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.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
Your name *
First Last
Olivia de Jongh G.

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
The University of British Columbia & BC Children's

Your e-mail address *
abc@gmail.com
olivia.djgonzalez@bcchr.ubc.ca

Title of your manuscript *
Provide the (draft) title of your manuscript.
The Aim2Be mHealth Intervention for Children with Overweight or Obesity and their Parents: A Person-Centered Analysis to Uncover Digital Phenotypes
Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Aim2Be

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Version 2

Language(s) *
What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English (RCT app version), English, French (cur

URL of your Intervention Website or App
e.g. a direct link to the mobile app on app store (iTunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

https://www.aim2be.ca/

URL of an image/screenshot (optional)

Your answer
Accessibility *
Can an enduser access the intervention presently?

- access is free and open
- access only for special usergroups, not open
- access is open to everyone, but requires payment/subscription/in-app purchases
- app/intervention no longer accessible
- Otros:

Primary Medical Indication/Disease/Condition *
e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Childhood obesity

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

BMI z-scores (zBMI), dietary behavior, physical

Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Tu respuesta
**Recommended "Dose"** *

What do the instructions for users say on how often the app should be used?

- [ ] Approximately Daily
- [ ] Approximately Weekly
- [ ] Approximately Monthly
- [ ] Approximately Yearly
- [ ] "as needed"
- [ ] Otros: engagement with the ‘active ingredient’ of the app

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**Approx. Percentage of Users (starters) still using the app as recommended after 3 months** *

- [ ] unknown / not evaluated
- [ ] 0-10%
- [ ] 11-20%
- [ ] 21-30%
- [ ] 31-40%
- [ ] 41-50%
- [ ] 51-60%
- [ ] 61-70%
- [ ] 71%-80%
- [ ] 81-90%
- [ ] 91-100%
- [ ] Otros:
Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Otros: In this secondary analysis of the RCT, specific patterns of app use pron...
Journal *
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)
- JMIR mHealth and UHealth
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal
- Otros:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- Pilot/feasibility
- Fully powered

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 article in JMIR)

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Otros: 35285
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

☐ Otros: This is not the RCT, this is a secondary analysis. Our title follows JMIF

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.

| Subitem not at all important | 1 | 2 | 3 | 4 | 5 | essential |
|-----------------------------|---|---|---|---|---|-----------|
|                             | ☐ | ☐ | ☐ | ☐ | ☐ | essential |

Borrar la selección

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

The title identifies that a mobile-Health (mHealth) intervention was examined.
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").

1 2 3 4 5

subitem not at all important ○ ○ ○ ● ○ essential

Borrar la selección

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

Not applicable for our study.

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

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subitem not at all important ○ ○ ○ ● ○ essential

Borrar la selección
Does your paper address subitem 1a-iii? *

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.

The title identifies the population/condition (i.e., children with overweight or obesity and their parents).

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

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

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (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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essential

Borrar la selección
Does your paper address subitem 1b-i? *
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 abstract does not include all key RCT elements as our paper is not a RCT. However, we included key/relevant elements for our secondary analysis. For example, the abstract identifies that this study is a secondary analysis of data from a RCT, provides information on the trial registration, and the intervention is summarized including when it was delivered, the duration of the intervention (or app use), and the three main domains (i.e., behavioral, gamified and social) that encompass most of the app features examined. Our comparator was not the randomization group but instead the engagement profile; thus, the comparisons made in our study reflect differences between app users.

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (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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Does your paper address subitem 1b-ii?
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

This is not not applicable/relevant for this study.
**1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT**

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), 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). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (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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| essential                     |   |   |   |   |

Does your paper address subitem 1b-iii?

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

We did not provide this level of detail in the abstract, but we did provide this information in the methods section (e.g., “Participating families (n=214) were recruited from six weight management clinic sites across Canada as well as through Facebook […] eligible participants completed an on-line survey, 24-hr dietary recalls and received assessment tools for height (measuring tape), weight (digital scale) and physical activity (Fitbit Flex 2) […] had access to the app after completing baseline measures”).
1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (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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Does your paper address subitem 1b-iv?

