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 (nonpharmacologic 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: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

Oraft saved

Your name * First Last

Jesse Golinkoff

Primary Affiliation (short), City, Country * University of Toronto, Toronto, Canada

University of Pennsylvania, Philadelphia, USA

Your e-mail address * abc@gmail.com

agolinko@nursing.upenn.edu

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

An Identity Affirming Web App to Help Sexual and Gender Minority Youth Cope with Minority Stress: Pilot Randomized Control 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.

imi

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

Your answer

Lano	luage	(s)) *
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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://imigui.de/

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)"

Minority Stress (Sexual and Gender Minority A

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Coping appraisals

Secondary/other outcomes

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

Cognitive and behavioral coping skills, identity affirmation, internalization of blame for minority stress, sense of belonging, anxiety and depression symptoms

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: Twice per week

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%
- O Other:

Ov	erall, was the app/intervention effective? *
0	yes: all primary outcomes were significantly better in intervention group vs control
۲	partly: SOME primary outcomes were significantly better in intervention group vs control
0	no statistically significant difference between control and intervention
0	potentially harmful: control was significantly better than intervention in one or more outcomes
0	inconclusive: more research is needed
0	Other:
	icle Preparation Status/Stage * hich stage in your article preparation are you currently (at the time you fill in this form)
	hich stage in your article preparation are you currently (at the time you fill in this form)
	hich stage in your article preparation are you currently (at the time you fill in this form) not submitted yet - in early draft status
	hich 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
	hich 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
	hich 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

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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:

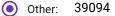
Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- 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)

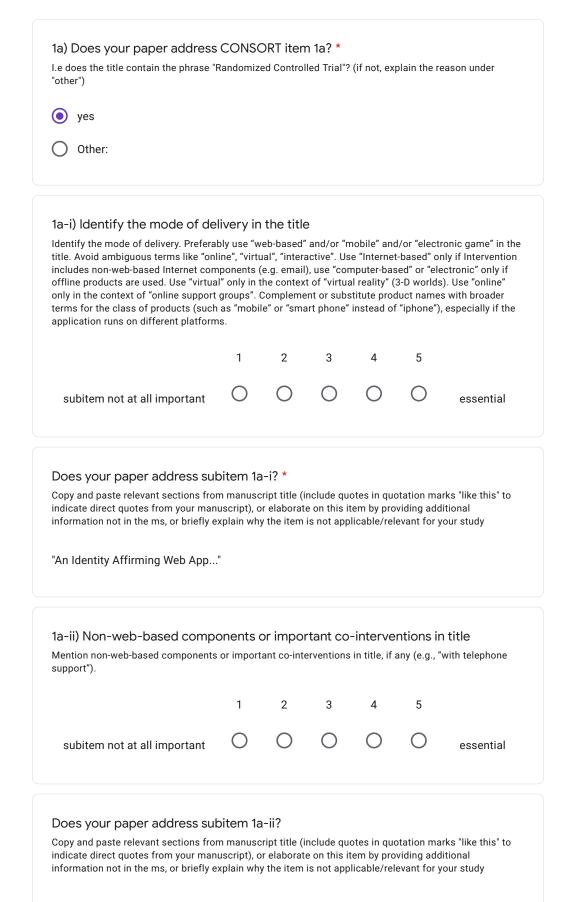
no ms number (yet) / not (yet) submitted to / published in JMIR



