

# 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

Claire Spears

Primary Affiliation (short), City, Country \*

University of Toronto, Toronto, Canada

Georgia State University, Atlanta, GA, USA

Your e-mail address \*

[abc@gmail.com](mailto:abc@gmail.com)

cspears@gsu.edu

Title of your manuscript \*

Provide the (draft) title of your manuscript.

Mobile Delivery of Mindfulness-based Smoking Cessation among Low-Income Adults during the COVID-19 Pandemic: Pilot Randomized Controlled Trial



**Name of your App/Software/Intervention \***

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

iQuit Mindfully

**Evaluated Version (if any)**

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

Your answer

**Language(s) \***

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

English

**URL of your Intervention Website or App**

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

Your answer

**URL of an image/screenshot (optional)**

Your answer



**Accessibility \***

Can an enduser access the intervention presently?

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

**Primary Medical Indication/Disease/Condition \***

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Tobacco dependence

**Primary Outcomes measured in trial \***

comma-separated list of primary outcomes reported in the trial

Attendance, retention, participant feedback

**Secondary/other outcomes**

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

Stress (since this pilot study took place during the COVID-19 pandemic, we were also interested in individuals' experiences with stress and smoking)



**Recommended "Dose" \***

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

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- Other:

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

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- Other:



Overall, was the app/intervention effective? \*

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Other: Results support the feasibility and acceptability of the intervention in 1

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: 25926



## 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Title includes "mobile."





**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Title includes "smoking cessation."



## 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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 abstract includes: "A text messaging program, iQuit Mindfully, was created to deliver just-in-time support for quitting smoking among low-income adults. A pilot study of iQuit Mindfully was conducted in spring 2020, right in the midst of the COVID-19 pandemic among low-income and predominantly African American smokers.... This pilot study examined the acceptability and feasibility of delivering Mindfulness-Based Addiction Treatment via mHealth during the COVID-19 pandemic.... Participants ... were randomly assigned to either 8 weeks of iQuit Mindfully as a fully automated standalone intervention or iQuit Mindfully in combination with in-person group treatment. For participant safety, in-person mindfulness groups were transitioned online and assessments took place online."



**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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 abstract includes that participants were "randomly assigned to either 8 weeks of iQuit Mindfully as a fully automated standalone intervention or iQuit Mindfully in combination with therapist-led in-person group treatment."

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The abstract notes: "For participant safety, in-person mindfulness groups were transitioned online and assessments took place online."

### 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

Your answer

### 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

This is not applicable because this pilot study was designed to assess feasibility and acceptability. The study was not statistically powered to determine differences in smoking cessation rates between conditions.

## 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The introduction includes: "Mobile health technology (mHealth) could be useful for increasing access to mindfulness interventions. In particular, SMS text messaging can provide tailored, just-in-time interventions at relatively low cost. For that reason, a mindfulness intervention for smoking cessation, iQuit Mindfully, was implemented with strong feasibility and acceptability among low-income, predominantly African American adults [23]. The text messages were developed and iteratively refined through feedback from the target population [24]. They were designed to be personalized and interactive, and can be implemented as a standalone program or as a between-session enhancement to in-person MBAT."

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The introduction includes: "Mindfulness is defined as "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" [6; p. 4]. A meta-analysis of randomized controlled trials showed that 25.2% of participants receiving mindfulness interventions for smoking cessation were abstinent four months post-intervention as compared to 13.6% of participants receiving usual care [7]. Mindfulness interventions have been shown to reduce stress [8], improve social-relationship functioning [9], and promote self-efficacy for coping with negative emotions without smoking [10]. Furthermore, mindfulness appears to target addiction by weakening associations of stress and craving with addictive behavior [11-14]. That is, through mindfulness training people learn to purposefully respond to stress, craving, and other unpleasant sensations rather than impulsively reacting by smoking. Mindfulness is also thought to buffer the negative mental and physical health consequences of stress [15]. This is particularly relevant for marginalized populations who disproportionately experience both acute and chronic stressors [16].... There is still much work to be done to extend the reach and cost-effectiveness of mindfulness interventions. For example, Mindfulness-Based Stress Reduction (MBSR [21]), Mindfulness-Based Cognitive Therapy (MBCT) [22], and Mindfulness-Based Addiction Treatment (MBAT) [20] all involve eight weekly in-person group sessions, each lasting at least 2 hours. Mobile health technology (mHealth) could be useful for increasing access to mindfulness interventions. In particular, SMS text messaging can provide tailored, just-in-time interventions at relatively low cost. For that reason, a mindfulness intervention for smoking cessation, iQuit Mindfully, was implemented with strong feasibility and acceptability among low-income, predominantly African American adults [23]."

**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

The introduction includes: "Given that mindfulness training has been shown to promote more adaptive responses to stress and that treatment could be offered through mobile technology during shelter-in-place orders, iQuit Mindfully was expected to be acceptable and feasible during the COVID-19 pandemic."



## 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 Method section includes: "After informed consent and baseline assessment, participants were randomized into one of two treatment groups (in-person MBAT treatment + iQuit Mindfully text messages, n=12, or iQuit Mindfully alone, n=11)."

