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

ı

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

* Required

Your name *

First Last

Beth Bourdeau

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

University of California, San Francisco, San Fra

Your e-mail address *

abc@gmail.com

Beth.Bourdeau@ucsf.edu

Title of your manuscript *

Provide the (draft) title of your manuscript.

The Efficacy of a Web-Based Intervention (Smart Choices 4 Teens) to Facilitate Parent-Adolescent Communication about Relationships and Sexuality: Randomized Controlled Trial

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.

Smart Choices 4 Teens

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Your answer

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.

Your answer

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)" Sexual Health
Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial
Parent-adolescent sexual communication
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?
Your answer

!

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:
Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
unknown / not evaluated
0-10%
O 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
on statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other:
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form) onot submitted yet - in early draft status 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:
Is this a full powered effectiveness trial or a pilot/feasibility trial? *
O 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) on ms number (yet) / not (yet) submitted to / published in JMIR Other: 19114

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.

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

"Web-Based" is included in the title

!

1a-ii) Non-web-based components support").		•				
	1	2	3	4	5	
subitem not at all important	•	0	0	0	0	essential
					C	Clear selection
Does your paper address sull Copy and paste relevant sections fro indicate direct quotes from your man information not in the ms, or briefly extended the contract of the cont	m manuso uscript), o	cript title (i or elaborat	e on this it	tem by pro	viding add	litional
1a-iii) Primary condition or ta Mention primary condition or target of Example: A Web-based and Mobile In Randomized Controlled Trial	group in th	e title, if a	ny (e.g., "f			
	1	2	3	4	5	
subitem not at all important	0	0	0	•	0	essential
					(Clear selection
Does your paper address sull Copy and paste relevant sections fro indicate direct quotes from your man information not in the ms, or briefly each of the title contains the words "Particle Particle Part	m manusc uscript), c xplain wh	cript title (i or elaborat y the item	e on this it	tem by pro	viding add	litional

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)

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

Clear selection

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 contains "healthy relationships and sexual decision-making component"

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) 1 2 3 4 5 subitem not at all important Clear selection

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 abstract contains "on-line self-paced intervention"

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)

	1	2	3	4	5	
subitem not at all important	0	•	0	0	0	essential
					C	Clear selection

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

This is mentioned in the manuscript but not in the abstract.

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)

1 2 3 4 5

subitem not at all important OOOOO essential

Clear selection

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 the abstract: "Families (N=411) with 16-17 year-old adolescents were randomly assigned to the intervention or a control condition." The intervention/control and uptake information are in the paper.

	1b-v) CONCLUSIONS/DISCU Conclusions/Discussions in abstract negative (primary outcome not chang results are attributable to lack of upta main paper is reporting. If this inform	for negati ged), and t ake and di	ive trials: [he interve scuss reas	iscuss the ntion was sons. (Note	e primary o not used, e: Only rep	outcome - discuss whoort in the	nether negative abstract what the
		1	2	3	4	5	
	subitem not at all important	•	0	0	0	0	essential
						C	Clear selection
	Does your paper address sul Copy and paste relevant sections fro this" to indicate direct quotes from you information not in the ms, or briefly e	m the mar our manus	nuscript abscript), or e	laborate o	n this iten	n by provic	ling additional
	This was not a negative trial.						
	INTRODUCTION						
	2a) In INTRODUCTION: Scie	ntific ba	ackgrou	nd and	explana	ation of	rationale
	2a-i) Problem and the type of Describe the problem and the type of intervention vs. incorporated in broad population? Goals of the intervention complement other solutions? (Note:	system/s der health , e.g., bein	colution that care progr ng more co	at is object am? Inten st-effectiv	ded for a բ e to other	oarticular p interventio	oatient ons, replace or
		1	2	3	4	5	
	subitem not at all important	0	0	0	•	0	essential
:						C	Clear selection

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

"there is a demonstrated need for interventions that support sexual communication between parents and adolescents that: a) support the continued relationship with parents through older adolescence and into emerging adulthood; b) engage the adolescent in full intervention participation; and c) address common barriers such as time limitations of participants and reduced cost via delivery in an easily accessible format for families."