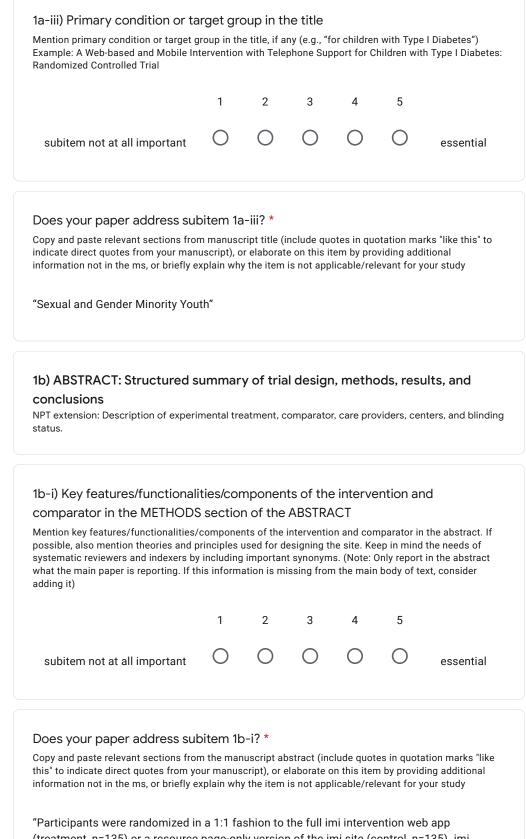
TITLE AND ABSTRACT

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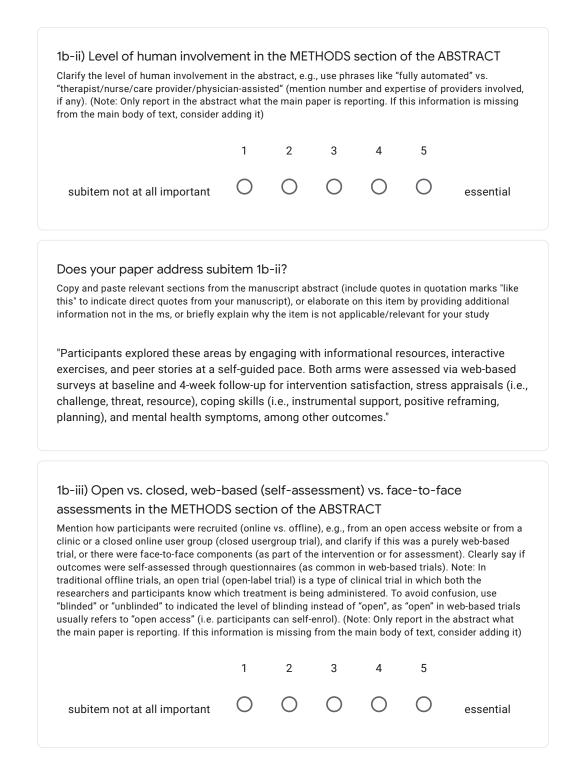
1a) TITLE: Identification as a randomized trial in the title



All components of this study were web-based.



(treatment, n=135) or a resource page-only version of the imi site (control, n=135). imi covered four topical areas: gender identity, LGBTQ+ identity, stress and coping, and internalized homophobia and transphobia. Participants explored these areas by engaging with informational resources, interactive exercises, and peer stories at a self-guided pace."



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

"SGMY(N=270) living in the US, ages 13 to 19 (Mean 16.5, SD 1.5 years) were recruited through Instagram ads."

"Both arms were assessed via web-based surveys at baseline and 4-week follow-up for intervention satisfaction, stress appraisals (i.e., challenge, threat, resource), coping skills (i.e., instrumental support, positive reframing, planning), and mental health symptoms, among other outcomes. Main 'intent-to-treat' analyses compared the arms at week 4, controlling for baseline values on each outcome."

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	0	0	0	0	0	essential

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

"Participants were randomized in a 1:1 fashion to the full imi intervention web app (treatment, n=135) or a resource page-only version of the imi site (control, n=135)." "Survey retention was 90% at week 4."

"Within the treatment arm, higher engagement with imi (>=5 sessions, >10 minutes, or >10 pages) predicted greater improvement in stress appraisals (all ps<.05)."

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)										
1 2 3 4 5										
subitem not at all important	0	0	0	0	0	essential				

Does your paper address subitem 1b-v?

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

N/A: this was not a negative trial.

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 2a-i? *

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

See the Introduction section.

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if 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	0	0	0	0	0	essential

Does your paper address subitem 2a-ii? *

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

"Efficacious mental health interventions for SGMY have focused on providing resources that scaffold SGMY's ability to perceive minority stressors as a challenge to be faced and overcome, rather than a threat, including strengthening SGMY's coping skills, affirming SGM identities, and strengthening supportive social connections."

"While prior research suggests that face-to-face interventions that include these components may improve the mental health of SGMY, the reach and scalability of these programs have been challenging, given their time intensity and need for synchronous interactions, which have become increasingly difficult to coordinate amidst the COVID-19 pandemic. At the same time, the need for scalable mental health resources has become particularly acute in recent years."

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

"Our study had four main objectives. First, we examined the acceptability of imi in a diverse sample of 270 SGMY. Given our use of human-centered design principles and the involvement of SGMY in imi's design, we expected that participants randomized to receive imi would report greater acceptability and satisfaction than participants assigned to the control arm. Second, we examined the preliminary efficacy of imi as a digital tool to increase adaptive stress appraisals among SGMY (primary outcome). Given imi's focus on teaching cognitive and behavioral coping skills, we hypothesized that participants assigned to receive imi would be more likely to appraise stress as a surmountable challenge and less likely to appraise stress as threatening by the 4-week follow up relative to the control arm. Third, we examined the preliminary efficacy of imi across 5 secondary outcomes related to SGMY's mental health: cognitive and behavioral coping skills, identity affirmation and connectedness to the LGBTQ+ community, internalization of blame for minority stress, sense of belonging, and anxiety and depression symptoms. We predicted that imi would be more likely to improve SGMY's outcomes across these domains relative to the control arm. Finally, as exploratory analyses, we examined participants' engagement with imi relative to the control arm. We also explored whether user engagement with imi (i.e., counts of user sessions, time spent on each intervention, and the number of pages visited) predicted improvement in primary and secondary outcomes."

