

# 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

\* Erforderlich

Your name \*

First Last

Philipp Schwaninger

Primary Affiliation (short), City, Country \*

University of Toronto, Toronto, Canada

University of Zurich, Zurich, Switzerland

Your e-mail address \*

abc@gmail.com

philipp.schwaninger@psychologie.uzh.ch

Title of your manuscript \*

Provide the (draft) title of your manuscript.

**Effectiveness of a dyadic buddy app for smoking cessation: Results of a 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.

SmokeFree buddy app



**Evaluated Version (if any)**

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

Version 4.0

**Language(s) \***

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

German, French, Italian

**URL of your Intervention Website or App**

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

<https://apps.apple.com/ch/app/smokefree-buddy-arreter-fumer/id955186104?l=de>; <https://>

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

<https://www.smokefree.ch/en/buddy-app/>

**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
- Sonstiges:

**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)"

Smoking cessation

**Primary Outcomes measured in trial \***

comma-separated list of primary outcomes reported in the trial

Self-reported smoking abstinence, carbon mo

**Secondary/other outcomes**

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

Smoked cigarettes per day (CPD)

**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"
- Sonstiges:



**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%
- Sonstiges:

**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
- Sonstiges:



**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
- Sonstiges:

**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
- Sonstiges:



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
- Sonstiges: 27162

## 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
- Sonstiges:



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

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

1            2            3            4            5

subitem not at all important                        essential

**Does your paper address subitem 1a-i? \***

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

**Title: "dyadic buddy app"; Manuscript: "The SmokeFree buddy app is available for free in the App Store and Google Play Store (Version 4.0)"**

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

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

1            2            3            4            5

subitem not at all important                        essential

**Does your paper address subitem 1a-ii?**

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

**The item is not applicable for our study, because there is no co-intervention.**





**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

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**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: "for 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)

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**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

**Key component of the intervention: "the IG used the SmokeFree buddy app, a multicomponent app that in particular facilitates social support from a buddy of choice"**

**Key component of the comparator: "(...) daily exhaled CO assessments. This assessment was administered via an app displaying results of exhaled CO, thus addressing self-monitoring in both groups."**

**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)

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**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 key component of the intervention is the involvement of a buddy of choice: "a multicomponent app that in particular facilitates social support from a buddy of choice."**



**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)

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**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

**"single-blind" trial; Outcomes were self-assessed through daily questionnaires: "end-of-day diaries"; Primary outcomes objectively assessed: "Daily smoking abstinence was verified via daily exhaled CO assessments."**

**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)

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**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

**"A total of 162 adult smokers participated in this single-blind, two-arm, parallel-group, intensive longitudinal RCT."; "Overall, low SmokeFree buddy app engagement and low reported perceived usefulness were observed."**

**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)

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**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

**"The SmokeFree buddy app did not have beneficial effects on smoking over and above the self-monitoring control condition. Future studies should examine whether and what support processes can effectively be stimulated and how app use can be improved to better achieve this goal."**

**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)

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**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

"Apps are promising means for smoking cessation interventions. However, there is a need for controlled trials in participants' daily life to evaluate the effectiveness of smoking cessation apps. Further, available apps have mainly neglected content regarding social support, although enabling social support resources is a key behavioral intervention component in smoking cessation treatment and may be provided via app when it is most needed."

**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.

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**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

**"A recent review of five studies testing the effectiveness of smoking cessation apps has shown no clear evidence for increasing quit rates. A body of scientific evidence on the effectiveness of smoking cessation apps is lacking. We echo the conclusion of the authors that more RCTs with long-term follow-ups (at least 6 months [Russell Standard]) are needed to provide evidence on the effectiveness of smoking cessation apps."**

**2b) In INTRODUCTION: Specific objectives or hypotheses****Does your paper address CONSORT subitem 2b? \***

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

**"This RCT examines, whether the SmokeFree buddy app promotes daily abstinence rates and reduces CPD in adult smokers at a self-set quit date, 3 weeks (end of intervention) and 6 months later in comparison to a control group which does not use the SmokeFree buddy app. We hypothesized that adult smokers in the intervention group will show higher daily abstinence rates and lower CPD at the self-set quit date, 3 weeks later (end of intervention) and 6 months later compared to the control group (hypothesis 1). (...) we additionally assumed a higher increase of daily abstinence rates and a higher decrease of CPD over time in the intervention group than the control group (hypothesis 2)."**