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 appropiate), 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 O O O 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

"Adolescents frequently report that parents are their preferred source for information about romantic relationships and sexuality [1,2]. Often this communication is more focused on daughters [3] than sons and more often initiated by mothers than fathers [4] although fathers' communication has been shown to increase after participation in interventions [5,6]. Higher amounts of parent-adolescent communication, regardless of topic or other characteristics, is strongly related to increased adolescent safer sex behavior [5,7,8]. Further, the connection between parent-adolescent communication about sex and adolescent sexual behaviors is robust, firmly established [8] and durable through older adolescence and into young adulthood [9-12]. This underscores the importance of encouraging and assisting parents in communicating with their adolescents about sexual decision-making.

Recent reviews of interventions designed to facilitate sexual communication between parents and adolescents [6,8,13] indicate that many interventions significantly increased parental levels of comfort and amount of communication about sex. However, one meta-analysis found that most interventions that address parent-adolescent sexual communication focus on parents of younger adolescents (early adolescents), are often group-based with a trained facilitator, and tend to focus on parents primarily with very few studies including adolescents [13]. Many of these programs are provided through schools [14,15], medical clinics [16], and community centers [17], and require a substantial time and logistic commitment on the part of participants. Although some programs demonstrate efficacy with their prioritized populations, there is a need to include adolescents within the intervention, while extending the reach to a broader audience and more diversified populations for whom time constraints, logistics, and delivery costs present compelling barriers to intervention participation [18].

Increasingly, digital and online delivery platforms [19], including DVDs [20], videogames [21,22], email [23], websites [24], text messages [25,26], and social media [27,28] are used as a way to address these barriers [29]. Theses delivery platforms hold promise as the vast majority of families have computer and Internet access, including via smart phones (89%) [30]."

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

Consistent with the theoretical frameworks of the intervention from which it was adapted, we hypothesized that adolescents who had exposure to the Relationships Component of the program, compared to those who did not:

- 1) Would report increased sexual communication with their parent (a main effect of intervention exposure); and
- 2) The increased sexual communication with their parent would vary by gender of the adolescent (interaction effect between intervention exposure and gender).

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

"Using a 1:1 allocation ratio, parent and adolescent dyads were randomly assigned to either the intervention (N=206) or control (N=205) condition using a computer-generated program as a randomized-controlled trial without a wait-list control group."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No, there were no important changes to methods after trial commencement.

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

subitem not at all important

•

 \bigcirc

0

0

essential

Clear selection

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

We did not make any changes once the RCT was initiated.

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

Eligibility requirements included: "parent with an adolescent aged 16–17; English speaking; and had a compatible tablet or computer for viewing the online intervention"

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

_	_
	\neg
	-)
-	_







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

We did not examine computer literacy.

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 O O O o cessential

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

From the manuscript:

"Families with a 16- or 17-year-old adolescent were recruited from U.S.-focused online panel vendors"

"The research team made separate contact with the adolescent to ensure eligibility, ascertain a separate email for the adolescent, and ensure confidentiality."

"baseline online surveys"

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.

1 2 3 4 5
subitem not at all important O O o essential

Clear selection

В

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

"Parents provided consent for themselves and permission for their adolescent, while adolescents provided assent for themselves"

"Dyads in both conditions received links to resources, including hotline numbers and websites providing information about adolescent alcohol and drug use, sexual behavior, suicide, support for gender and sexual minority adolescents, and other health issues. All families also had access to an 800 number throughout the duration of the project for contact with the research team."

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

Yes: "online surveys" was used to describe administration

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

subitem not at all important O O O essential

Clear selection

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

Yes: "online surveys" was used to describe administration

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

Clear selection

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

Aside from affiliation through contact information on the consent/assent, PIRE and KB (Klein Buendel) were not identified.

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

0 0 0 0

Clear selection

essential

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

This intervention was an adaptation of two other interventions which are credited/cited.

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 O O o 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

From the manuscript: "Both programs have evidence of efficacy and effectiveness and were adapted for the following considerations: 1) age-appropriateness for 16-17-year-olds; 2) parallel materials for the adolescent; and 3) delivery of the materials to an on-line platform. The adaptation process included creating instructional objectives, content outline, activity descriptions, and scripts, through a series of iterative development cycles that included review by expert panel and input from two rounds of focus groups with parents and adolescents. Additional information on the adaptation of the interventions is available with the results of the Alcohol Component [31]."