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

"This pilot randomized controlled trial evaluated the acceptability and initial efficacy of imi at the end of the 4-week active study period. Participants were randomly assigned in a 1:1 fashion to receive either imi (treatment arm), or a resource page-only version of the imi site called "asterix", which linked out to a series of LGBTQ+ specific external mental health resources (resource-only control arm). We collected survey data via online self-completed Qualtrics surveys administered at baseline and at a four-week follow-up."

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

N/A: no important changes occurred 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].



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

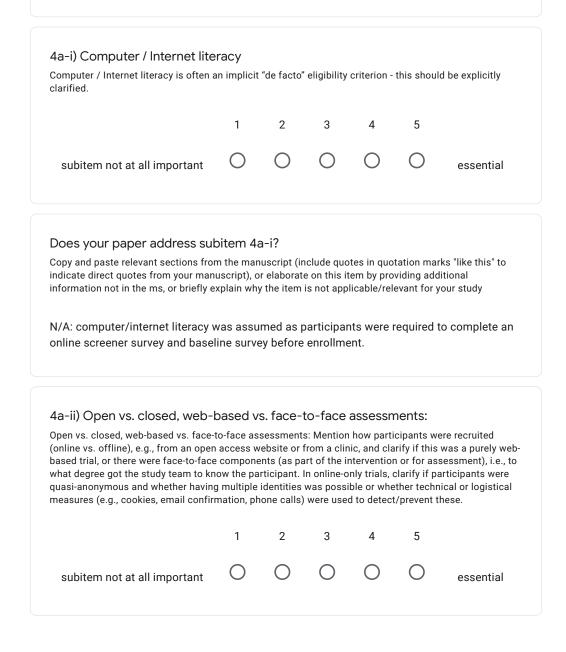
N/A: no bug fixes, downtime, or content changes during the trial.

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

"To be eligible for this study, youth had to 1) be 13-19 years old (inclusive), 2) identify as a sexual and/or gender minority, 3) reside within the US, 4) be English literate, 5) have access to a device with internet access, a web browser, and SMS capabilities, 6) be willing to participate in study activities for four weeks."



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

"Participants were SGMY recruited on Instagram between October and November 2021.." "All study activities were conducted remotely, and web-based screening and survey assessments were delivered through Qualtrics Software."

"Study staff manually checked all screeners that met basic eligibility criteria to eliminate duplicate and fraudulent entries. Of the 1580 individuals who completed the screening survey, 923 met all inclusion criteria and passed the duplicate and fraudulent entry checks." "The baseline survey contained eight of the same or similar questions as were asked in the screener. Following established best practices for participant verification, staff compared each applicant's screener and baseline data for these eight questions. If any significant inconsistencies were identified, applicants were emailed and asked to respond via email or phone to resolve the issue."

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.

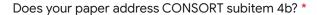
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

"A total of 488 individuals were emailed a link to the baseline survey, which contained the informed consent form, and participants were given two-weeks to complete the survey. A waiver of parental consent was granted to ensure that youth that might not yet be out to their parents or have less parental support, and thus could benefit from an identity affirming tool, could participate in the study."

4b) Settings and locations where the data were collected

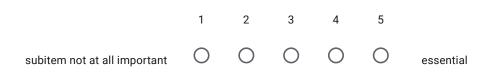


Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"All study activities were conducted remotely, and web-based screening and survey assessments were delivered through Qualtrics Software."

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.



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

"All study activities were conducted remotely, and web-based screening and survey assessments were delivered through Qualtrics Software."

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)



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

N/A: Some recruitment advertisements included a small University of Pennsylvania logo. The intervention and control web apps had a footer link to a "Study Consent" page. The Study Consent page contained the informed consent form that the participant had previously digitally signed. This was the only page within the web apps that displayed "The University of Pennsylvania" affiliation to participants.

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	0	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

"imi is a mobile app co-developed by Hopelab, CenterLink, and It Gets Better Project. While all three organizations were involved in the development of the product, CenterLink will ultimately be responsible for the operation and distribution of imi. As a free digital tool created and distributed by non-profit organizations, none of the organizations involved stand to profit financially from the product. The research reported here as well as the development of imi were supported by the non-profit Hopelab Foundation. Hopelab develops behavioral interventions to improve the health and well-being of young people. The design, conduct, analysis, and reporting of this study represent a scientific collaboration between Hopelab and the Program on Sexuality, Technology, & Action Research at the University of Pennsylvania School of Nursing. EBS, FD, AT, JL, LR, and JH are employed by Hopelab Foundation. The study sponsor was involved in the study design, collection, analysis, and interpretation of data; writing of the article; and decision to submit it for publication."

