CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

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

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption): Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126

URL: <http://www.jmir.org/2011/4/e126/>

doi: 10.2196/jmir.1923

PMID: 22209829

* Required

Your name *

First Last

Harold Lee

Primary Affiliation (short), City, Country *

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Your e-mail address *abc@gmail.com

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Title of your manuscript *

Provide the (draft) title of your manuscript.

Health Research Using Facebook to Identify and Recruit Pregnant Women who Use
E-cigarettes: Internet-based Protocol for a Non-Randomized Pilot Study

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.

Facebook Business

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.

<https://business.facebook.com/>

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)"

Pregnant Women who Use E-cigarettes

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

number of participant enrolled, cost assoc

Secondary/other outcomes

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

saliva sample, photo of e-cigarette device, physician contact information

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: n/a

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

☐ unknown / not evaluated

☐ 0-10%

☐ 11-20%

☐ 21-30%

☐ 31-40%

☐ 41-50%

☐ 51-60%

☐ 61-70%

☐ 71%-80%

☐ 81-90%

☐ 91-100%

☒ Other: n/a

Overall, was the app/intervention effective? *

- ☐ yes: all primary outcomes were significantly better in intervention group vs control
- ☐ partly: SOME primary outcomes were significantly better in intervention group vs control
- ☐ no statistically significant difference between control and intervention
- ☐ potentially harmful: control was significantly better than intervention in one or more outcomes
- ☒ inconclusive: more research is needed
- ☐ Other:

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

- ☐ not submitted yet - in early draft status
- ☐ not submitted yet - in late draft status, just before submission
- ☐ submitted to a journal but not reviewed yet
- ☒ submitted to a journal and after receiving initial reviewer comments
- ☐ submitted to a journal and accepted, but not published yet
- ☐ published
- ☐ Other:

Journal *

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ☐ not submitted yet / unclear where I will submit this
- ☐ Journal of Medical Internet Research (JMIR)
- ☐ JMIR mHealth and UHealth
- ☐ JMIR Serious Games
- ☐ JMIR Mental Health
- ☐ JMIR Public Health
- ☐ JMIR Formative Research
- ☒ Other JMIR sister journal
- ☐ Other:

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

- ☒ Pilot/feasibility
- ☐ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ☐ no ms number (yet) / not (yet) submitted to / published in JMIR
- ☒ Other: 12444

TITLE AND ABSTRACT

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

1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

☒ yes

☐ Other:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

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

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

"Internet-based", "Health Research Using Facebook "

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

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

Does your paper address subitem 1a-ii?

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

n/a

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes")
Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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

Does your paper address subitem 1a-iii? *

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

"Pregnant Women who Use E-cigarettes"

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	☐	☐	☐	☐	☐	essential

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 primary aim of the paper is to provide information to researchers who seek to recruit participants from rare populations using social media for studies with rather demanding protocols. We describe a pilot study protocol that identified and enrolled currently pregnant women (second or third trimester) who were exclusive electronic cigarette (e-cigarette) users. We describe the recruitment methods, time, and cost; examine advertisement types that were more or less successful; discuss participant retention and relationship management; and describe the process of collecting biological data"

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	☐	☐	☐	☐	☐	essential

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 advertisements invited individuals to complete a fully automated eligibility screener based on Qualtrics. "

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 ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 1b-iii?

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

"In an open access non-randomized pilot study, we placed Facebook advertisements selectively targeting women who were likely to be pregnant and interested in e-cigarettes or vaping. "

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 ☐ ☐ ☐ ☐ ☐ 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

"We enrolled 20 participants in two months at a cost of \$3421.28 USD. Baseline data was collected for all 20 participants. Of the 20 women enrolled, 16 provided a saliva sample, 4 provided a photo of the e-cigarette device, and 10 provided physician contact information. Of the 10 physicians contacted by mail, 6 responded with information on the participants and their babies."