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).

1 2 3 4 5
subitem not at all important

O
O
O
O
O
O
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

The intervention was not modified after the RCT commenced.

i-iv) Quality assurance meth						_
rovide information on quality assura rovided [1], if applicable.	ince meth	ods to ens	sure accura	acy and qu	uality of inf	formation
	1	2	3	4	5	
subitem not at all important	•	0	0	0	0	essential
					C	Clear selection
Does your paper address sul	oitem 5	-iv?				
Copy and paste relevant sections from ndicate direct quotes from your man nformation not in the ms, or briefly e	m the mar uscript), c	nuscript (ir or elaborat	e on this it	em by pro	viding add	itional
						opportunities

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

O O O 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

The source code is not publicly available; there were no algorithms used. Screen shots can be provided on request.

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.

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

The intervention is not publicly available.

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 2 3 4 5

subitem not at all important OOOOO 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

From the manuscript: "Automated e-mails and texts were sent to invite families to complete the follow-up surveys at 6-, 12-, and 18-months after baseline."

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 O O O essential

Clear selection

П

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

"For each component, Smart Choices 4 Teens required that parents and adolescents complete on-line materials separately. Following completion, they chose two of four possible scenarios to discuss. These scenarios were designed to use the skills and knowledge that were addressed in the component activities. After the discussion was completed, participants moved to the next component."

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.

subitem not at all important O O O essential

Clear selection

5

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

"Given the imposed chronological order of the components, families first completed the Communications (21.83 minutes for parents, 18.75 minutes for adolescents) and Alcohol (16.34 minutes for parents, 15.53 minutes for adolescents) components before moving forward with the Relationship component. The average time spent on the Relationship component was nearly identical between parents (19.79 minutes) and adolescents (19.71 minutes). Families typically completed the intervention over the course of several weeks."

5

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).

subitem not at all important O O O essential

Clear selection

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

"All families also had access to an 800 number throughout the duration of the project for contact with the research team."

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).

1 2 3 4 5
subitem not at all important O O O 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

"Automated e-mails and texts were sent to invite families to complete the follow-up surveys at 6-, 12-, and 18-months after baseline. One week after the follow-up survey invitations were sent, reminder e-mails and texts were sent to participants who had not completed the surveys, with the e-mails/texts repeated after another week of nonresponse. If not completed within two weeks, phone calls were made to participants to encourage completion."

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.

subitem not at all important

O
O
O
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.

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

"Overall sex communication frequency. Overall frequency of sex communication was assessed with a single item adapted from the evaluation of the program Parent Handbook for Talking with College Students about Alcohol [52]: 'Overall, how often have you talked to your parent about sex' with response options ranging from (1) 'never' through (5) 'very often'. Topics of conversation about sex. Adolescents were asked to report whether their parents had talked about specific topics with them, adapted from the evaluation of Family Matters [53]. Delaying sex. Three items asked whether a parent had cautioned the adolescent: not to have sex, not to have a serious relationship in high school, and not to have sex specifically because their religion/values forbid sex outside of marriage. A sum of the three items was taken and reliability was adequate (T0: α =.62; T1: α =.64; T2: α =.68; T3: α = .70). Health risks. Two items were summed for discussions of Health Risks: 'sex can result in pregnancy' and 'sex can result in a sexually transmitted infection'. The two items were significantly (p <.01) correlated for all four waves (T0: r2 = .58; T1: r2 = .71; T2: r2 = .74; T3: r2 = .77). Birth control. A single item asked, 'if you are sexually active, [your parent(s)] will provide birth control'. Sex permissive. For adolescents, two items were summed to create a 'sex permissive message' including 'being sexually active is okay' and 'under what circumstances, if any, it is ok to be sexually active'. The two items were significantly correlated at all four waves (T0: r2 = .49; T1: r2 = .54; T2: r2 = .51; T3: r2 = .42). Monitoring / Dating rules. Adolescents were each asked about the expectations for behavior in romantic relationships that they had decided upon [54]. They were asked to respond no (0) or yes (1) to a list of 15 possible rules, e.g., 'no dates on school nights', 'come home at an agreed-upon time (curfew)', 'use good judgment' and 'be a gentleman/lady'. Responses were summed. Internal consistency was good (T0: α =.83; T1: α =.87; T2: α = .86; T3: α = .89).