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	0	0	0	0	0	essential

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

"imi was built by Hopelab, a non-profit social innovation lab, in collaboration with CenterLink, an international non-profit organization and member-based association of LGBTQ+ centers serving their local and regional communities. Before launching the pilot trial, Hopelab conducted formative work through interviews, focus groups, co-design sessions, and surveys of SGMY. The web app content and visual elements were tailored based on youth feedback and contributions."

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	0	0	0	0	0	essential

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

N/A: the intervention content was frozen during the trial

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	0	0	0	0	0	essential

Does y	/our	paper	address	subitem	5-iv?
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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 baseline survey contained eight of the same or similar questions as were asked in the screener. Following established best practices for participant verification, staff compared each applicant's screener and baseline data for these eight questions. If any significant inconsistencies were identified, applicants were emailed and asked to respond via email or phone to resolve the issue."

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	0	0	0	0	0	essential

Does your paper address subitem 5-v?

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

See Multimedia Appendix 1 for screen-capture video.

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, <u>webcitation.org</u>, 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	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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 web-app can be found at https://imigui.de/. A screen-capture video can be found in the Multimedia Appendix.

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).



Does your paper address subitem 5-vii? *

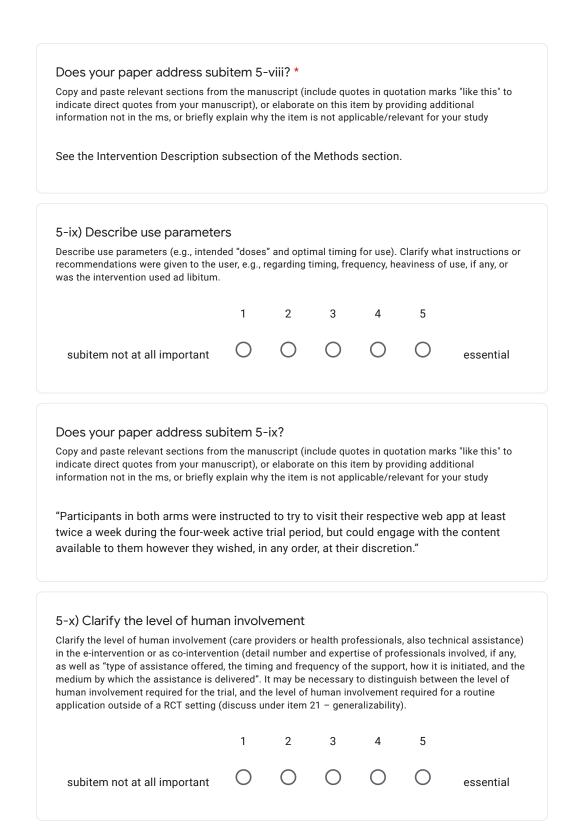
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Within 1 business day of completing the baseline survey, each participant was emailed a unique link to the imi or asterix web app. Participants were compensated with a USD \$30 Amazon e-gift card once they registered for an account on imi or asterix."

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].





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

"imi delivers fully automated information and skill practice across guides covering four content areas 1) gender identity exploration (the gender guide), 2) sexual orientation and broader LGBTQ+ identity exploration (the queerness guide), 3) stress and coping (the stress guide), and 4) internalized homophobia and transphobia (the stigma guide)."

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	0	0	0	0	0	essential

Does your paper address subitem 5-xi? *

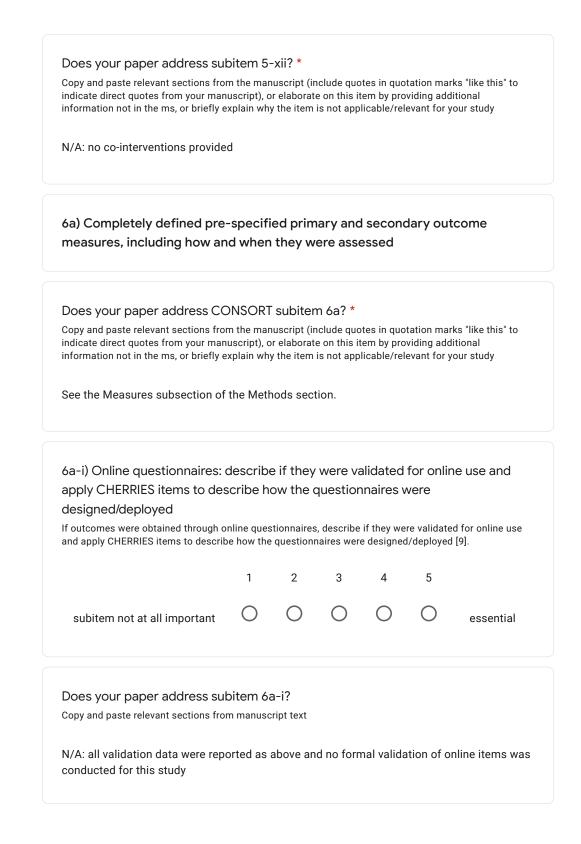
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Based on their preferences, participants received either weekly texts or emails reminding them to log into their web app."