**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

"We conducted a single-blind, two-arm, parallel-group, intensive longitudinal randomized controlled trial (...); "The interviewer conducting the BA randomly assigned participants to one of the two groups (intervention [IG] and control group [CG]), according to a computer-generated allocation sequence that was concealed in a set of sealed, numbered envelopes. Participants were blinded to the group assignment (i.e., single-blind RCT; for the detailed randomization procedure see the study protocol)."

**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 item is not applicable, because there were no changes to methods after trial commencement.

**3b-i) Bug fixes, Downtimes, Content Changes**

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

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**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

**The item is not applicable, because there were no changes made on the intervention or comparator during the trial and no other unexpected events.**

**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

**"Participants were adult smokers smoking at least one cigarette per day, intending to quit smoking during the study and owning a smartphone with access to mobile internet. Exclusion criteria were insufficient knowledge of the German language, working in 24-hour shifts, usage of a smoking cessation app or participation in a professional smoking cessation program."**

**4a-i) Computer / Internet literacy**

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

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**Does your paper address subitem 4a-i?**

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

The item is not applicable, because computer/internet literacy was not an implicit "de facto" eligibility criterion.

**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.

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**Does your paper address subitem 4a-ii? \***

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

"Participants were recruited via advertisements in newspapers, online platforms, on webpages, and flyers at the university, medical facilities and local companies from April 2018 until August 2019 in Switzerland."; There were face-to-face components: Participants were invited to the lab for a background assessment (BA), set a quit date and were instructed to the iCO Smokerlyzer and to the SmokeFree buddy app (intervention group only). The other assessments were web-based: end-of-day diary questionnaires: "The trial consisted of a baseline diary (3 consecutive days), a background assessment (BA), a challenge diary from 7 days before the self-set quit date until 20 days after the self-set quit date (28 consecutive days) and a follow-up diary 6 months after the self-set quit date (3 consecutive days)."



**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.

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**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

Meine Antwort

**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 RCT took place in Switzerland and data were collected at the University of Zurich (background assessment) and in participants' daily life.

**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.

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**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

**Primary outcomes: "Participants indicated in a daily evening diary questionnaire whether they smoked that day or not by answering the question "Did you smoke today (including only one puff)?" (coded as 0 = yes and 1 = no). To assess the smoking abstinence objectively, participants were instructed to assess exhaled CO with their personal iCO Smokerlyzer® (Bedfont Scientific Ltd.) on a daily basis."; Secondary outcome: "If participants answered the smoking abstinence measure with yes (= today smoked), they were asked to report how many cigarettes they had smoked that day. Otherwise, the daily number of cigarettes smoked was coded as 0."**

**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)

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**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

**Meine Antwort**

**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

"The SmokeFree buddy app was developed by the Federal Office of Public Health in Switzerland in collaboration with the Institute of Global Health of the University of Geneva in Switzerland."

### 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.

|                              |                       |                       |                       |                       |                       |           |
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| 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-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

Meine Antwort



**5-iii) Revisions and updating**

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

|                              |                       |                       |                       |                       |                       |           |
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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

The RCT evaluated Version 4.0 of the SmokeFree buddy app: "The SmokeFree buddy app is available for free in the App Store and Google Play Store (Version 4.0)."

**5-iv) Quality assurance methods**

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

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| 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

Meine Antwort



**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.

|                              |                       |                       |                       |                       |                       |           |
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| 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

Meine Antwort

**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.

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| 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-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

Meine Antwort



**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).

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| 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

**Participants had free access to the Smokefree buddy app via App Store and Google Play Store: "The SmokeFree buddy app is available for free in the App Store and Google Play Store (Version 4.0)."**

**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].

|                              |                       |                       |                       |                       |                       |           |
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| 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 manuscript describes relevant information: "The SmokeFree buddy app was developed by the Federal Office of Public Health in Switzerland in collaboration with the Institute of Global Health of the University of Geneva in Switzerland. The app is designed to be used simultaneously by a smoker and a personal buddy of choice. A chat function is the direct communication channel and connects the smoker and the personal buddy. The app provides evidence-informed background information as well as pre-set supportive messages for the buddy which can be customized or supplemented with a personal comment. Further, a knowledge base contains information on smoking and quitting and a performance statistic shows the smokers' achievement to date (e.g., number of smoke-free days). For more details about the SmokeFree buddy app, please see the study protocol."; Please see the "intervention" section in the manuscript for further description of the intervention components and comparator (e.g., BCTs).