### 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

The manuscript includes: "In efforts to understand participants' experiences with the pandemic (and with the iQuit Mindfully intervention during this time), we added measures to assess their experiences specifically during COVID-19. Survey questions asked participants about changes in their smoking habits and quit attempts as well as their perceptions of the mindfulness and text messaging intervention in the context of the pandemic."





### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

### 4a) Eligibility criteria for participants



### Does your paper address CONSORT subitem 4a? \*

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

Eligibility criteria are described in the Methods section: "Inclusion criteria were: ages 18-65 years; able to speak, read and write in English; smoking at least five cigarettes per day; expired carbon monoxide (CO) >6ppm; motivated to quit smoking within 30 days; and at least sixth grade health literacy (Rapid Estimate of Adult Literacy in Medicine) [32]. Exclusion criteria were: contraindication for nicotine patches which were provided by the study; problematic substance use (Severity of Dependence Scale >4) [33, 34] or positive response on at least two of the five Patient Health Questionnaire (PHQ) Alcohol Abuse/Dependence Scale items [35]; clinically significant depressive symptoms (PHQ-2 >3 [36, 37]; self-reported diagnosis of schizophrenia or bipolar disorder or use of antipsychotic medications; and pregnancy or lactation. Individuals currently using tobacco cessation medications and regular (at least weekly) users of tobacco products other than cigarettes were also excluded, though participants were not excluded for e-cigarette use."

#### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer



#### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Recruitment procedures are described in the Methods section: "Recruitment involved study flyers in the metro-Atlanta area (e.g., downtown Atlanta, near train and bus stops, in local community health centers) and posted online (e.g., Craigslist and neighborhood listservs). Although eligibility was not determined based on income, recruitment targeted low-income adults."

#### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

### 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

The manuscript describes: "Participants completed in-person assessments at baseline. Remote assessments took place online at weeks 8 (end of treatment), 9 (follow-up), and 10 (COVID-19 survey) due to shelter-in-place restrictions."

#### 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

The manuscript describes: "Participants completed in-person assessments at baseline. Remote assessments took place online at weeks 8 (end of treatment), 9 (follow-up), and 10 (COVID-19 survey) due to shelter-in-place restrictions."



**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

### 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

The manuscript describes that "the text messages were developed and iteratively refined through feedback from the target population" (with a citation to a manuscript that details the formative work).

### 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

Your answer

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

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](http://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.

subitem not at all important      1      2      3      4      5      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

Your answer





### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The Methods section indicates: "Individuals did not have to own a mobile phone in order to participate; they were given the choice of using their own mobile phone or one provided by the study."

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The interventions are described in detail under "Interventions" in the Methods section. The theoretical framework supporting the use of mindfulness for smoking cessation is described in the Introduction.

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The frequency of text messaging is described under "iQuit Mindfully" under "Interventions."

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | essential |



### Does your paper address subitem 5-x?

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

The Method section includes: "Participants in the MBAT + iQuit Mindfully condition also received eight weekly 2-hour group sessions, by a certified MBSR teacher and licensed professional counselor." For the iQuit Mindfully standalone condition, the following description is provided: "After the initial set-up on the Upland Mobile Messaging platform, the text message intervention was fully automated."

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Text message prompts are described under "iQuit Mindfully" within "Interventions."



**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Mindfulness-Based Addiction Treatment (MBAT) is described in detail under "Interventions."

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

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

The manuscript describes: "The a priori outcomes for this feasibility study were treatment attendance, retention, and participant feedback about the interventions." Actual measures are described in detail in the "Measures" section.



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

Your answer

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

Your answer



### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | essential |

### Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Qualitative feedback was obtained through individual surveys (described in the "Measures" section).

### 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

The manuscript describes: "The a priori outcomes for this feasibility study were treatment attendance, retention, and participant feedback about the interventions. Because of the onset of the COVID-19 pandemic and our shift to remote intervention and assessment, this manuscript also focuses on participants' experiences specifically in the context of COVID-19."

### 7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care providers 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

This was a pilot feasibility study that was not designed to have adequate statistical power.

**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

This was a pilot feasibility study without interim analysis.

**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

The manuscript describes: "Co-author MJH generated the random allocation sequence using SAS Software System, Version 9.4."

**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

The manuscript describes: "Stratified block randomization was implemented with block sizes of 4 and stratification by race and poverty status."

**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

The manuscript describes: "A research staff member (unaware of the size of the blocks) assigned participants to interventions using opaque sealed envelopes marked according to the allocation schedule."





## 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

The manuscript describes: "Co-author MJH generated the random allocation sequence using SAS Software System, Version 9.4. A research staff member (unaware of the size of the blocks) assigned participants to interventions using opaque sealed envelopes marked according to the allocation schedule."

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

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

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

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

1            2            3            4            5

subitem not at all important                        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

The manuscript describes: "Apart from members of the research team who were unmasked to handle randomization and delivery of interventions, other study personnel were masked to treatment condition."