5-xii) Describe any co-interventions (incl. training/support)

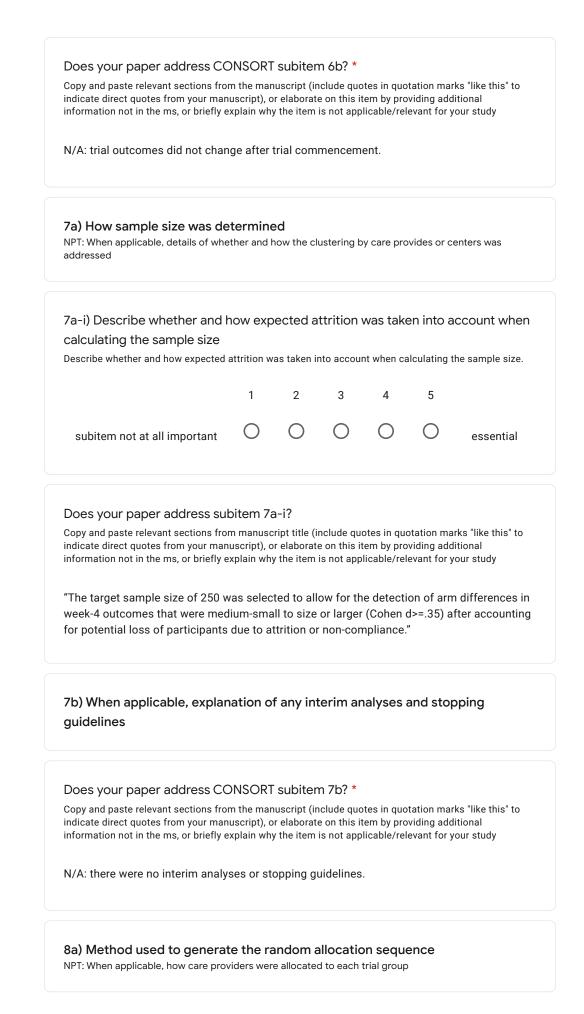
Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to 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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential



(logins, logfile analysis, etc.). Use/ad- reported in any ehealth trial.	-	-	-			ured/monitored at should be
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address sub						
See the Engagement subsection	of the M	lethods s	ection.			
6a-iii) Describe whether, how was obtained Describe whether, how, and when qua emails, feedback forms, interviews, fo	litative fe	edback fro				
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address sub Copy and paste relevant sections fror						
"A measure of intervention satisf study also were included. The me would you rate your overall exper was analyzed as a continuous va product be more helpful to you?"	easure c rience of rriable, a	onsists of this proc nd free te	of a multij duct?" (1=	ple-choic ="Very ba	e questio Id" to 7="I	n (e.g., "How Excellent") th
				d by two		aing ranid

6b) Any changes to trial outcomes after the trial commenced, with reasons



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

"Participants were randomized in a 1:1 fashion to the full imi intervention web app (treatment, n=135) or a resource page-only version of the imi site (control, n=135)."

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

We used simple 1:1 randomization.

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

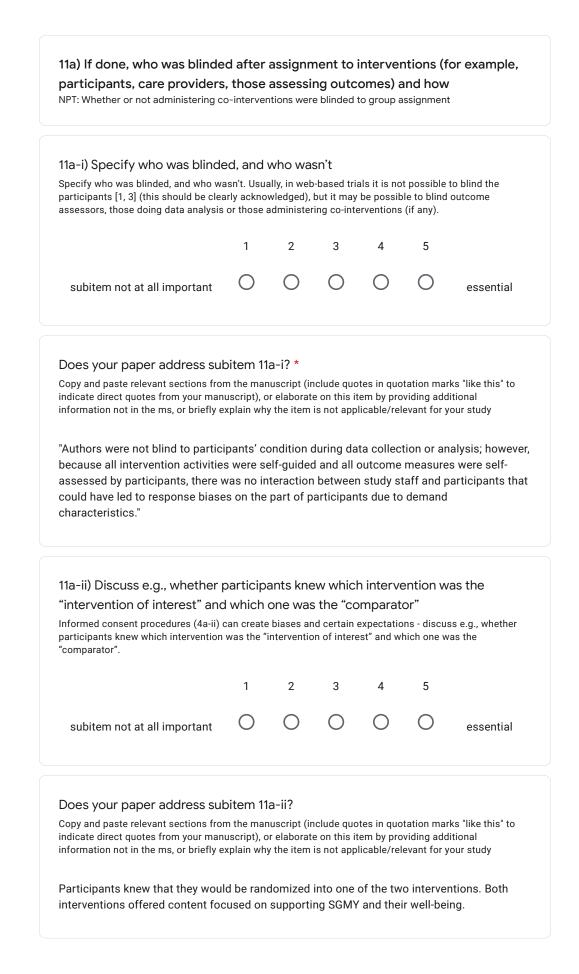
N/A: the simple 1:1 randomization sequence was not concealed.