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

☐
☐
☐
☐
☐

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 ☐ ☐ ☐ ☐ ☐ 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

"Participant recruitment is frequently a challenge in public health research, particularly when the study aims to enroll those who are difficult to reach or recruit into research studies [1, 2]. The population of interest may be rare among the overall population (e.g., cystic fibrosis, Huntington disease, or Duchenne muscular dystrophy), difficult to identify or contact (e.g., sex workers), or hesitant to participate due to stigma or legality (e.g., people with substance use disorders, abuse victims, or illegal immigrants) [3-5]. To obtain a sufficient number of hard-to-reach participants, a researcher could conduct multi-center trials, but this can be quite expensive. One approach that has been increasingly used to address this challenge is to utilize social media to recruit from the larger population. "

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

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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

"Social recruitment" of study participants using Facebook (business.facebook.com) has gained significant traction in recent years [6-8]. According to Pew Research Center's survey in 2018, about 80% of US adults aged 18-49 use Facebook [9]. Facebook enables researchers to place targeted advertisements to reach populations with certain socio-demographic attributes (e.g., age, sex, ethnicity, location) and who communicate about their interests in a manner that makes them most likely to have the specific attributes needed for a given study. In addition, the platform enables individuals to enroll in a study by simply clicking on an advertisement and then being directed to the study site. Facebook recruitment has been successfully employed in recruiting tobacco users [10], substance abusers [6, 8], and those suffering from depression [7]. Nascent literature on recruitment of e-cigarette users using social media (e.g., Facebook and Twitter), conducted by our team [11] and other [12], has shown promising results. However, the previous research solely relied on self-report measures to assess relevant variables (e.g., e-cigarette usage, pregnancy status). A more rigorous approach requires corroboration of survey reports with objective evidence."

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

"Thus, the purpose of present study was to examine the utility of Facebook to recruit pregnant women who used e-cigarettes into a study with a protocol that required acquisition of saliva samples, extensive surveys assessing details of e-cigarette use (20-30 minutes), photographs of the e-cigarette device, and physician corroboration regarding the pregnancy and infant."

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

"The present study was open access (i.e., participants self-enroll) non-randomized pilot study."

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

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	5	
subitem not at all important	☐	☐	☐	☐	☐	essential

Does your paper address subitem 3b-i?

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

"We first used a "conversion tracking" advertisement and later used a "traffic tracking" advertisement [14, 15]. While both methods use Facebook pixel to gather information from Facebook users, they target slightly different groups. Conversion tracking gathers information from only those who end up at the final webpage (e.g., those who purchase an item, sign up for a study, or provide contact information). On the other hand, traffic tracking gathers information from those who click through the processes (e.g., an advertisement, screener, study explanation, or baseline questionnaire)."

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

"The advertisement invited them to complete an online eligibility-screening questionnaire. Inclusion criteria for this study were as follows: 1) pregnant women who were in their 2nd or 3rd trimester, 2) age 18-50, 3) currently non-smoker of tobacco, 4) e-cigarette user (≥ 5 days per week). "

4a-i) Computer / Internet literacy

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

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

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

"The enrolled participants likely had high literacy level considering that 65% of the participants were at least 'some college' or above."

"In addition, the requirements to read the consent form online and complete questionnaires online suggest that a relatively high literacy level, as well as high "Internet literacy", would be required for participation. "

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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

"The present study was open access (i.e., participants self-enroll) non-randomized pilot study."

"With respect to human involvement, advertisement, screening, and enrollment into the study was purely web-based, and once enrolled, research assistant contacted the participants only via email and there were no on-site visits."

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	☐	☐	☐	☐	☐	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

"Safety and security procedures were elaborated in the informed consent form, which was collected online via Qualtrics. With respect to harms or unintended effects, we noted the only risk to you of participating would be if personal information about you or your baby reached people other than the researchers. We will be extremely careful to do everything we can to make sure that doesn't happen. Your data will be stored on a computer at Brown University, never on a laptop or memory stick. The data will only be seen by people on the research team who need to work with it or the Brown Institutional Review Board overseeing the study. There are no direct benefits to you from being in the study. However, you may be contributing to research that will help us provide more accurate information about e-cigarettes and health to expectant mothers in the future."

