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
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829
Your name *
First Last
Sasha Fleary

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
CUNY Graduate School of Public Health and Hi

Your e-mail address *
abc@gmail.com
sasha.fleary@sph.cuny.edu

Title of your manuscript *
Provide the (draft) title of your manuscript.

Health Literacy as a Vehicle to Reduce Obesogenic Behaviors Among Adolescents: Protocol of a Randomized Pilot Feasibility Study for a Parallel Randomized Controlled Trial on Adding Health Literacy Skills Development to a Web-based Obesity Prevention Intervention

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.

HL-Squared/Health Literacy and Healthy Lifest

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

not evaluated yet

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

English
URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (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://hlx2.com/course/

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
- Other:

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)"

Obesity

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

retention rates, completion rates, treatment fid

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

health literacy, physical activity, healthy eating, sedentary activity
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"
- Other:  app is used as a self-paced or school-paced series of lessons then av

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%
- Other:
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
- Other: not evaluated yet

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- not submitted yet - in early draft status
- not submitted yet - in late draft status, just before submission
- 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
- published
- Other:

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
- Other: JMIR Research Protocols
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
- Other: JRP 40191

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
- Other:

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.

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

Clear selection
**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.

Health Literacy as a Vehicle to Reduce Obesogenic Behaviors Among Adolescents: Protocol of a Randomized Pilot Feasibility Study for a Parallel Randomized Controlled Trial on Adding Health Literacy Skills Development to a “Web-based” Obesity Prevention Intervention

**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

**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 required because there are no non-web-based conditions

**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

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

**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.

Health Literacy as a Vehicle to Reduce “Obesogenic Behaviors Among Adolescents”: Protocol of a Randomized Pilot Feasibility Study for a Parallel Randomized Controlled Trial on Adding Health Literacy Skills Development to a Web-based Obesity Prevention Intervention

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUup1bwOc_OimqcS64RdfIAFvmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGIKdZZ...
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)

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 intervention includes two arms: (1) an experimental arm that will receive a HL module and three obesity prevention modules and (2) a comparison arm that will receive a vaping module and three obesity prevention modules.

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)

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.

"The intervention will be fully web-based."
1b-ii) 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 user group 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 indicate 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)

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

"Participants will complete measures of their HL and obesogenic behaviors-related health knowledge, motivation, and behaviors at three time points (baseline, 1 month post-intervention, 3 months post-intervention) via online surveys."

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)

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

there are no results to report
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)

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)

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

no results to discuss
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

"The main study goal is to develop and preliminarily evaluate a digital obesity prevention intervention with and without health literacy for adolescents. This study distinguishes between HL and health knowledge – these two concepts tend to be inaccurately substituted in some research literature. However, HL is a precursor to health knowledge [32], that is, HL is the skills needed to access, understand, and utilize health information for a specific behavior. Despite this, HL is understudied and rarely addressed in health behavior interventions. This study seeks to fill this gap. Aim 1 of this study is to modify and use successful components of existing obesity interventions into an interactive digital platform with an added-on HL component. Aim 2 of this study is a two-arm randomized clinical trial of the adapted digital obesity prevention intervention for adolescents with and without a HL component. The purpose of this pilot RCT is to determine the feasibility and preliminary effectiveness of the intervention to inform the full scale RCT. Specifically, the primary objectives of this study are to (1) assess the acceptability of the intervention for adolescents; (2) determine the elements of the intervention with the highest adolescent engagement; and (3) determine the suitability and appropriateness of the intervention modality and implementation for school settings by examining the recruitment, retention, completion, and fidelity rates. The secondary objectives of the study are to measure the preliminary efficacy of the intervention to improve obesogenic behaviors and HL and to collect data to calculate effect sizes and power analyses to inform the sample size needed for the full scale RCT to be able to determine if adding a HL component to an obesity prevention intervention improves adolescents’ obesity prevention behaviors more than an obesity prevention intervention alone. *

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 |   |   |   |   |   |
| essential                     |   |   |   |   |   |