Program Participation

A measure of program participation was captured in two dichotomous variables: 1 for those participants who only engaged with the communication and/or alcohol components only (0 all others), and 1 for those who engaged with some or all the Relationships component (0 all others). Thus, participants in the control group and those in the intervention group who did not initiate the program were the referent for the analyses.

Controls

Five baseline adolescent characteristics were included: gender, age, race/ethnicity, sexual orientation, and sexual experience. Gender was dichotomized as female (0) and male (1) and age was treated as a continuous variable. Participants were encouraged to choose all racial/ethnic backgrounds that applied to them (American Indian/Alaska Native, Asian, Black of African American, Native Hawaiian or other Pacific Islander, White, Other) and asked separately if they identify as Latino/Hispanic. Race/ethnicity was dichotomized with White Non-Hispanic coded 0 and any affirmative racial or ethnic minority coded 1. The measure of sexual identity followed recommended practice for assessing sexual orientation [55] as a composite of several responses: how they identify (heterosexual or straight, gay or lesbian, bisexual, other), to whom they are attracted (only females, mostly females, equally males and females, mostly males, only males), and with whom they have had sexual contact (males only, females only, both, neither) [56]. Using their reported gender identity, participants were considered sexual minority if they: 1) chose a non-heterosexual selfidentification; or 2) reported any same-sex sexual contact; or 3) reported any attraction to the same sex. This was recoded into one final item indicating heterosexual (80.9%) (0) and sexual minority (19.1%) (1). Finally, adolescent response to the question 'Have you ever had cay (vaginal aral or anal)? was coded such that negative responses were '0' and affirmative

6a-i) Online questionnaires: 6 apply CHERRIES items to designed/deployed If outcomes were obtained through 6 and apply CHERRIES items to describe	scribe h	ow the o	questior s, describe	nnaires v	vere re validate	ed for online use
	1	2	3	4	5	
subitem not at all important	0	•	0	0	0	essential
					C	Clear selection
Copy and paste relevant sections from		·	script.			
6a-ii) Describe whether and defined/measured/monitored Describe whether and how "use" (incl (logins, logfile analysis, etc.). Use/ad reported in any ehealth trial.	d luding inte	ensity of u	se/dosage	e) was defi	ned/meas	ured/monitored
	1	2	3	4	5	
subitem not at all important	0	0	0	•	0	essential
						Clear selection

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

"Given the imposed chronological order of the components, families first completed the Communications (21.83 minutes for parents, 18.75 minutes for adolescents) and Alcohol (16.34 minutes for parents, 15.53 minutes for adolescents) components before moving forward with the Relationship component. The average time spent on the Relationship component was nearly identical between parents (19.79 minutes) and adolescents (19.71 minutes). Families typically completed the intervention over the course of several weeks."

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

subitem not at all important O • O O essential

Clear selection

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

There was insufficient space for including information from the evaluation surveys

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

There were no changes to the outcomes after the trial commenced.

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.

1 2 3 4 5

subitem not at all important O O o essential

Clear selection

_

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

"Because parents and adolescents could choose how far to continue with the program, selection bias may confound the dosage analyses. One approach to help account for such biases is to model the selection process and then to include an instrumental variable representing it as a predictor in the primary analyses [57]. In the present case, we conducted a probit analysis to predict completion of the Relationships Component from relevant baseline measures and calculated an inverse Mills ratio for each respondent based on the probit model. The IMR (non-selection hazard) was calculated in Stata using the two-step procedure described in Heckman [57]. This ratio is a function of the predicted probability (propensity) of completing the component and represents the underlying selection processes. Given the focus of the Relationship Component, the baseline predictors included measures of parents' and adolescents' evaluations of and levels of communication in their relationship, parent-adolescent trust, parental monitoring, sexual communication, and demographics. Overall communication, adolescents' report of ever having sex, gender, sexual orientation, and age were included in the selection models. Parents' self-report of their gender and income and ethnicity were also used. When the IMR is significant in a model, this indicates that the predicted probability of completing the component is associated with the outcome. That is, the same factors that predispose families to complete (or not complete) the component are related to the outcomes. In models where program exposure is significant, this indicates that even accounting for factors that are related to completing the program, that participation in the intervention is still related to outcomes. Selection models provide several benefits, including ease of use and wide use in research (a 700% increase in use over the last decade [58,59]). Selection models also address with selection on unobservable factors, while alternatives such as propensity score matching requires self-selection of participants to be explained completely by observable factors [59]."