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

In addition to the primary outcomes assessed, our abstract includes usability information for both children and parents, including patterns of engagement among Aim2Be users, a brief description of some of the patterns identified, and the relative sample size and % for each group of users (e.g., “Among parents, 5 digital phenotypes were identified: Socially engaged (n=35, 16%); Independently engaged (n=18, 9%) (parents who used the behavioral or the social features of the app, respectively), Fully engaged (n=26, 12%); Partially engaged (n=32, 15%), and Unengaged (n=103, 48%) users […] LCA revealed 4 phenotypes among children: Fully engaged (n=32, 15%); Partially engaged (n=61, 28%); Dabblers (n=42, 20%) and Unengaged (n=79, 37%) users.”).

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 〇 〇 〇 〇 〇 essential
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 primary outcomes assessed in our paper significantly changed and were discussed in the abstract.

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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subitem not at all important ◯ ◯ ◯ ● ◯ essential
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.

As our paper is not the RCT but a new proposal to uncover intervention effects, our introduction included some of these requested elements, as well as the importance of our analytical approach. Regarding the problem and type of solution only, we discussed: 1) the problem of childhood obesity in Canada (e.g., "Childhood obesity remains a significant health problem in Canada..."); 2) limitations of current interventions (e.g. "a 2018 meta-analysis found that family-based multicomponent behavioral interventions have a small effect in reducing children's BMI in efficacy trials versus standard of care controls..."); and 3) potential benefits of mHealth interventions (e.g., "Several reviews and meta-analyses suggest that mHealth interventions offer multiple advantages to in-person interventions (e.g. real-time data collection; intervention in natural environments; lower costs; health behavior tracking with feedback; incorporation of gamified elements)...”). A detailed description of the intervention is provided in the methods section.

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.

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Our introduction discusses the need and benefits of our analytical approach which is based on the identification of digital phenotypes of mHealth users, explaining why such phenotypes are important to understand intervention results (e.g. "Dose-response analyses are often measured in terms of total minutes or percentage of content examined, but this approach does not provide a nuanced picture of how users may benefit from different mHealth intervention components (i.e., what design elements of the app may be more successful in engaging participants and promoting health behavior change). Studies examining how intervention exposure impacts behavior change cannot solely focus on the quantity of the intervention received but must also consider how participants engaged with the ‘active ingredients’ of the intervention – namely the features that support behavior change. mHealth interventions are particularly well suited to examine in greater detail which components of the intervention participants engage with through app-analytics data. Recently, there have been calls to develop analytical methods to process the vast amounts of data that become available using mHealth technologies and identify ‘digital phenotypes’ (i.e., user typologies derived from individuals’ patterns of interactions with specific app features). While digital phenotypes have been used in other areas of health research (e.g., diabetes, sleep, mental health), and dietary and physical activity behaviors in a non-clinical sample, there has been little attention in the treatment of childhood obesity. Some studies have investigated which app features participants use and individual characteristics associated with partial or total use of an intervention. However, most studies evaluated usability derived from self-reported measures (e.g., asking participants about their preferences and use of app features), total app use, or use of individual features instead of focusing on patterns of app use. To our knowledge, no study targeting childhood obesity has identified users’ typologies based on participants’ engagement with different objectively measured components of an mHealth intervention.")
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

The introduction states: “This study aimed to: 1) identify digital phenotypes of Canadian children with overweight and obesity and their parents who used an mHealth app (the Aim2Be app [25]) over a 3-month period; 2) explore whether participants’ characteristics differed by digital phenotype; and 3) evaluate 3-month changes in children's BMI z-scores (zBMI), dietary, physical activity and screen-time behaviors across digital phenotypes.” The methodology we employed uncover patterns of use and as such is an exploratory procedure. As a result we have not included any hypotheses.