Clear selection
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.
"Children and adolescents are increasingly experiencing obesity-related "chronic degenerative diseases" that were once categorized as adult health problems [1]. For example, in the US, there was a 30.5% increase in Type 2 diabetes diagnosis in adolescents from 2001 to 2009 [2] and more recent data suggest a 7.1% annual increase of diagnoses [3]. A diagnosis of Type 2 diabetes in childhood is related to risk for kidney, nerve, and eye diseases, and increased risk of renal failure and other life-threatening and life-altering complications in young adulthood [4]. Similar to type 2 diabetes, other life-threatening adult chronic health issues such as cancer and heart disease are associated with obesity [5-7] and adolescent health behaviors [8]. Approximately 34% of US adolescents are overweight or obese [9,10]. Further, adolescents’ obesity prevention health behaviors are low: ~42% and ~41% eat less than one fruit and vegetable daily, respectively, ~77% are physically activity for less than 60 minutes per day [11]. Prevalence rates of fruits and vegetable consumption and sufficient physical activity are lower among adolescents with low family income [12] and who identify as racial and ethnic minorities [13]. The prevalence rates of these behaviors must be improved to reduce current and future chronic disease risk for adolescents.

There are several obesity prevention interventions targeting determinants of obesogenic behaviors including adolescents’ social support and motivation [14-18], behavioral skills [15-18], attitudes [16,18], environment [15,19,20] or health knowledge [15,16], however, their impact on adolescents’ obesogenic behaviors have been mixed. Further, most of these interventions have not addressed all the aforementioned determinants in a single study design. Single determinant-focused interventions likely underestimate the role of individual-context interrelationships, the interrelatedness of the determinants, and the role of adolescent developmental attributes in health decision-making. Importantly, individuals’ decision-making is complex as multiple determinants of health behaviors are either deliberately or unintentionally integrated during the decision-making process. Therefore, though adolescents may prefer or 'lean in' on certain types of information and determinants, interventions targeting adolescents’ obesity prevention behaviors should integrate multiple determinants including knowledge and skills and incorporate the impact of developmental characteristics and contextual influences to affect long-term change.

This intervention borrows elements from three existing interventions that address multiple determinants in a single design: New Moves [17,21], Go Girls! [16] and Dutch Obesity Intervention in Teenagers (DOiT) [15]. The school-based New Moves intervention aimed to improve adolescents’ diet- and PA-related knowledge, attitudes, beliefs, skills, and self-efficacy as well as provide strategies for improving social support [17,21]. The community-based Go Girls! intervention aimed to improve knowledge, self-efficacy, social support, motivation, and behavioral skills for healthy eating and physical activity [16]. The school-based DOiT intervention aimed to increase adolescents’ knowledge, awareness, behavioral skills, social support, habits, and self-efficacy regarding energy intake and output [15,22]. All three studies reported significant improvements in obesogenic-related behaviors post intervention.

These studies included activities that can be adapted for a digital platform and provide a strong basis for our intervention. However, similar to other adolescent obesity prevention interventions, the New Moves, Go Girls! and DOiT interventions do not include building adolescents’ general skills for transferring knowledge into behavior (i.e., health literacy [HL]). HL entails people’s knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and make decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course’ [23, p. 3]. In adults, HL is positively related to engagement in preventive health behaviors, interpretation of health messages, and medical adherence [24-28]. Though HL is understudied in adolescents, existing research link HL to adolescents’ health behaviors [29] and their health decision-making [30,31]. We hypothesize that including correlates of health decision-making in health behavior interventions during a critical transitional time to health decision-making independence for adolescents may significantly improve intervention outcomes. To our knowledge, the direct impact of HL on adolescent health behavior change interventions has not been examined.

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_OimqCS64RdfIAFvrmTbSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGlKd2...
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