**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.

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**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

Meine Antwort





**5-x) Clarify the level of human involvement**

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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| subitem not at all important | <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

**Meine Antwort**

**5-xi) Report any prompts/reminders used**

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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| subitem not at all important | <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

**This item is not applicable, because no prompts/reminders were used.**



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

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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subitem not at all important                        essential

**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

**This item is not applicable, because no co-interventions were provided.**

**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

"Primary outcome: Daily smoking abstinence (self-reported and CO-verified). Participants indicated in a daily evening diary questionnaire whether they smoked that day or not by answering the question "Did you smoke today (including only one puff)?" (coded as 0 = yes and 1 = no). To assess the smoking abstinence objectively, participants were instructed to assess exhaled CO with their personal iCO Smokerlyzer® (Bedfont Scientific Ltd.) on a daily basis. (...) Secondary outcome: Cigarettes per day (CPD). If participants answered the smoking abstinence measure with yes (= today smoked), they were asked to report how many cigarettes they had smoked that day. Otherwise, the daily number of cigarettes smoked was coded as 0."; "The trial consisted of a baseline diary (3 consecutive days), a background assessment (BA), a challenge diary from 7 days before the self-set quit date until 20 days after the self-set quit date (28 consecutive days) and a follow-up diary 6 months after the self-set quit date (3 consecutive days)."

**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].

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| 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-i?**

Copy and paste relevant sections from manuscript text

Meine Antwort



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

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

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**Does your paper address subitem 6a-ii?**

Copy and paste relevant sections from manuscript text

Meine Antwort

**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).

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| 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

Meine Antwort

**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 item is not applicable, because trial outcomes did not change after the trial commenced.**

**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                        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

Meine Antwort

**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

**Item is not applicable, because no interim analyses were conducted and no stopping guidelines were set.**

**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

**Before the beginning of the study, a computerized random-number generator (<http://www.randomization.com>) was used for sequence generation of blocks. This allocation sequence was generated by an assistant not part of the study team and to ensure allocation concealment concealed in a set of sealed, numbered envelopes until group assignment; "The interviewer conducting the BA randomly assigned participants to one of the two groups (intervention [IG] and control group [CG]), according to a computer-generated allocation sequence that was concealed in a set of sealed, numbered envelopes."**

**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

**Blocking as means of restricted randomization was used: To meet balance and predictability criteria variable blocks (4, 6, 8) were used. Within a block of participants, 50% are assigned to the intervention group and the control group; "(...) for the detailed randomization procedure see the study protocol)."**

**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 allocation sequence was generated by an assistant not part of the study team and to ensure allocation concealment concealed in a set of sealed, numbered envelopes until group assignment; "The interviewer conducting the BA randomly assigned participants to one of the two groups (intervention [IG] and control group [CG]), according to a computer-generated allocation sequence that was concealed in a set of sealed, numbered envelopes. Participants were blinded to the group assignment (i.e., single-blind RCT (...))."**

**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 allocation sequence was generated by an assistant not part of the study team and to ensure allocation concealment concealed in a set of sealed, numbered envelopes until group assignment; "The interviewer conducting the BA randomly assigned participants to one of the two groups (intervention [IG] and control group [CG]), according to a computer-generated allocation sequence that was concealed in a set of sealed, numbered envelopes. Participants were blinded to the group assignment (i.e., single-blind RCT (...))."

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

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

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

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

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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 interviewer conducting the BA randomly assigned participants to one of the two groups (intervention [IG] and control group [CG]), according to a computer-generated allocation sequence that was concealed in a set of sealed, numbered envelopes. Participants were blinded to the group assignment (i.e., single-blind RCT (...))."