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

"All surveys were conducted online using the Qualtrics platform [16]. "

"With respect to human involvement, advertisement, screening, and enrollment into the study was purely web-based, and once enrolled, research assistant contacted the participants only via email and there were no on-site visits. "

4b-i) Report if outcomes were (self-)assessed through online questionnaires

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

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

Does your paper address subitem 4b-i? *

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

"All surveys were conducted online using the Qualtrics platform [16]. "

"With respect to human involvement, advertisement, screening, and enrollment into the study was purely web-based, and once enrolled, research assistant contacted the participants only via email and there were no on-site visits. "

4b-ii) Report how institutional affiliations are displayed

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

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

Does your paper address subitem 4b-ii?

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

Figure 1 shows Facebook Advertisement title, "Brown University's Expecting Moms Research Study"

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

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

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

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

"To ensure tracking all conversions with the Facebook Pixel in ads, a) Click "Show Advanced Options" under Ads in Ads Manager, b) Check "Track all conversions from my Facebook Pixel", c) Click Save and Close, d) Apply to all campaigns if not default tracking with Facebook Pixel."

"An integral metric to determine the cost-effectiveness of conversion vs. traffic is "Cost per results", which can be found in the summary table provided in Facebook Ads Manager. Cost per results counts the number of results (e.g., conversion or traffic) a researcher received based on the settings for the ad. For example, if a researcher selected conversions as their campaign objective, the results metric may show the number of "View contents" that occurred due to someone seeing his or her ad. "

5-ii) Describe the history/development process

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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

"Nascent literature on recruitment of e-cigarette users using social media (e.g., Facebook and Twitter), conducted by our team [11] and other [12], has shown promising results."

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 ☐ ☐ ☐ ☐ ☐ 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

These aspects were detailed in Table 1 and 2.

5-iv) Quality assurance methods

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

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

Does your paper address subitem 5-iv?

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

"Among 36 participants, research staff excluded 16 participants (44%) who appeared to be dishonest in their responses, presumably to collect the incentive. For example, some participants attempted to enroll twice in the study using a different name but the same contact information. One participant claimed that she has not received the Amazon.com incentive after our research team had received an automated message from Amazon.com stating that she had redeemed her gift card."

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

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

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

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

"To ensure tracking all conversions with the Facebook Pixel in ads, a) Click "Show Advanced Options" under Ads in Ads Manager, b) Check "Track all conversions from my Facebook Pixel", c) Click Save and Close, d) Apply to all campaigns if not default tracking with Facebook Pixel."

"After the eight advertisement sets using conversion tracking, we contacted Facebook marketing consultant (Job title: Marketing Expert) due to the low screening rate. Through phone meetings and emails, the Facebook consultant helped us understand how to optimize current campaigns but this service was provided for only 28-day period. The consultant suggested us to use traffic tracking instead of conversion tracking. The suggestion was motivated by the fact that screening process of the present study is more like a process (i.e., ideal for traffic tracking) than a snapshot decision (i.e., ideal for conversion tracking). An integral metric to determine the cost-effectiveness of conversion vs. traffic is "Cost per results", which can be found in the summary table provided in Facebook Ads Manager. Cost per results counts the number of results (e.g., conversion or traffic) a researcher received based on the settings for the ad. For example, if a researcher selected conversions as their campaign objective, the results metric may show the number of "View contents" that occurred due to someone seeing his or her ad. In the present study, for conversion, the cost per results was "View Contents". For traffic, the cost per result was "Link Clicks" and the cost was significantly lower."