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

Your answer

**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

The manuscript describes that both conditions received the iQuit Mindfully text message intervention, but only those in the MBAT + iQuit Mindfully condition also received eight weeks of MBAT treatment.

**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

Statistical methods are described under "Data Analysis."

**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

The Methods section describes: "Missing data were not coded as smoking because of the bias that can be associated with this "missing = smoking" assumption."

**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

Additional analyses were not conducted.

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

|                              |                       |                       |                       |                       |                       |           |
|------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------|
|                              | 1                     | 2                     | 3                     | 4                     | 5                     |           |
| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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 manuscript describes: "The study was approved by the Georgia State University Institutional Review Board (H19243), and all participants provided written informed consent."



### x26-ii) Outline informed consent procedures

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

1            2            3            4            5

subitem not at all important                        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

Your answer

### 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

Your answer

## 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

This information is described in the text and in the CONSORT flow diagram (Figure 1).

**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

This is shown in the CONSORT flow diagram (Figure 1).

**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

Your answer

### 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

The manuscript describes: "Participants were enrolled in January and February 2020 and began the 8-week treatment on February 13, 2020 in Atlanta, Georgia."

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

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

1            2            3            4            5

subitem not at all important                        essential



**Does your paper address subitem 14a-i?**

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

The following description is provided: "Participants were enrolled in January and February 2020 and began the 8-week treatment on February 13, 2020 in Atlanta, Georgia.... During this time, the novel coronavirus disease 2019 (COVID-19) pandemic began to significantly impact the U.S. By the middle of March 2020 all 50 states reported confirmed COVID-19 cases [25]. At that time the governor of Georgia declared a Public Health State of Emergency for COVID-19 and a few weeks thereafter a mandatory shelter-in-place was issued statewide. For participant safety, the in-person mindfulness groups were transitioned online (via WebEx, although participants chose to join via audio only), and all assessments took place online."

**14b) Why the trial ended or was stopped (early)****Does your paper address CONSORT subitem 14b? \***

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

The trial was not stopped early.

**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

This is provided in Table 1.





**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

This is shown in Table 1. In addition, the manuscript describes: "This study aimed to recruit a racially/ethnically diverse sample of predominantly low-income adult cigarette smokers."

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Denominators are provided throughout.

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

**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

Results are provided for each group. As this is a small pilot study, confidence intervals are not relevant.



### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

### 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

This is a pilot study without adequate statistical power to determine differences between groups, but exact numbers of participants who quit smoking are provided for both groups.

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



**Does your paper address CONSORT subitem 18? \***

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

The manuscript describes: "The a priori outcomes for this feasibility study were treatment attendance, retention, and participant feedback about the interventions. Because of the onset of the COVID-19 pandemic and our shift to remote intervention and assessment, this manuscript also focuses on participants' experiences specifically in the context of COVID-19."

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer

**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

The text messaging program did not have adverse effects that we are aware of.

**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

Your answer

**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

Qualitative feedback is included in the Results section.

## 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

This is provided under "Principal Findings" in the Discussion section.



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

Highlight unanswered new questions, suggest future research.

|                              |                       |                       |                       |                       |                       |           |
|------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------|
|                              | 1                     | 2                     | 3                     | 4                     | 5                     |           |
| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Suggestions for future research are provided (e.g., "whether income or other sociodemographic variables moderate the effectiveness of the intervention").

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

These are described in the "Limitations" paragraph of the Discussion section.

### 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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Your answer





### 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

Your answer

### 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

This study was not registered on clinicaltrials.gov because it was funded by the U.S. National Institutes of Health (NIH) and this pilot study is not considered a clinical trial according to the NIH definition. NIH made this determination for our study based on NIH Case Study #29, in which case a randomized trial is not a clinical trial if it is designed to assess feasibility (<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>).

Specifically:

- "Does the study involve human participants? Yes, the study involves human participants.
- Are the participants prospectively assigned to an intervention? Yes, the participants are prospectively assigned to a behavioral intervention.
- Is the study designed to evaluate the effect of the intervention on the participants? No, the study is not designed to evaluate the effect of the behavioral intervention on the participants. It is designed to assess user acceptability.

**24) Where the full trial protocol can be accessed, if available****Does your paper address CONSORT subitem 24? \***

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

The protocol is available from the corresponding author upon reasonable request.

**25) Sources of funding and other support (such as supply of drugs), role of funders**

**Does your paper address CONSORT subitem 25? \***

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

This is provided under "Acknowledgements."

**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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

A "Conflicts of Interest" section is included.

**About the CONSORT EHEALTH checklist**



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

- yes, major changes
- yes, minor changes
- no

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

Added information about masking/blinding.

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

3 hours

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

- yes
- no
- Other:



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

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

- yes
- no
- Other:

Clear selection

### Any other comments or questions on CONSORT EHEALTH

Your answer

### STOP - Save this form as PDF before you click submit

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

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

Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!

### Final step: Click submit !

Click submit so we have your answers in our database!

Submit

Never submit passwords through Google Forms.

This content is neither created nor endorsed by Google. [Report Abuse](#) - [Terms of Service](#) - [Privacy Policy](#).

Google Forms