**11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”**

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Meine Antwort

**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

Item is not applicable/relevant.

**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

**"To account for the nested structure of repeated measures within individuals, multilevel modelling was used."; "To investigate the intervention effect 6 months after the quit date, group differences regarding the primary and secondary outcome measures were examined by conducting independent samples t-tests (averaged days 1-3 of the follow-up diary phase per person)."**

**12a-i) Imputation techniques to deal with attrition / missing values**

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

**"In line with recommended outcome criteria in smoking cessation trials (Russell Standard), our final models included all randomized subjects (intention-to-treat). Participants lost to the challenge or follow-up diary phase were treated as smokers for analysis with the primary outcome variables (daily abstinence measures = 0 [not abstinent]). Intermittent missing values were handled by maximum likelihood (ML) estimations."**

**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

**For sensitivity analyses, multilevel modelling was used.**

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

**X26-i) Comment on ethics committee approval**

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| subitem not at all important | <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

**Meine Antwort**

**x26-ii) Outline informed consent procedures**

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

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Meine Antwort

**X26-iii) Safety and security procedures**

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

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Meine Antwort

**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

**"In line with recommended outcome criteria in smoking cessation trials (Russell Standard), our final models included all randomized subjects (intention-to-treat)."**

**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

**For the flow diagram, please see Figure 1 in the manuscript.**

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

**Meine Antwort**



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

Does your paper address CONSORT subitem 14a? \*

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

"Participants were recruited via advertisements in newspapers, online platforms, on webpages, and flyers at the university, medical facilities and local companies from April 2018 until August 2019 in Switzerland."; "(...) a follow-up diary 6 months after the self-set quit date (...)."

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

Meine Antwort

**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 item is not applicable, because the trial not ended or 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

**For a table with baseline demographic characteristics, please see Table 1 in the manuscript.**

**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.

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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

**Please see Table 1 in the manuscript.**



**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

**Please see the sample description in the results section in the manuscript.  
Number of participants included in each analysis are described. Please see also  
Table 3 and 4.**

**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

Meine Antwort

**17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)**

**Does your paper address CONSORT subitem 17a? \***

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

Please see Table 3 and 4 for results and the estimated effect sizes with 95% confidence intervals.

**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

Meine Antwort

**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

For effect sizes, please see the section "intervention effects at the quit date and end of intervention" and Table 3 in the manuscript.

**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

Please see Table A2, Table A3 and Table A4 in the supplement.



**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).

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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

Meine Antwort

**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

**Both groups significantly reduced their smoking behavior. The item is not applicable, because no unintended effects were observed.**



**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].

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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 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

**Meine Antwort**

**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.

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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 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

**Meine Antwort**



**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).

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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-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

**Study questions and hypotheses were restated and answers suggested by the data summarized.**

**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

Meine Antwort

**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.

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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

Typical limitations are discussed: e.g., "(...) data indicated a low app engagement that may have limited potential intervention effects."

**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

|                              |                       |                       |                       |                       |                       |           |
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|                              | 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

Meine Antwort

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

Meine Antwort

**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

**"Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN) 11154315; <https://www.isrctn.com/ISRCTN11154315>."**

**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

**<https://doi.org/10.1186/s12889-019-7723-z>**

**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

**"Janina Lüscher (CR1211\_166348/1) was funded by the Swiss National Science Foundation (SNSF) while writing this manuscript. The assessment of Flurry Analytic data was supported by the Federal Office of Public Health. The funder played no role in the design of the study, the analysis and the interpretation of data and in writing the manuscript"**



**X27) Conflicts of Interest (not a CONSORT item)****X27-i) State the relation of the study team towards the system being evaluated**

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

1            2            3            4            5

subitem not at all important                        essential

**Does your paper address subitem X27-i?**

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

Meine Antwort

**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?

No changes yet

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

half day

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

\*

- yes
- no
- Sonstiges: **Manuscript already submitted**

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
- Sonstiges:

**Auswahl löschen**

Any other comments or questions on CONSORT EHEALTH

Meine Antwort



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