5-vi) Digital preservation

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

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

"Social recruitment" of study participants using Facebook (business.facebook.com) has gained significant traction in recent years [6-8]. "

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 ☐ ☐ ☐ ☐ ☐ essential

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

"Social recruitment" of study participants using Facebook (business.facebook.com) has gained significant traction in recent years [6-8]. "

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

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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

"One of the advantages of recruiting on Facebook or other social media platforms is that the platform uses a "pixel" code—a short programming script that is placed on an advertiser's website to track traffic conversions from the platform advertisements [13]. The pixel code allows Facebook's algorithm to characterize users who interact with an advertisement (e.g., like, share or directly click the post), and then further disseminate the advertisement to other Facebook users with similar characteristics."

"We first used a "conversion tracking" advertisement and later used a "traffic tracking" advertisement [14, 15]. While both methods use Facebook pixel to gather information from Facebook users, they target slightly different groups. Conversion tracking gathers information from only those who end up at the final webpage (e.g., those who purchase an item, sign up for a study, or provide contact information). On the other hand, traffic tracking gathers information from those who click through the processes (e.g., an advertisement, screener, study explanation, or baseline questionnaire). As an analogy, on a clothing store website, conversion tracking would collect customer information from only those who purchased clothing, whereas traffic tracking would collect customer information from those who did not purchase any clothing but showed significant interest in certain items such as viewing it or adding it to their cart. "

5-ix) Describe use parameters

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

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

Does your paper address subitem 5-ix?

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

"We incrementally fine-tuned our parameters for the subsequent set based on the turnout of the ongoing one. The specifics of daily budget and audience details were informed by our team's previous research [11]. Ad sets one and two used same search terms, which included "electronic cigarettes", "vapor", and "pregnancy" and enrolled five participants. Because many people were screening out from Ad set one, we added "baby shower" and "new moms" to the existing search terms in Ad set three and four and enrolled an additional nine participants. This may have influenced the reduction in per enrollment cost from ~\$165 (Ad sets one and two) to ~\$150 (Ad sets three and four). In Ad set five, we increased the daily money spent to \$300 (from \$200) and enrolled an additional three participants, but this resulted in a higher per enrollment cost of ~\$200. In Ad set six, daily money spent was reduced to \$150; the number of advertisements within an Ad set was reduced from three to one; and conversion window was reduced to one day from seven days. However, Ad set six enrolled no participants. In Ad set seven, we expanded age restriction from 18-25 to 18-50 but enrolled no additional participants. In Ad set eight, we moved up the conversion to screeners from the final webpage but this only resulted in enrolling one additional participant."

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).

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

Does your paper address subitem 5-x?

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

"With respect to human involvement, advertisement, screening, and enrollment into the study was purely web-based, and once enrolled, research assistant contacted the participants only via email and there were no on-site visits. "

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 ☐ ☐ ☐ ☐ ☐ 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

"The Facebook advertising tool placed messages in their feed selectively to target women who were likely to be pregnant and interested in e-cigarettes or vaping."

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 ☐ ☐ ☐ ☐ ☐ essential

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 were no co-intervention.

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

"An integral metric to determine the cost-effectiveness of conversion vs. traffic is "Cost per results", which can be found in the summary table provided in Facebook Ads Manager. Cost per results counts the number of results (e.g., conversion or traffic) a researcher received based on the settings for the ad. For example, if a researcher selected conversions as their campaign objective, the results metric may show the number of "View contents" that occurred due to someone seeing his or her ad. In the present study, for conversion, the cost per results was "View Contents". For traffic, the cost per result was "Link Clicks" and the cost was significantly lower."

"The survey instrument collected detailed information on (1) the exact type of e-cigarette device and e-liquid used, (2) the frequency and intensity of use for the 3 months before pregnancy and during each trimester of pregnancy. Eight weeks after the baby's due date, we requested a photograph of each participant's e-cigarette device to allow corroboration of self-report, and the baby's birthweight and gestational age from the mother's physician."