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

JG created the random allocation sequence, assignment, and enrollment



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

N/A: not relevant for this eHealth trial

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

"Analyses of all primary and secondary outcome variables were performed using an intention-to-treat approach, which included all available data from participants randomly assigned to the two arms, regardless of whether participants created an account within their respective web resource. We took a two-step approach to these analyses. First, within each arm, we examined the mean changes from baseline to follow-up using paired t-tests. Then we used linear regression to test the main effect of arm (treatment=1 vs. control=0) on week 4 outcomes, adjusting for the baseline value of each respective outcome as a covariate."

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	0	0	0	0	0	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

"Analyses of all primary and secondary outcome variables were performed using an intention-to-treat approach, which included all available data from participants randomly assigned to the two arms, regardless of whether participants created an account within their respective web resource."

"Our survey retention rate at the 4-week follow-up was 90.4%. In attrition analyses, comparing those who completed the follow-up survey (n=244) with those who did not (n=26), we found no significant condition differences in attrition linked to demographic characteristics or baseline scores on primary or secondary outcomes. Collapsing across the two arms, participants who did not complete the follow-up survey were more likely to be younger (Mean 15.42, SD 1.53 vs. Mean 16.60, SD 1.44 years; t268=-3.95; p-value [p]<.001) and reported fewer cognitive and behavioral coping skills at baseline (see Supplement 1; all ps <.01)."

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

٨

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

N/A: We did not have the statistical power to carryout 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								
	1	2	3	4	5			
subitem not at all important	0	0	0	0	0	essential		

Does your paper address subitem X26-i?

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

"The University of Pennsylvania Institutional Review Board approved all study procedures (Protocol #849509) and the study was registered on ClinicalTrials.gov (NCT05061966)."

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	
subitem not at all important	0	0	0	0	0	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

"A total of 488 individuals were emailed a link to the baseline survey, which contained the informed consent form, and participants were given two-weeks to complete the survey. A waiver of parental consent was granted to ensure that youth that might not yet be out to their parents or have less parental support, and thus could benefit from an identity affirming tool, could participate in the study."

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

"Participants in both arms received access to resources webpages that linked to freely accessible, pre-existing crisis and non-crisis resources. Crisis resources included the National Suicide Prevention Lifeline, as well as resources specific to LGBTQ+ youth, like TrevorChat."

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

N=270; Control N=135; Intervention N=135

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram)

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

See Figure 1 for CONSORT flow diagram.

tables demonstrating usage/dose/er	ngagement	Γ.				
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address su	bitem 13	3b-i?				
Copy and paste relevant sections fro quotes in quotation marks "like this" item by providing additional informat applicable/relevant for your study	to indicate	e direct qu	otes from	your man	uscript), or	elaborate on th
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See Supplement 1 for Attrition d		recruitn	nent and	d follow	-up	
14a) Dates defining the per Does your paper address CC Copy and paste relevant sections fro indicate direct quotes from your mar	iods of r DNSORT m the mar buscript), o	subiter	m 14a? * nclude quo e on this it	otes in quo tem by pro	tation man	litional
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14a) Dates defining the per Does your paper address CC Copy and paste relevant sections fro indicate direct quotes from your mar information not in the ms, or briefly e "Participants were SGMY recruit "On day 28, participants were se	iods of r DNSORT m the mar buscript), o explain why ed on Ins ent a link t mber 202 ular eve Il into the s	subiter nuscript (ir or elaborat y the item tagram b to the fol 21) nts" fell study perio	m 14a? * nclude quo e on this if is not app between (low-up su into the od, e.g., sig	otes in quo tem by pro licable/rel Dottober a urvey, wh e study p gnificant o	tation man widing add evant for y and Nover ich they h beriod hanges in	litional your study mber 2021." nad 14 days to

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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

N/A: no critical secular events occurred.

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 ended once all 270 participants completed their 28-day follow-up survey or failed to do so within the two-week window.