"This study distinguishes between HL and health knowledge – these two concepts tend to be inaccurately substituted in some research literature. However, HL is a precursor to health knowledge [32], that is, HL is the skills needed to access, understand, and utilize health information for a specific behavior. Despite this, HL is understudied and rarely addressed in health behavior interventions. This study seeks to fill this gap. Aim 1 of this study is to modify and use successful components of existing obesity interventions into an interactive digital platform with an added-on HL component. Aim 2 of this study is a two-arm randomized clinical trial of the adapted digital obesity prevention intervention for adolescents with and without a HL component. The purpose of this pilot RCT is to determine the feasibility and preliminary effectiveness of the intervention to inform the full scale RCT. Specifically, the primary objectives of this study are to (1) assess the acceptability of the intervention for adolescents; (2) determine the elements of the intervention with the highest adolescent engagement; and (3) determine the suitability and appropriateness of the intervention modality and implementation for school settings by examining the recruitment, retention, completion, and fidelity rates. The secondary objectives of the study are to measure the preliminary efficacy of the intervention to improve obesogenic behaviors and HL and to collect data to calculate effect sizes and power analyses to inform the sample size needed for the full scale RCT to be able to determine if adding a HL component to an obesity prevention intervention improves adolescents’ obesity prevention behaviors more than an obesity prevention intervention alone."

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

"Trial design elements are reported consistent with the Consolidated Standards for Reporting Trials (CONSORT) guidance for pilot and feasibility studies [33]. This study is a parallel randomized controlled pilot trial and feasibility study with 1:1 classroom allocation to two study arms (experimental, comparison 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.

This is not applicable, study has not started.

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].

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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.

This is not applicable, study has not started.

4a) Eligibility criteria for participants

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.

"Seventy-six adolescents between 13 and 16-years-old who attend high school in Boston, Massachusetts will be recruited for the study. The other inclusionary criterion is parental permission for participation. Adolescents who are already participating in interventions related to healthy eating, physical activity, and/or obesity prevention or treatment or who have medical conditions that prevent them from engaging in physical activity or requires they adhere to extremely restricted diets (e.g., ketogenic diet) will be excluded from the study."
4a-i) Computer / Internet literacy

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

Does your paper address subitem 4a-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.

This is not included because the intervention is in the context of a classroom where compute use is part of their daily routine

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.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

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.

Data collection will be completed online via the Qualtrics survey platform.
4a-ii) 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.

1 2 3 4 5

subitem not at all important ◯ ◯ ◯ ◯ ◯ essential

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

"For the first phase of recruitment, school administrators will give study flyers to students and email the study flyer to parents of students in participating classes. The emailed flyer will include a Qualtrics link for parents to access the parent permission form and a brief demographic survey. The class or advisory group with the highest returned parent forms rate (regardless of whether permission was granted or denied) will receive a class prize (e.g., donation to class field trip fund) at the end of the first 2 weeks of the recruitment period. Characteristics of enrolled participants will be monitored to determine progress on recruiting the desired sample with regards to sex and racial and ethnic minority status. At the two-week time point during Phase 1 recruitment, the second phase of recruitment will be initiated in an attempt to achieve the desired sample. In Phase 2, adolescents whose parents did not complete the permission form online will be given a study flyer with a QR code for parents to access the Qualtrics link. A paper permission form and demographic survey will also be attached to the flyer. At each phase of recruitment, teachers will also make announcements about the study in class encouraging students to have their parents complete the permission forms. Recruitment will end 2 weeks after the initiation of Phase 2 recruitment. The class with the highest increase in returned consent forms at the end of the 2nd phase of recruitment will be incentivized with a class prize (e.g., donation to their class trip/dance). Phase 1 recruitment strategy is ongoing throughout the 4 weeks of recruitment as parents will be sent weekly reminder emails to complete the permission form and demographic survey. These procedures are consistent with several national studies (e.g., National Survey of Family Growth [35,36], National Survey of College Graduates [37]). Active monitoring of participant enrollment will occur throughout the four weeks of study recruitment and enrollment. To ensure participation is voluntary and not coerced, incentives are attached to consent form return rather than study enrollment. All recruitment and consent materials will be available in English, Spanish, and Haitian Creole to accommodate Haitian Creole- and Spanish-speaking parents with limited English language proficiency. Adolescent assent will be obtained prior to data collection. Note that parent permission and adolescent assent is specific to data collection related to the study."

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

"Seventy-six adolescents between 13 and 16-years-old who attend high school in Boston, Massachusetts will be recruited for the study."

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.

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

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

"Data collection will be completed online via the Qualtrics survey platform. After a team member verbally explains the assent form, adolescents will be provided with a link where the first page will include the written assent form. After providing assent, adolescents will be routed to the survey."