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

Our paper reports general information on the RCT regarding the intervention and waitlist control group, but not in detail since our analyses are not based on an RCT design – meaning that we did not compare intervention versus control group participants. A more detailed description of the design is also provided in the RCT protocol cited in our paper.

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

Not applicable for our study.

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].

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

Not applicable for our study.
Does your paper address CONSORT subitem 4a? *
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

Our paper provides a general description of eligibility (i.e., “Children were eligible to participate if they were aged 10-17 years and had overweight or obesity as defined by the age and sex specific World Health Organization cut-offs”) and a more detailed description is available in the study protocol cited in our paper.

4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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essential

This element was not one of the eligibility criteria, only that participants would need a mobile or computer with Internet access.
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

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.

Does your paper address subitem 4a-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

We specified in our methods section that the recruitment occurred both online and in-person at the clinic, and that several measurements were online and self-reported, whereas others were objectively taken through Fitbits and app-analytics (“Participating families were recruited from six weight management clinic sites across Canada as well as through Facebook. After providing consent, eligible participants completed an on-line survey, 24-hr dietary recalls and received assessment tools for height, weight and physical activity (Fitbit Flex 2) to complete baseline measurements. Participants completed follow-up assessments at the 3- and 6-month follow-ups. Families randomized to the experimental group had access to the app after completing baseline measures. Waitlisted control families were given access to the app after completing their assessment at the 3-month follow-up. […] Parents were mailed a digital scale and a measuring tape with instructions to accurately measure their child’s height and weight at home. […] Children’s dietary behaviors were evaluated with the Waterloo Eating Behavior Questionnaire, a 24-hour web-based dietary recall […] Parents’ dietary behaviors were evaluated using 7 items which were adapted from the Canadian Community Health Surveys. Parents reported their own consumption of… […] Children wore the Fitbit for 7-14 days at baseline, 3 and 6 months and their daily steps count was obtained by our team using Fitabase […] children completed an online survey which included 5 questions from the Physical Activity Questionnaire for Older Children; a 7-day recall inquiring about… […] Parents’ physical activity was evaluated with 7 items from the Physical Activity Questionnaire Short Form […] Children’s and parents’ screen-time was evaluated with 2 items adapted from the Sedentary Behavior Questionnaire […] App-analytics were used to track how many times children and parents used each Aim2Be app feature…”.
4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

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Does your paper address subitem 4a-iii?

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.

Our manuscript briefly states that all participants provided online consent and cites the protocol paper which includes a detailed explanation of the consent and assent processes.

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

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.

Our data were collected online and for some objectively measured information we clarified the data we used (e.g. Fitbit data were downloaded from Fitbase, and app-analytics data were provided by Ayogo, the app developers). The diet data were collected and sent to us (de-identified). All data that was sent to us were de-identified and transmitted to us via secured transfers (FTP transfer connections).
4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

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| Item not at all important |   |   |   |   |   |

Does your paper address subitem 4b-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.

We specified in our methods section that the data collection occurred online, and that several measurements were self-reported, whereas others were objectively taken through Fitbits and app-analytics ("After providing consent, eligible participants completed an on-line survey, 24-hr dietary recalls and received assessment tools for height, weight and physical activity (Fitbit Flex 2) to complete measurements. Parents were mailed a digital scale and a measuring tape with instructions to accurately measure their child’s height and weight at home. [...] Children’s dietary behaviors were evaluated with the Waterloo Eating Behavior Questionnaire, a 24-hour web-based dietary recall [...] Parents’ dietary behaviors were evaluated using 7 items which were adapted from the Canadian Community Health Surveys. Parents reported their own consumption of [...] Children wore the Fitbit for 7-14 days at baseline, 3 and 6 months and their daily steps count was obtained by our team using Fitabase [...] children completed an online survey which included 5 questions from the Physical Activity Questionnaire for Older Children; a 7-day recall inquiring about [...] Parents’ physical activity was evaluated with 7 items from the Physical Activity Questionnaire Short Form [...] Children’s and parents’ screen-time was evaluated with 2 items adapted from the Sedentary Behavior Questionnaire [...] App-analytics were used to track how many times children and parents used each Aim2Be app feature...").
4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

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Does your paper address subitem 4b-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

Not applicable/relevant for this study.