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? *

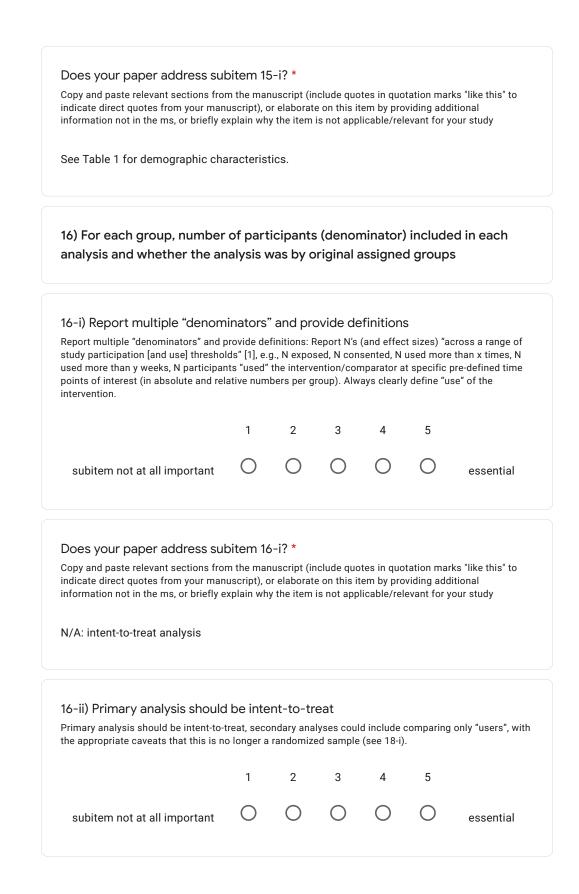
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See Table 1 for demographic characteristics.

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	0	0	0	0	0	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

"Analyses of all primary and secondary outcome variables were performed using an intention-to-treat approach, which included all available data from participants randomly assigned to the two arms, regardless of whether participants created an account within their respective web resource."

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

See Table 2 for primary and secondary outcome data.

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

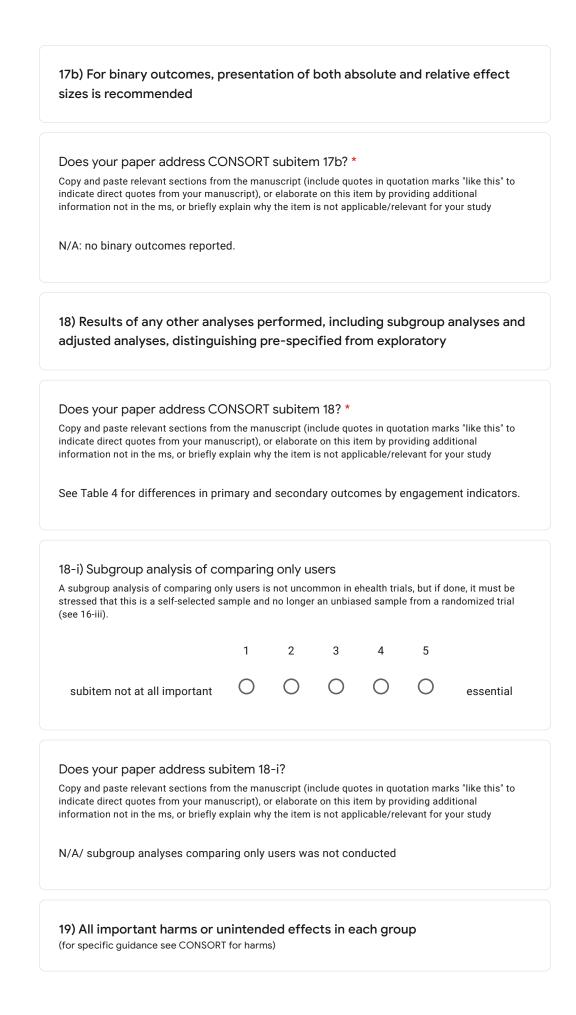
In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous 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).

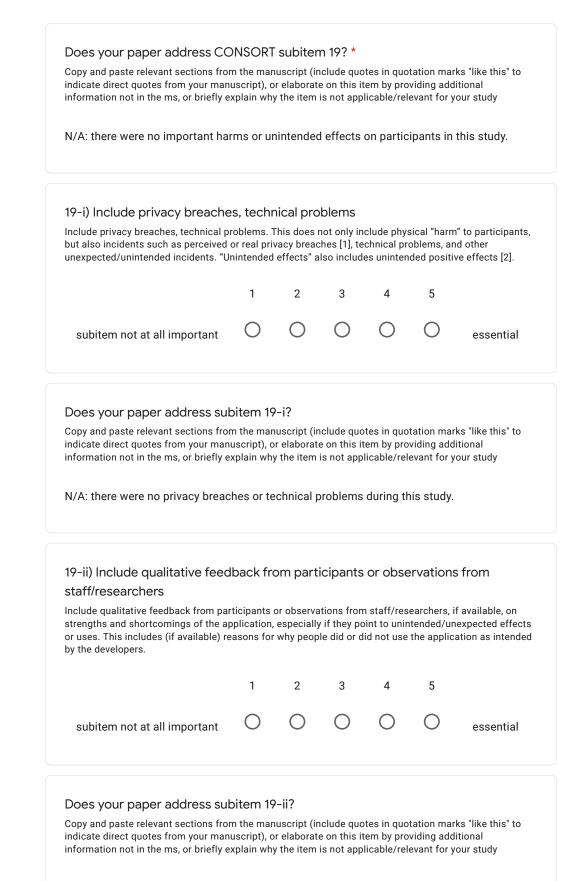
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

"Given the absence of standardized and generalizable threshold indicators to suggest adequate engagement across digital health interventions, we adopted an exploratory approach to the analysis of this data, and created thresholds to define participants' engagement with the intervention. After examining the distribution of the engagement data, we selected the following to define thresholds of use: 4 or more sessions, 10 minutes or more, 10 unique pages or more viewed, and 1 or more clicked external links."