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)

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

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

This is not relevant to the 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).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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.

"Note that all content was developed by the author and her team and the content is hosted using DeLP, an online platform developed by 3C Institute [38] that uses a mix of didactic instructions with self-assessments, demonstration videos, and interactive practice activities to apply learned skills."

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.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection
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

"Regarding specific content, initial focus groups with adolescents informed the initial content of the HL modules while prior obesity prevention intervention studies informed the content for the obesity prevention modules. In a pre-intervention development study by the author, adolescents participated in multiple focus groups where they described how they view HL, how they knew they were using HL, and what type of HL skills they felt they lacked [30,31]. Analyses of adolescents’ responses resulted in the development of the IMBM for Use of HL in Health Decision-Making in Adolescents [30]. The conceptual underpinnings of the IMBM for Use of HL in Health Decision-Making in Adolescents and specific focus group findings were used to determine which key features of HL should be included in the intervention and how to present the content in a way that matches the context in which adolescents view themselves as engaging in HL. The obesity prevention modules were informed by successful components of New Moves [17,21], Go Girls! [16] and Dutch Obesity Intervention in Teenagers (DOIT) [15].

Regarding acceptability and usability, adolescents’ participated in cognitive interviews while completing the HL and Behavior Skills modules. This was done prior to the building out of the other modules of the intervention. The feedback provided on the HL and Behavior Skills modules was used to revise those modules and applied to the development of the remaining intervention modules.”

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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subitem not at all important  ○  ○  ○  ○  ○ essential
Clear selection

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

Not applicable, intervention not tested yet
5-iv) Quality assurance methods

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

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

Not relevant to this study.

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.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

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 not relevant to this study as this is a feasibility study and replicability will be more important once the study is a full scale RCT
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.

[1-5 rating scale]

subitem not at all important  ○ ○ ○ ○ ○ essential

Clear selection

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.

This is not included. This is a pilot and this process will be done after any changes prior to the full scale RCT.

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).

[1-5 rating scale]

subitem not at all important  ○ ○ ○ ○ ○ essential

Clear selection

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.

"For this feasibility study, all adolescents in participating classes or advisory group will access the intervention on school computers during their homeroom or advisory periods. The intervention will be provided in lieu of class activities."
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].

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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

'This intervention is informed by the relational developmental systems framework, the Information-Motivation-Behavioral Skills Model (IMBM), adolescents’ input, and prior studies. The relational developmental systems framework, a developmental science framework, centers the mutually influential relationships between individuals and contexts as well as the plasticity of the relationships as the individual or context changes [39]. Research applying relational developmental systems framework seeks to answer what important characteristics of individuals (e.g., motivation, autonomy, health identity, health knowledge, HL), among individuals of what status (e.g., adolescents, low income), in relation to what elements of the context (e.g., family, peers, neighborhood) are likely to be associated with what aspects of adaptive functioning (e.g., healthy eating and PA)? As such, this intervention is designed to account for and intervene on the mutually influential relationship of adolescents’ individual and developmental characteristics, social determinants of health, health knowledge, and HL on health behaviors. The relational developmental systems framework is complementary to the more predictive IMBM [40]. The IMBM includes three critical determinants of performance of health behaviors: health-related information (facts, beliefs), motivation (personal attitudes, social support) and behavioral skills (objective skills and confidence for performing the behavior). Information and motivation support behavioral skills to influence behavior (Figure 2, arrows a-c). However, information and motivation may directly impact behavior when only basic skills are needed (Figure 1, arrows d-e). Health behaviors ultimately predict health outcomes (Figure 2, arrow f).

The relational developmental systems framework was used to determine what variables were explored in the IMBM. Given that the health-related information and behavioral skills constructs in the IMBM are specific to the health behavior, and that HL is a precursor to health knowledge32, and likely independently influences motivation, behavioral skills, and behavior, HL was included as a separate construct in the model (dashed lines in Figure 2). We expect HL to directly predict information, motivation, behavioral skills, and health behaviors (Figure 2, arrows g-j), and indirectly predict health behaviors through information (g → d, g → a → c), motivation (j → e, j → b → c), and behavioral skills (i → c). Therefore, improvements are expected in the experimental condition on all variables in the model compared to the comparison group.'