5) 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

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

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subitem not at all important ○ ○ ○ ○ ○ essential

Borrar la selección
Does your paper address subitem 5-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 manuscript states: “Briefly, the app, co-created by Ayogo Health Inc. and the Childhood Obesity Foundation with expert input”.

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5-ii) Describe the history/development process
Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

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Does your paper address subitem 5-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

In our paper we mentioned that we examined Aim2Be version 2, briefly described the rational for design of the intervention, and cited the protocol paper which includes detailed information on previous research during the development of Aim2Be, as well as another study that examined participants’ engagement with the version 1 of the app. This is mostly described in the methods subsection entitled 'The Aim2Be Intervention'.
5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

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Does your paper address subitem 5-iii?

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.

In our paper we mentioned that we examined Aim2Be version 2, and that our data were collected between March 2019 and June 2020. No major events were reported.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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Does your paper address subitem 5-iv?
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

We did not report this as it was detailed in the protocol paper which we cited.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used
Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

subitem not at all important  ○  ○  ○  ●  ○  essential

Does your paper address subitem 5-v?
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

This is included in our paper as Figure 2. We also provided the link for the intervention.
5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

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Does your paper address subitem 5-vi?

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.

We provided the link for the intervention and Figures 2 & 3 which illustrate the main components of the intervention.

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

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Does your paper address subitem 5-vii? *

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.

This item is not relevant for this study.

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

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1], whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback* [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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Does your paper address subitem 5-viii? *

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.

As we examined patterns of engagement with the app, two full sections of our paper described this content in detail: 1) the section entitled ‘The Aim2Be intervention’ explains the theoretical foundation of the intervention, the main components, and the versions designed for different populations (e.g. pre-teens, teens, parents), and 2) the section entitled ‘Use of Aim2Be app features’ which explains each of the features included in the app, the app-analytics data examined, and the participants for whom the features were made available. In addition, we included figures that show the app features and process.
5-ix) Describe use parameters

Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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Does your paper address subitem 5-ix?

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

We specified that participants were given access to the app over a 3-months period, and whether participants used the app or not and how they used it was one of the outcomes we examined in this paper.

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as “type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered”. It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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Does your paper address subitem 5-x?

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

No involvement was necessary other than the interactions with the live coach. We specified in our paper that an app feature called “live coach” was available to some participants, meaning that they could chat with a health coach through the app. Our analysis did not focus on the live coach itself, though the number of chat sessions with the live coach was one of the 13 app features included in our Latent Class Analysis.

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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Does your paper address subitem 5-xi? *

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

This is not applicable to our study.
5-xii) Describe any co-interventions (incl. training/support)
Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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Does your paper address subitem 5-xii? *
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

Not applicable to our study.

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Does your paper address CONSORT subitem 6a? *

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 outcomes were pre-specified as indicated in the protocol paper even though our paper is a secondary analysis of data from the RCT. Regarding the pre-specified outcomes, our paper states: "After providing consent, eligible participants completed an on-line survey, 24-hr dietary recalls and received assessment tools for height, weight and physical activity (Fitbit Flex 2) to complete measurements. Participants completed follow-up assessments at the 3- and 6-month follow-ups. Parents were mailed a digital scale and a measuring tape with instructions to accurately measure their child’s height and weight at home. […] Children’s dietary behaviors were evaluated with the Waterloo Eating Behavior Questionnaire, a 24-hour web-based dietary recall […] Parents’ dietary behaviors were evaluated using 7 items which were adapted from the Canadian Community Health Surveys. Parents reported their own consumption of… […] Children wore the Fitbit for 7-14 days at baseline, 3 and 6 months and their daily steps count was obtained by our team using Fitabase […] children completed an online survey which included 5 questions from the Physical Activity Questionnaire for Older Children; a 7-day recall inquiring about… […] Parents’ physical activity was evaluated with 7 items from the Physical Activity Questionnaire Short Form […] Children’s and parents’ screen-time was evaluated with 2 items adapted from the Sedentary Behavior Questionnaire […] App-analytics were used to track how many times children and parents used each Aim2Be app feature…".