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

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

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

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

"Eight weeks after the mother's due date, we collected a photograph of each participant's e-cigarette device to allow corroboration of self-report and the baby's birth weight and gestational age from the participant's physician."

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

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

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

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

"An integral metric to determine the cost-effectiveness of conversion vs. traffic is "Cost per results", which can be found in the summary table provided in Facebook Ads Manager. Cost per results counts the number of results (e.g., conversion or traffic) a researcher received based on the settings for the ad. For example, if a researcher selected conversions as their campaign objective, the results metric may show the number of "View contents" that occurred due to someone seeing his or her ad. In the present study, for conversion, the cost per results was "View Contents". For traffic, the cost per result was "Link Clicks" and the cost was significantly lower."

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

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

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

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"Negative postings may influence the recruitment process since prospective respondents can see the unfavorable comments and might avoid the advertisement. We responded to negative comments from a Facebook user who later enrolled in the study. This user posted a comment on one of the advertisements in the Ad set three (September 4-8), questioning the ethical basis for this research on the presumption that a pregnant woman's e-cigarettes usage would have a negative effect on the baby. We responded to the post explaining the scientific rationale and ethical ground of this research (Figure 3). "

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 trial 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 ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 7a-i?

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

"Our initial plan was to enroll 30 participants and determine how many we were able to retain throughout the study."

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

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

"The recruitment was ceased after exhausting pre-determined budget allocated for recruitment."

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

n/a. The present study was not a randomized controlled trial.

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

n/a. The present study was not a randomized controlled trial.

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 present study was not a randomized controlled trial.

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

n/a. The present study was not a randomized controlled trial.

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).

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subitem not at all important	☐	☐	☐	☐	☐	essential

Does your paper address subitem 11a-i? *

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

n/a. The present study was not a randomized controlled trial.

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	☐	☐	☐	☐	☐	essential

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

n/a. The present study was not a randomized controlled trial.

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. The present study was not a randomized controlled 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

n/a. The present study was not a randomized controlled trial.

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	☐	☐	☐	☐	☐	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

n/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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

n/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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

X26-i) Comment on ethics committee approval

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subitem not at all important

☐☐☐☐☐

essential

Does your paper address subitem X26-i?

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

"The procedures presented in this paper were approved by Brown University's Institutional Review Board. All participants were required to provide informed consent to participate in this study."

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

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subitem not at all important

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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

"Safety and security procedures were elaborated in the informed consent form, which was collected online via Qualtrics. With respect to harms or unintended effects, we noted the only risk to you of participating would be if personal information about you or your baby reached people other than the researchers. We will be extremely careful to do everything we can to make sure that doesn't happen. Your data will be stored on a computer at Brown University, never on a laptop or memory stick. The data will only be seen by people on the research team who need to work with it or the Brown Institutional Review Board overseeing the study. There are no direct benefits to you from being in the study. However, you may be contributing to research that will help us provide more accurate information about e-cigarettes and health to expectant mothers in the future."

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

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

"Safety and security procedures were elaborated in the informed consent form, which was collected online via Qualtrics. With respect to harms or unintended effects, we noted the only risk to you of participating would be if personal information about you or your baby reached people other than the researchers. We will be extremely careful to do everything we can to make sure that doesn't happen. Your data will be stored on a computer at Brown University, never on a laptop or memory stick. The data will only be seen by people on the research team who need to work with it or the Brown Institutional Review Board overseeing the study. There are no direct benefits to you from being in the study. However, you may be contributing to research that will help us provide more accurate information about e-cigarettes and health to expectant mothers in the future."

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/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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

n/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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	☐	☐	☐	☐	☐	essential

Does your paper address subitem 13b-i?

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

"The flow diagram of Facebook advertisement clicks (n=3,891) to final enrollment (n=20) is illustrated in Figure 2."

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

Does your paper address CONSORT subitem 14a? *

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

"Participants were recruited between August 19, 2017 and October 26, 2017. "

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

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

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subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 14a-i?