See Table 1
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.

1 2 3 4 5
subitem not at all important   essential

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.

"Adolescents will complete one lesson per homeroom or advisory period with 1-2 lessons per week depending on their class schedule."

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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subitem not at all important   essential

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.

"The intervention will be provided in lieu of class activities and will be solely online. Specifically, teachers will only be involved in instructing adolescents to login to the web-based platform but all other activities of the intervention will occur via the web-based platform."
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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subitem not at all important
essential

Clear selection

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

"The intervention will be provided in lieu of class activities and will be solely online. Specifically, teachers will only be involved in instructing adolescents to login to the web-based platform but all other activities of the intervention will occur via the web-based platform."

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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subitem not at all important
essential

Clear selection

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

There are no co-interventions for this study as they are not necessary to achieve the goals of the 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.

See tables 2 and 3 for outcome measures and how assessed.

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].

1 2 3 4 5
subitem not at all important

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

Preliminary outcomes measures are feasibility items.

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/adoption metrics are important process outcomes that should be reported in any ehealth trial.

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subitem not at all important

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

"Treatment fidelity will be assessed using web analytics data gathered during the intervention. Median time spent on each intervention task will be calculated and participants who spent less than three median absolute deviations below the median will be assumed to have not engaged with the content enough to be fully exposed to the treatment. Treatment fidelity percentages will be calculated based on users meeting the a priori thresholds."
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

|   | 1 | 2 | 3 | 4 | 5 |
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| subitem not at all important |   |   | ☑ |   |   |
| essential                     |   |   |   |   |   |

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"Adolescents will be randomly selected to complete qualitative interviews at the end of the intervention to gather feedback on usability, acceptability, and suggestions for changes."

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

This evaluation has not started yet so this is not relevant

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

7a-ii) 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.

|   | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| subitem not at all important |   |   | ☑ |   |   |
| essential                     |   |   |   |   |   |
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

"The sample size was based on power calculations computed using preliminary data. Preliminary data suggest that a sample 60 participants with 30 per group would be sufficient. We plan on enrolling and randomizing 76 participants to allow for a 20% dropout at 3-month follow-up. The sample size is sufficient to calculate feasibility metrics, preliminary efficacy, and inform future power calculations for the more complex full-scaled RCT. "

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

The data collection has not started yet so no interim analyses to report

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

"Specifically, a blinded research team member who is not involved in providing assent and who has no knowledge of the students in the classes/advisory groups will assign each classroom/advisory group a number from 1 to 4 then a computerized random number generator will be used to assign the classroom/advisory group to the conditions. "

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

"Simple randomization will be done using a random number computer program. "
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

"Specifically, a blinded research team member who is not involved in providing assent and who has no knowledge of the students in the classes/advisory groups will assign each classroom/advisory group a number from 1 to 4 then a computerized random number generator will be used to assign the classroom/advisory group to the conditions."

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

"a blinded research team member who is not involved in providing assent and who has no knowledge of the students in the classes/advisory groups"

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-1) 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).

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subitem not at all important ❌ ❌ ❌ ❌ ❌ essential

Clear selection
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

There was no blinding to 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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subitem not at all important □ □ □ □ □ essential  
Clear selection

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

Participants were not explicitly made aware whether they were in the experimental or comparison group. However, it was not possible to ‘blind’ them to their condition as the experimental condition was obvious.

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 an 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

This is not relevant, the experimental condition got a health literacy module and the comparison condition got a vaping module. It was important that the length of both modules be similar but other than that having differences in content was important.

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

This is not relevant. There were 2 study conditions and they were analyzed as such.

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

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

"For each outcome, we will also analyze the time points together in the same model, using linear and logistic mixed effects models with random subject-specific intercepts and slopes. This will permit analysis of all participants, including those who drop out. Mixed models can accommodate missingness at random."

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

This is a pilot RCT and is not powered to conduct subgroup analyses

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

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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

"All study procedures are approved by the City University of New York Institutional Review Board (2020-0575-PHHP) and will be carried out in accordance with what is outlined in the approved application. Data will only be used from participants with signed parent permission forms and who assent to participate."

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.