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

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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

Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoptions metrics are important process outcomes that should be reported in any ehealth trial.

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Subitem 6a-ii)
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

App engagement, including participants’ use of each app feature, was objectively assessed with app-analytic and described in the Measures section (e.g., “App-analytic were used to track how many times children and parents used each Aim2Be app feature […] aims – number of high-level goals users chose while indicating their perceived importance and potential obstacles; 2) tasks – number of activities users completed to accomplish their aims; 3) check-ins – number of times users self-monitored their progress regarding specific health behaviors with short recommendations on how to improve their behaviors; 4) articles read – number of articles providing educational content the user read, and 5) articles reflected on – number of written responses the user provided after reading an article… “ etc.).
Does your paper address subitem 6a-iii?

Participants from our study did not provide any qualitative data or feedback; however, we cited the protocol paper which details how previous versions of the app were developed and the qualitative assessments conducted as part of such development.

Does your paper address CONSORT subitem 6b? *

Not applicable, no changes occurred.

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

Not applicable as we did not compute sample size for our study (we conducted secondary analysis of an RCT). However, details on the RCT sample size calculation are published in the protocol paper we cited.

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

Not applicable for our study.

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.

Not applicable. We did not compare randomized groups as our study is not an RCT (we only used data collected as part of an RCT to conduct secondary analyses).

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 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.

Not applicable. We did not compare randomized groups as our study is not an RCT (we only used data collected as part of an RCT to conduct secondary analyses).

9) 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

Does your paper address CONSORT subitem 9? *

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.

Not applicable. We did not compare randomized groups as our study is not an RCT (we only used data collected as part of an RCT to conduct secondary analyses).
10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

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

Not applicable. We did not compare randomized groups as our study is not an RCT and all of our participants participated in the intervention.

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn’t

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 11a-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

Not applicable. We did not compare randomized groups as our study is not an RCT and all of our participants participated in the intervention.
11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

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Does your paper address subitem 11a-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

Not applicable. We did not compare randomized groups as our study is not an RCT and all of our participants participated in the intervention.

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

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

Not applicable. We did not compare randomized groups as our study is not an RCT and all of our participants participated in the intervention, however, some of our participants did not have access to one of the app features (the live coach) and this was detailed in the measures section of our paper.
12a) Statistical methods used to compare groups for primary and secondary outcomes
NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *
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 Statistical Approach section of our paper provides a detailed description of the analyses conducted, though we did not compare intervention vs control as this was not part of our aims.

12a-i) Imputation techniques to deal with attrition / missing values
Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

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subitem not at all important ○ ○ ○ ♦ ○ essential

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Does your paper address subitem 12a-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

In our study, participants who did not engage with the intervention were still analyzed as a group of 'unengaged' users; thus, no imputation was used in this case. However, as per study design, half of the participants did not have access to one of the app features and as such they had missing data in that particular feature. As those participants were randomly selected, that missing data were missing at random and imputed as such. In our Statistical Approach section, we specified that "The LCA used Full Information Maximum Likelihood to handle data missing at random in the live coach feature (no other variable included in the LCA had missing data)".

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

Not applicable, all of our analyses were 'additional' as our study is a secondary analyses of RCT data.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)
X26-i) Comment on ethics committee approval

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.

Yes, this is detailed in section entitled ‘Ethics Approval’.

x26-ii) Outline informed consent procedures

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

We specified that all participants provided online consent to participate in the RCT study. We conducted secondary analyses of the RCT data; thus, we did not recruit participants for our study.
X26-iii) Safety and security procedures
Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

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Does your paper address subitem X26-iii?
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

Not applicable, we did not recruit participants for our study, we conducted secondary analyses of the RCT data already collected.