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

There were no interim analyses and stopping guidelines.

н

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

"Using a 1:1 allocation ratio, parent and adolescent dyads were randomly assigned to either the intervention (N=206) or control (N=205) condition using a computer-generated program as a randomized-controlled trial without a wait-list control group."

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

This item does not apply to our study

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

This item does not apply to our study

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

" ...using a computer-generated program"

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).

1 2 3 4 5

subitem not at all important

•

 \bigcirc

 \bigcirc

0

O

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

This item does not apply to our study as we did not use blinding

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".

1 2 3 4 5

subitem not at all important O O 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

The control condition did not offer another intervention but only access to resources.

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

"Dyads in both conditions received links to resources, including hotline numbers and websites providing information about adolescent alcohol and drug use, sexual behavior, suicide, support for gender and sexual minority adolescents, and other health issues."

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

"Outcomes were assessed using Generalized Estimating Equations using SPSS (v.25) to account for repeated measures of each outcome (inclusive of baseline report) nested within participants. In each analysis, variables included adolescent gender, age, ethnicity, sexual minority status, report of sexual experience at baseline, measurement time period, the Inverse Mills Ratio, and the two dichotomous variables for exposure to the Intervention (one or two components: Communications and Alcohol only; all three components: Communications, Alcohol, and Relationships Component) such that those with no exposure comprised the referent group. Hypothesis 1 analyses included only tests of the main effects of the variables. Hypothesis 2 analyses added an interaction term for gender by exposure to the intervention."

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]).

1 2 3 4 5

subitem not at all important

o o essential

Clear selection

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

We used expectation-maximization to impute within-survey missing data.

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

"Hypothesis 1 analyses included only tests of the main effects of the variables. Hypothesis 2 analyses added an interaction term for gender by exposure to the intervention."

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval									
subitem not at all important	1	2	3	4	5				
	0	0	0	0	•	essential			
					C	Clear selection			

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 were approved by the Institutional Review Board of the Pacific Institute for Research and Evaluation."

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.

1 2 3 4 5

Clear selection

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

"Parents provided consent for themselves and permission for their adolescent, while adolescents provided assent for themselves"

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)

1 2 3 4 5

subitem not at all important

) essential

Clear selection

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 research team made separate contact with the adolescent to ensure eligibility, ascertain a separate email for the adolescent, and ensure confidentiality."

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

Table 1. Intervention Dosage and Survey Completion

Intervention Control N % N %

Baseline (T0) Survey Completion 206 100.0% 205 100.0%

Intervention Exposure

No exposure 29 14.1%

Communication +/- alcohol 89 43.2%

Communication + alcohol + relationships 88 42.7%

6-month (T1) Survey Completion 150 72.8% 165 80.5% 12-month (T2) Survey Completion 147 71.4% 164 80.0% 18-month (T3) Survey Completion 145 70.4% 164 80.0%

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

Table 1. Intervention Dosage and Survey Completion

Intervention Control

N % N %

Baseline (T0) Survey Completion 206 100.0% 205 100.0%

Intervention Exposure

No exposure 29 14.1%

Communication +/- alcohol 89 43.2%

Communication + alcohol + relationships 88 42.7%

6-month (T1) Survey Completion 150 72.8% 165 80.5% 12-month (T2) Survey Completion 147 71.4% 164 80.0%

18-month (T3) Survey Completion 145 70.4% 164 80.0%

В

essential

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.