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

"The emailed flyer will include a Qualtrics link for parents to access the online parent permission form and a brief demographic survey. Parents will select ‘yes’ or ‘no’ to indicate if they agree for their adolescent to participate in the study."

"A paper permission form, demographic survey, and empty envelope will also be attached to the flyer. Parents who complete the paper permission form will be asked to put it in the envelope, seal the envelope, and have their adolescent return the envelope to their teacher."

"Adolescent assent will be obtained online prior to data collection as the first page of the online survey. Adolescents who select ‘no’ to assent will be exited out of the survey and those who select ‘yes’ will be able to see the survey."
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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subitem not at all important ○ ○ ○ ○ essential

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

"The intervention website includes a contact us button so that students may report any concerns or comment. This will be closely monitored by research staff and staff will work to resolve issues as quickly as possible."

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

The study has not been done yet, therefore this is not applicable.

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

The study has not been done yet, therefore this is not applicable.
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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subitem not at all important 0 0 0 0 essential

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.

The study has not been done yet, therefore this is not applicable.

14a) Dates defining the periods of recruitment and follow-up

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"

1 2 3 4 5
subitem not at all important 0 0 0 0 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 study has not been done yet, therefore this is not applicable.
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.

The study has not been done yet, therefore this is not applicable.

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.

The study has not been done yet, therefore this is not applicable.

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.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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.

The study has not been done yet, therefore this is not applicable.

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.

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

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

The study has not been done yet, therefore this is not applicable.

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).

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

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

The study has not been done yet, therefore this is not applicable.

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

The study has not been done yet, therefore this is not applicable.
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

The study has not been done yet, therefore this is not applicable.

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

The study has not been done yet, therefore this is not applicable.

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

The study has not been done yet, therefore this is not applicable.
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

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.

The study has not been done yet, therefore this is not applicable.

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

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.

The study has not been done yet, therefore this is not applicable.
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.

1 2 3 4 5

- subitem not at all important
- essential

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.

The study has not been done yet, therefore this is not applicable.

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

Does your paper address subitem 22-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 has not been done yet, therefore this is not applicable.
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

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

The study has not been done yet, therefore this is not applicable.

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

The study has not been done yet, therefore only a few limitations can be discerned. " However, the small sample means preliminary efficacy is mostly useful for calculating RCT sample needs rather than making strong inferences about the utility of the intervention. Another limitation of the study is the use of schools. Schools are an isolated portion of the adolescent population as it excludes adolescents who may be home-schooled or out of school for other reasons. These excluded adolescents may have different HL and health behavior change needs and access to resources so the efficacy and effectiveness of the intervention for these adolescents cannot be determined from this study. Further, it is not possible to implement blinding. This may impact results as adolescents in different conditions may discuss and compare what they are doing in their conditions and this can lead to information seeking that conflates the findings."
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) Generalisability to other populations
Generalisability to other populations: In particular, discuss generalisability 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 |
|---|---|---|---|---|
|  |  |  |  | essential |

subitem not at all important

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

"Schools are an isolated portion of the adolescent population as it excludes adolescents who may be home-schooled or out of school for other reasons."

21-ii) Discus 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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|  |  |  |  | essential |

subitem not at all important

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

This is critical as interventions using digital platforms extend the reach and use of the intervention modules as geography, personnel, and time constraints minimally impact implementation.
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

Clinicaltrials.gov Identifier: NCT04252677

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

The protocol can be accessed at ClinicalTrials.Gov

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

This project is funded by the NIH (grant #: 1R21DK117345, 1K12HD092535, L30DK126209). The funders had no influence on the content of the intervention and will not have influence on the interpretation of the results.

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

None declared. The study team has no affiliation with 3C Institute, the vendor for the intervention platform.

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?

Adding more details in the intervention section

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

5 hours.........................

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

- yes
- no
- Other:
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
- Other:

Any other comments or questions on CONSORT EHEALTH

There should be a separate version for pilot and feasibility studies as a lot of the items did not apply. Further, the form is cumbersome as it requires a minimum of 25 characters for all items and this not always apply (e.g., website for clinical trials, clinical trials number)

STOP - Save this form as PDF before you click submit
To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.

When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.

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