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center
Does your paper address CONSORT subitem 13a?*

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.

We reported the number of participants allocated into each group in the RCT, however, we did not compare randomized groups. As we identified and compared latent groups considering all participants who had access to the intervention, we reported the relative sample size for each latent group analyzed. The different groups and samples are shown in figures 1 (RCT) and 5 (latent groups) from our paper.

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.

All participants who participated in the RCT were analyzed in our paper, including those who did not engage with the intervention, who were also kept as part of our analytical sample.

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.
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

In our secondary analysis of RCT data, all participants from the RCT, including those who did not use the app ('unengaged' users), were included as part of the analytical sample. As our paper was concerned with how participants engaged with the app during 3 months and the 'dose' of the app they received, we reported all participants' use of the app during this period, including their use of each app feature. This is summarized in Figure 5.

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

Each participant was recruited and started using the app in a different date, thus, we are only able to specify the overall period when the data collection occurred, which was mentioned in the 'Study design' section ("Data analyzed in this study were collected from March 2019 to June 2020"). We also reported that the follow-up measures were taken 3 and 6 months after the baseline assessment.

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

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subitem not at all important ○ ○ ○ ● ○ essential
Does your paper address subitem 14a-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 COVID-19 pandemic started toward the end of the trial.

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *  
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

Not applicable for our study.

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

Does your paper address CONSORT subitem 15? *  
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. We mentioned that our participants were recruited through Facebook and six clinical centers across Canada, a general demographic description of the participants is provided in the results section entitled ‘Demographic Characteristics of the Participants’, and the characteristics for each latent group are shown in Table 2.
15-i) Report demographics associated with digital divide issues
In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

Does your paper address subitem 15-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. A general demographic description is provided in the results section entitled 'Demographic Characteristics of the Participants’ and the characteristics for each latent group are shown in Table 2.

16) 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
Report multiple “denominators” and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.
Does your paper address subitem 16-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.

Our main analyses were not by originally assigned groups as we conducted secondary analyses of an RCT where we identified latent subgroups of users based on their use of the mHealth app. We combined and analyzed data of all participants who had access to the app, and provided relative sample sizes for each assessment based on the originally assigned groups (Figure 1) as well as for each group of users based on how they used the mHealth app (Figure 5), including those who did not use it (the ‘unengaged’ group). Our methods section details that ‘use’ is defined as the number of times participants accessed an app feature and was objectively evaluated with app-analytics.

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).

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Does your paper address subitem 16-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.

We conducted secondary analyses of an RCT and our sample is no longer a randomized sample. However, all of our analyses are ‘intent-to-treat’ as our analytical sample included all participants who had access to the app, regardless of whether they used it or not.

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Does your paper address CONSORT subitem 17a? *

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.

We reported the precision of our results using p-values and effect sizes.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

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).

Does your paper address subitem 17a-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.

Our study is not the RCT, thus, we did not provide a detailed explanation of all process outcomes. However, as our analysis was concerned with participants’ engagement, we reported participants’ use of the app based on their patterns of use of each app feature.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Does your paper address CONSORT subitem 17b? *

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.

Not applicable. We do not have binary outcomes.

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

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.

As we conducted a secondary analysis of RCT data, all of our analyses were 'other analyses' and were based on latent subgroups identified among app users.

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Borrar la selección
19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address subitem 18-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

As we conducted a secondary analysis of RCT data, all of our analyses were 'other analyses' and were based on latent subgroups identified among app users. This is clear in our paper (see Figure 1 and ‘Data collection protocol’ section: “Families randomized to the experimental group had access to the app after completing baseline measures. Waitlisted control families were given access to the app after completing their assessment at the 3-month follow-up. This study combined data collected from baseline to 3 months in the intervention group and from 3-6 months in the waitlisted control group”).

Does your paper address CONSORT subitem 19? *
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

Not applicable for our study as this did not occur.