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

“To our knowledge, there was no critical secular events (e.g., significant changes in Internet resources available) during this period.”

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 recruitment was ceased after exhausting pre-determined budget allocated for recruitment.”

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

“Demographic characteristics of the enrolled participants are shown in Table 3. ”

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

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

Does your paper address subitem 15-i? *

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

"The enrolled participants likely had high literacy level considering that 65% of the participants were at least 'some college' or above."

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions

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

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

Does your paper address subitem 16-i? *

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

"Of 3,891 Facebook users who clicked the advertisement, 1,349 (34.7%) completed the screener. Among the 1,349 participants who completed the screener, only 47 (3.1%) met the eligibility criteria. Among 1,349 participants who completed the screener, 92 (6.8 %) were dual users, 72 (5.3 %) used tobacco only, 105 (7.8 %) used e-cigarettes only, and 794 (58. 9%) used neither tobacco nor e-cigs. Among the 197 e-cigarette users, 98 of them (49.7%) were ineligible because low frequency of e-cigarette use (< 5 days per week). Most who completed the screener (1,267 or 95.6%) were pregnant, 59 (4.4%) were not pregnant, and 23 (1.7%) missing. Among those completing the screener, 1,051 (77.9%) were in their second or third trimester, 211 (15.6%) were in their first trimester, and 87 (6.4%) did not indicate a trimester. Taken altogether, there were 47 survey respondents, who simultaneously met all of the inclusion criteria who were then directed to the second page, "Informed Consent," and almost all did so (46/47), with 36 (78%) going on to complete the intake interview. "

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

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

	1	2	3	4	5	
subitem not at all important	☐	☐	☐	☒	☐	essential

Does your paper address subitem 16-ii?

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

n/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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

n/a. The present study was not a randomized controlled trial and we did not perform statistical analyses to quantify a difference.

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 ☐ ☐ ☐ ☐ ☐ 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

n/a. This was a non-randomized pilot study, which provides information to researchers who seek to recruit participants from rare populations using social media for studies with rather demanding protocols.

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

n/a. This was a non-randomized pilot study, which provides information to researchers who seek to recruit participants from rare populations using social media for studies with rather demanding protocols. We did not perform statistical analyses.

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

n/a. This was a non-randomized pilot study, which provides information to researchers who seek to recruit participants from rare populations using social media for studies with rather demanding protocols. We did not perform statistical analyses.

18-i) Subgroup analysis of comparing only users

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

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

Does your paper address subitem 18-i?

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

n/a. This was a non-randomized pilot study, which provides information to researchers who seek to recruit participants from rare populations using social media for studies with rather demanding protocols. We did not perform statistical analyses.

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

"With respect to harms or unintended effects, we noted the only risk to you of participating would be if personal information about you or your baby reached people other than the researchers. We will be extremely careful to do everything we can to make sure that doesn't happen. Your data will be stored on a computer at Brown University, never on a laptop or memory stick. The data will only be seen by people on the research team who need to work with it or the Brown Institutional Review Board overseeing the study. There are no direct benefits to you from being in the study. However, you may be contributing to research that will help us provide more accurate information about e-cigarettes and health to expectant mothers in the future."

19-i) Include privacy breaches, technical problems

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

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

Does your paper address subitem 19-i?

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

"With respect to harms or unintended effects, we noted the only risk to you of participating would be if personal information about you or your baby reached people other than the researchers. We will be extremely careful to do everything we can to make sure that doesn't happen. Your data will be stored on a computer at Brown University, never on a laptop or memory stick. The data will only be seen by people on the research team who need to work with it or the Brown Institutional Review Board overseeing the study. There are no direct benefits to you from being in the study. However, you may be contributing to research that will help us provide more accurate information about e-cigarettes and health to expectant mothers in the future."

19-ii) Include qualitative feedback from participants or observations from staff/researchers

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 19-ii?