See the Intervention Acceptability subsection of the Results section.



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	0	0	0	0	0	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

See the Discussion section.

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

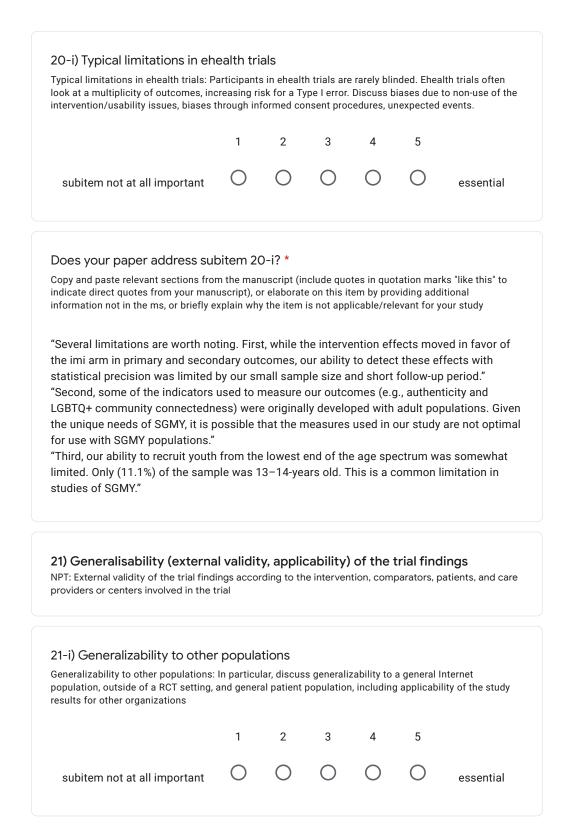
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

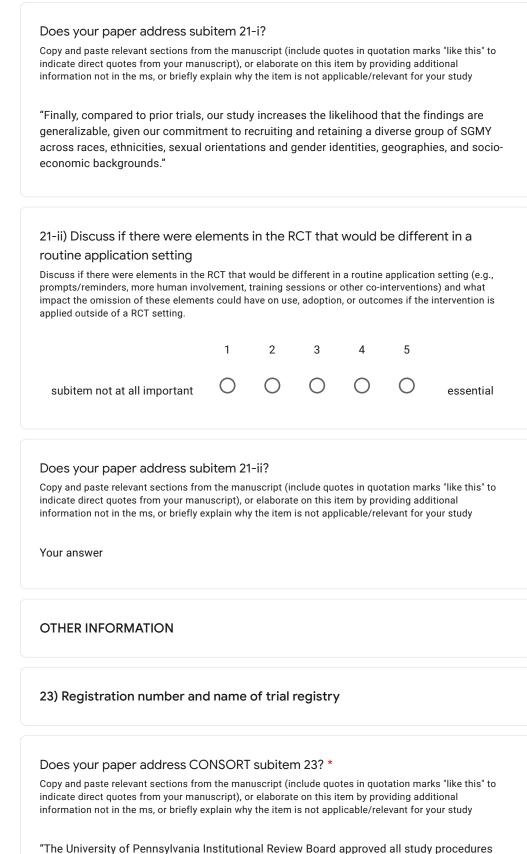
Does your paper address subitem 22-ii?

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

See the Discussion section.

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





(Protocol #849509), and the study was registered on ClinicalTrials.gov (NCT05061966)."

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

N/A: full protocol not available

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

"The research reported here as well as the development of imi were supported by the nonprofit Hopelab Foundation. Hopelab develops behavioral interventions to improve the health and well-being of young people."

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	0	0	0	0	0	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

Your answer

Abo	out the CONSORT EHEALTH checklist
Asa	a result of using this checklist, did you make changes in your manuscript? *
0	yes, major changes
•	yes, minor changes
0	no
	at were the most important changes you made as a result of using this ecklist?
You	r answer
	w much time did you spend on going through the checklist INCLUDING king changes in your manuscript
	spent approximately 8 hours going through the checklist INCLUDING making changes ir manuscript.
Asa	a result of using this checklist, do you think your manuscript has improved? *
•	yes
0	no
0	Other:
Wo	uld 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 lanation and Elaboration" document
0	yes
0	no
\bigcirc	Other:

Any other comments or questions on CONSORT EHEALTH

Your answer

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