19-i) Include privacy breaches, technical problems
Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
|  |  |  |  |  |

subitem not at all important

essential
Does your paper address subitem 19-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

Not applicable for our study as this did not occur.

19-ii) Include qualitative feedback from participants or observations from staff/researchers
Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

Does your paper address subitem 19-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

Not applicable as no qualitative data were collected in this study.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

1 2 3 4 5

subitem not at all important ○ ○ ○ ● ○ essential

Yes, the first paragraph of our discussion under the subsection entitled 'Principal findings' restate the study objectives by summarizing what was done in the study and the main findings.

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

1 2 3 4 5

subitem not at all important ○ ○ ○ ● ○ essential

Yes, the first paragraph of our discussion under the subsection entitled 'Principal findings' restate the study objectives by summarizing what was done in the study and the main findings.
Does your paper address subitem 22-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.

Yes. Our discussion includes a section entitled ‘Future directions’ where we discuss implications and the future research needed based on our findings and on what our study did not answer.

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 20-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, our discussion includes a section entitled ‘Limitations and strengths’ where the study limitations are discussed.

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

https://docs.google.com/forms/d/e/1FAIpQLSIfZBSUlp1bwOc_OimqcS64RdfIAFvnrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGlKd2... 53/59
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.

1 2 3 4 5

subitem not at all important 〇 〇 〇 〇 essential

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.

Yes, we recognized that “our study included a clinical sample (children with overweight or obesity), thus, our findings are limited to this population”.

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.

1 2 3 4 5

subitem not at all important 〇 〇 〇 〇 essential
Does your paper address subitem 21-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

Not applicable as we did not conduct an RCT, only secondary analyses of RCT data.

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

Yes: "The trial was registered in ClinicalTrials.gov (NCT03651284) on 29 August 2018."

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

Yes, the RCT protocol paper is cited. "The detailed study protocol has been published elsewhere [25]."
25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

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

Funding section: “The Childhood Obesity Foundation received funding, in part, from the Public Health Agency of Canada with matched financial and in-kind funds from Ayogo Health Inc. (Aim2Be developer), Merck Canada Inc., Heart & Stroke, Obesity Canada, Diabetes Canada, Dietitians of Canada, Canadian Society for Exercise Physiology, Craving Change, David Suzuki Foundation, and Pacific Blue Cross Foundation. Supplemental funding was obtained from a Team Grant in Bariatric Care (Team to Address Bariatric Care in Canadian Children – Team ABC3) from the Canadian Institutes of Health Research (Institute of Nutrition, Metabolism and Diabetes); from Alberta Health Services, Alberta Innovates, Obesity Canada, the Ontario Ministry of Health and Long-Term Care, and the Women and Children's Health Research institute. LCM receives salary support to conduct this research which is provided by the BC Children's Hospital Research Institute. ODJG receives a postdoctoral salary from the University of British Columbia and received PhD scholarships from the National Council of Science and Technology (Conacyt) of Mexico and from Universidad Iberoamericana of Mexico City. CTL received a postdoctoral fellowship from the Canadian Institutes of Health Research. EJB received a postdoctoral fellowship from the BC Children's Hospital Research Institute. GDCB received funding from an Alberta Health Services Chair in Obesity Research.”

X27) Conflicts of Interest (not a CONSORT item)
X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5

subitem not at all important

essential

Does your paper address subitem X27-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.

Competing Interests: “The authors declare that they have no competing interests.”

About the CONSORT EHEALTH checklist

As a result of using this checklist, did you make changes in your manuscript? *

○ yes, major changes

○ yes, minor changes

○ no

What were the most important changes you made as a result of using this checklist?

Tu respuesta
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

Two days (around 16 hours).

As a result of using this checklist, do you think your manuscript has improved? *

- [ ] yes
- [ ] no
- [ ] Otros:

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- [ ] yes
- [ ] no
- [ ] Otros:

Any other comments or questions on CONSORT EHEALTH

Tu respuesta
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