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

"Negative postings may influence the recruitment process since prospective respondents can see the unfavorable comments and might avoid the advertisement. We responded to negative comments from a Facebook user who later enrolled in the study. This user posted a comment on one of the advertisements in the Ad set three (September 4-8), questioning the ethical basis for this research on the presumption that a pregnant woman's e-cigarettes usage would have a negative effect on the baby. We responded to the post explaining the scientific rationale and ethical ground of this research (Figure 3)."

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

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

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 22-i? *

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

"Results from this study may help to inform strategies used to recruit pregnant women who use e-cigarettes but not tobacco into a study with a protocol that has multiple, somewhat demanding components. Based on the results of the Facebook advertisements, the specific lesson learned from the present study regarding identifying rare populations was the importance of targeting criteria."

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

Highlight unanswered new questions, suggest future research.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 22-ii?

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

"A more integrated survey approach in which users attach the photo directly to the survey may be less burdensome and more successful. "

"Each of these components calls for evaluation of the study's burden, financial incentives, and privacy considerations."

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

20-i) Typical limitations in ehealth trials

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

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

Does your paper address subitem 20-i? *

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

"It is worth noting possibility of sampling bias such that Facebook users may not be representative of general population. A systematic review of this topic suggest that Facebook-recruited samples were generally representative of samples recruited through traditional methods, except socioeconomic status was higher among Facebook users [19]. Higher socioeconomic status among Facebook users has been also highlighted by a study that examined the representativeness of social media in Great Britain [20]. In addition, the requirements to read the consent form online and complete questionnaires online suggest that a relatively high literacy level, as well as high "Internet literacy", would be required for participation. Taken together, the present study may have recruited those with higher education level than general population. Finally, to the extent of our knowledge, a Facebook Ad user has no insight into Facebook's placement of the ads under either traffic or conversion tracking. As such, it is impossible to evaluate the potential for bias beyond our initial target criteria. As with other types of quota sampling, conversion or traffic tracking strategies monitor the returns as they come in, which allows a researcher to promptly modify the recruitment criteria to optimize the sampling bias."

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

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

Does your paper address subitem 21-i?

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

"It is worth noting possibility of sampling bias such that Facebook users may not be representative of general population. A systematic review of this topic suggest that Facebook-recruited samples were generally representative of samples recruited through traditional methods, except socioeconomic status was higher among Facebook users [19]. Higher socioeconomic status among Facebook users has been also highlighted by a study that examined the representativeness of social media in Great Britain [20]. In addition, the requirements to read the consent form online and complete questionnaires online suggest that a relatively high literacy level, as well as high "Internet literacy", would be required for participation. Taken together, the present study may have recruited those with higher education level than general population. Finally, to the extent of our knowledge, a Facebook Ad user has no insight into Facebook's placement of the ads under either traffic or conversion tracking. As such, it is impossible to evaluate the potential for bias beyond our initial target criteria. As with other types of quota sampling, conversion or traffic tracking strategies monitor the returns as they come in, which allows a researcher to promptly modify the recruitment criteria to optimize the sampling bias."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

1 2 3 4 5

subitem not at all important

☐
☐
☐
☐
☐

essential

Does your paper address subitem 21-ii?

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

n/a.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

"The funding for the study was provided by Brown University, Pilot Study of E-Cigarettes and Pregnancy Outcome (#1707001839)."

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

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 funding for the study was provided by Brown University, Pilot Study of E-Cigarettes and Pregnancy Outcome (#1707001839). Harold Lee was supported by National Heart Lung and Blood Institute (1F31HL140817)."

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

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

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

Does your paper address subitem X27-i?

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

"The authors declare that there is no conflict of interest."

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

- ☒ yes, major changes
- ☐ yes, minor changes
- ☐ no

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

As a result of using this checklist, we added information about human involvement.

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

4-5 hours.

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

☒ yes

☐ no

☐ Other:

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☐ yes

☒ no

☐ Other:

Any other comments or questions on CONSORT EHEALTH

Your answer

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