1 2 3 4 5

subitem not at all important OOOOO

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

Table 1. Intervention Dosage and Survey Completion

Intervention Control

N % N %

Baseline (T0) Survey Completion 206 100.0% 205 100.0%

Intervention Exposure

No exposure 29 14.1%

Communication +/- alcohol 89 43.2%

Communication + alcohol + relationships 88 42.7%

6-month (T1) Survey Completion 150 72.8% 165 80.5% 12-month (T2) Survey Completion 147 71.4% 164 80.0%

18-month (T3) Survey Completion 145 70.4% 164 80.0%

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

"Families with a 16- or 17-year-old adolescent were recruited from U.S.-focused online panel vendors, companies that match and recruit participants for targeted survey studies [32], between November 2014 and November 2015"

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

 \bigcirc

(

essential

Clear selection

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

This item does not apply to our study

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 trial was ended when the targeted recruitment/enrollment was met.

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

There is no table, however the information is provided: "At baseline, adolescents were 16 or 17 years of age (M = 16.4, SD = 0.5) and slightly more than half (55.3%) of were girls. About one-tenth (9.5%) of the adolescents were Hispanic/Latino. Adolescents reported the following race/ethnicities: 72.5% White, 1.9% Asian, 11.7% African American, 1.0% Native American, 8.3% Multiracial, 2.7% some other race, and 1.9% unreported. There were no significant differences were found on demographic characteristics between the experimental and control conditions, nor between amounts of intervention dosage."

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 O O essential

Clear selection

В

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

All participants were screened for having a tablet/computer prior to enrollment; also "At baseline, adolescents were 16 or 17 years of age (M = 16.4, SD = 0.5) and slightly more than half (55.3%) of were girls. About one-tenth (9.5%) of the adolescents were Hispanic/Latino. Adolescents reported the following race/ethnicities: 72.5% White, 1.9% Asian, 11.7% African American, 1.0% Native American, 8.3% Multiracial, 2.7% some other race, and 1.9% unreported. There were no significant differences were found on demographic characteristics between the experimental and control conditions, nor between amounts of intervention dosage."

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	0	0	0	0	•	essential
					C	lear selection

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

Table 1. Intervention Dosage and Survey Completion

Intervention Control N % N %

Baseline (T0) Survey Completion 206 100.0% 205 100.0%

Intervention Exposure

No exposure 29 14.1%

Communication +/- alcohol 89 43.2%

Communication + alcohol + relationships 88 42.7%

6-month (T1) Survey Completion 150 72.8% 165 80.5% 12-month (T2) Survey Completion 147 71.4% 164 80.0% 18-month (T3) Survey Completion 145 70.4% 164 80.0%

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 O O O essential

Clear selection

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

"Examining alternative models such as dosage models have been proposed for trials with limited control over program exposure and where substantial portions of participants do not appear motivated to fully adhere to the intervention implementation protocol [60]. Participants may lack motivation to complete prevention programs because the illnesses or discomforts have not yet happened [60,61] in comparison to treatment trials that typically aim to improve an existing problem or condition (e.g., alcoholism, diabetes). High rates of non-adherence in prevention trials could introduce Type 2 error by under-estimating the intervention's effectiveness [60]. For these reasons, we examined outcomes for experimental participants based on level of program exposure, testing the hypothesis that some program exposure, more so Relationship Component exposure, will be related to increased sexual communication."

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

Please see Tables 2 and 3 for these outcomes.

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).

subitem not at all important OOOOOcessential

Clear selection

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

See also Table 1 inserted above. "Given the imposed chronological order of the components, families first completed the Communications (21.83 minutes for parents, 18.75 minutes for adolescents) and Alcohol (16.34 minutes for parents, 15.53 minutes for adolescents) components before moving forward with the Relationship component. The average time spent on the Relationship component was nearly identical between parents (19.79 minutes) and adolescents (19.71 minutes). Families typically completed the intervention over the course of several weeks."

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

There were no binary outcomes in this study.

В

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

"Three interaction effects were added to assess the impact of the intervention over time and by gender: (1) intervention by survey administration time; (2) intervention by gender; and (3) intervention by time by gender (data not shown)."

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

•

 \bigcirc

 \bigcirc

essential

Clear selection

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

We did not complete analyses of users only without also including the control group.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

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

There were no reported harms or unintended effects as reported to us by the participating families.

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

Clear selection

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

There were none of these issues that were reported during/after the study.

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.

subitem not at all important O • O O essential

Clear selection

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

Due to space limitations we did not report on the evaluations completed by the participants.

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