRIPP) on anthropometric
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 C C C essential
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 "Several reviews have shown that (online) computer tailored interventions may have a positive effect on energy-balance related behaviours [25-28], compared to general information or no information. "

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

yes

"The aim of this study was to establish the efficacy of an online, computer-tailored weight management intervention (GRIPP) on anthropometric outcome measures at 6-months post-intervention and on energy balance related behaviours (intake of sugar sweetened drinks, snacks and fat, and physical activity) at 1- and 6-months post-intervention compared to a generic information control group. The hypotheses were that:

1. Anthropometric outcomes (BMI, waist circumference and skin fold

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

"A two-group randomised controlled trial was conducted, in which the
computer-tailored intervention (TI, n=270) was compared with a generic
information intervention (GI, n=270) control group. "

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

NA	

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].

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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

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4a-ii) Open vs. closed, we									

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.

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Copy and paste relevant sections from manuscript text

"Self-reported measures of use and appreciation were included in the one-month post-intervention questionnaire. If not stated otherwise, answer categories ranged from 'totally disagree' (1) to 'totally agree' (5)."

"Amount of information read was assessed by the question 'To what extent did you read the information in the program?". Answering categories ranged from 'none of it' (0) to 'all of it' (5). Perceived length of the texts was assessed by the question 'What do you think of the lengths of the texts in

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

NA			

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides 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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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

"A power calculation showed that a number of 200 participants in each study group would be sufficient to detect 0.4 difference in BMI points between the intervention and control group (caused by weight gain of 0.3 kg in the control group and weight maintenance or slight weight reduction in the intervention group) with a power of 0.80 and a significance level of p<.05. To account for drop-out between the measurements 600 participants needed to be recruited for 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

NA			

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

"After baseline assessment, participants were allocated to one of the two study groups (1:1), by means of sex-stratified computer block randomisation (block size: 10)."

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

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example, participants, care providers, those assessing outcomes) and

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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 NA X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item) X26-i) Comment on ethics committee approval subitem not at all important (() () () essential 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 "The study received a declaration of no objection from the Erasmus MC medical ethics committee. The trial registration number is NTR1862 " 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. 2 3 subitem not at all important (() () () essential 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

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information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Weight, height, waist circumference and skin fol hospital site. Participants signed the informed co their anthropometric measurements taken."	
X26-iii) Safety and security procedures Safety and security procedures, incl. privacy conslikelihood or detection of harm (e.g., education ar	
subitem not at all important C C C	○ essential
Does your paper address subitem X26-iii? Copy and paste relevant sections from the manusindicate direct quotes from your manuscript), or einformation not in the ms, or briefly explain why th NA, this was a healthy participant population, and were expected.	e item is not applicable/relevant for your study
RESULTS	
13a) For each group, the numbers assigned, received intended treatn primary outcome	of participants who were randomly nent, and were analysed for the
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Figure 1 reports this data/	

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.			

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.

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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			

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

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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

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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).

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Does your paper address subitem 18-i? Dopy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to adicate 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 NA 19) All important harms or unintended effects in each group for specific guidance see CONSORT for harms) Does your paper address CONSORT subitem 19? Dopy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to adicate 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 such effects have taken place. 9-i) Include privacy breaches, technical problems not under the privacy breaches, technical problems. This does not only include physical "harm" to harticipants, but also incidents such as perceived or real privacy breaches [1], technical problems, and their unexpected/unintended incidents. "Unintended effects" also includes unintended positive effect 2. 1 2 3 4 5 Tubitem not at all important	see 16-iii).	1	2	3	4	5	
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"Limitations are the self-reported measures for physical activity and dietary intake, which may have resulted in less reliable outcomes. Specifically, over-reporting of physical activity seems to be a problem. In general, physical activity in Dutch adults is much lower (about 60% of the population is physically active for more 30 minutes per day) {Hildebrandt, 2010 #953}. Furthermore, the different number of modules for the tailored intervention group (4 modules) and the generic information group (3 modules) limits the comparability between the two study groups because the participants are

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

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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

"Even though initially our sample size was sufficient for detecting the anticipated effect, retention of participants in the study was much lower than we had anticipated, thus reducing the actual power of the study."

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.

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NA
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: NTR1862
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
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