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

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating webbased 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: <a href="http://www.jmir.org/2011/4/e126/">http://www.jmir.org/2011/4/e126/</a>

doi: 10.2196/jmir.1923 PMID: 22209829

\*Required

### Your name \*

First Last

Kathleen Walsh

### Primary Affiliation (short), City, Country \*

University of Toronto, Toronto, Canada

University of Toronto Scarborough, Toro

### Your e-mail address \*

abc@gmail.com

k.walsh@mail.utoronto.ca

### Title of your manuscript \*

Provide the (draft) title of your manuscript.

Effects of a Mindfulness-Meditation App on Subjective Well-Being: An Active Randomized Controlled Trial and Experience Sampling Study

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

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

Wildflowers Mindfulness

### **Evaluated Version (if any)**

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

Your answer

### Language(s) \*

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

**English** 

### URL of your Intervention Website or App \*

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

https://itunes.apple.com/ca/app/wildflc

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
<ul> <li>access is open to everyone, but requires payment/subscription/in-app purchases</li> </ul>
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)"  Psychological Well-Being
Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial
well-being, attentional control, interocep
Secondary/other outcomes  Are there any other outcomes the intervention is expected to affect?

Your answer

Recommended "Dose" * What do the instructions for users say on how often the app should be used?
Approximately Daily
Approximately Weekly
Approximately Monthly
Approximately Yearly
o "as needed"
Other:
Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
unknown / not evaluated
0-10%
<ul><li>0-10%</li><li>11-20%</li></ul>
O 11-20%
<ul><li>11-20%</li><li>21-30%</li></ul>
<ul><li>11-20%</li><li>21-30%</li><li>31-40%</li></ul>
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<ul> <li>☐ 11-20%</li> <li>☐ 21-30%</li> <li>☐ 31-40%</li> <li>☐ 41-50%</li> <li>☐ 51-60%</li> <li>☐ 61-70%</li> <li>☐ 71%-80%</li> </ul>

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



### 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	
$\bigcirc$	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	0	0	0	$\circ$		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

The title includes "Mindfulness-Meditation App"

# 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").

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subitem not at all important

O O 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

This item is not applicable to the study as there were no non-web-based components accompanying the intervention app.

### 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

### 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

"Effects of a Mindfulness-Meditation App on Subjective Well-Being".

## 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	0	0	0	$\bigcirc$		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 present study investigated a newly developed MT [mindfulness training] application called Wildflowers, which was co-developed with the lab for use in mindfulness research" and "Undergraduate students completed 3-weeks of MT with Wildflowers (n=45), or 3-weeks of mathematical problem-solving training with a game called 2048 (n=41)".

# 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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subitem not at all important	$\circ$	$\circ$		$\circ$	$\circ$	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

We do not consider this information relevant for the abstract, but it is included in the body of the manuscript that participants had human contact with our research assistants before and after 3-weeks of training for assessment of subjective well-being, attentional control, and interoceptive integration.

# 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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subitem not at all important	0	0	$\circ$	$\circ$		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

"Undergraduate students completed 3-weeks of MT with Wildflowers (n=45), or 3-weeks of mathematical problem-solving training with a game called 2048 (n=41). State training effects were assessed through pre- and post-session ratings of current mood, stress level, and heart rate. Trait training effects were assessed through pre- and post-intervention questionnaires canvassing subjective well-being, and behavioural task measures of attentional control and interoceptive integration."

### 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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subitem not at all important	0	$\bigcirc$	$\bigcirc$	$\bigcirc$		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

"Undergraduate students completed 3-weeks of MT with Wildflowers (n=45), or 3-weeks of mathematical problem-solving training with a game called 2048 (n=41)."

### 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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subitem not at all important O O 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

Does not apply.

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 standalone 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)

### 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

"Despite well-established benefits of mindfulness-based interventions, and some understanding of the mechanisms involved, [mindfulness training] dissemination can be difficult. For example, MBCT and MBSR require a commitment of weekly meetings and at-home practice of learned mindfulness skills for 8-weeks [3,18,19]. Moreover, these interventions are costly and not easily accessible due to the requirement of therapists to implement these interventions [20,21]. ....Computer delivered mindfulness-based interventions have proven to be successful in reducing anxiety, depression, and stress [20], and a variety of mindfulness based smartphone applications have been developed that seek to replicate the success of group interventions [27]. [W]hile smartphone apps are scalable and accessible to a wider swath of population, their benefits remain largely untested."

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

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

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subitem not at all important	0	0	$\bigcirc$	$\bigcirc$		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

"Computer delivered mindfulness-based interventions have proven to be successful in reducing anxiety, depression, and stress [20], and a variety of mindfulness based smartphone applications have been developed that seek to replicate the success of group interventions [27]. ... Yet despite a booming user base, only two randomized controlled trials have investigated the efficacy of smartphone apps for MT, and only one of these trials used an active control group. ... Although these studies found some benefits from using these MT applications, they both relied solely on subjective self-reports, which may be confounded with participant expectancy. ... Moreover, these studies investigated the effects of MT while only comparing longitudinal 'trait' outcomes without evaluating the local or 'state' effects of meditation sessions. Exploring state effects may be useful in demonstrating the immediate benefits of MT by limiting retrospective bias."

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

"With few investigations of the effectiveness of [mindfulness training] applications on well-being, further research is warranted. The goal of this current study was to better evaluate the local and longitudinal effects of app-delivered [mindfulness training] relative to a randomized active-control group. ...It was hypothesized that [mindfulness training] via a smartphone app would improve trait subjective well-being and behavioural indices of attention, albeit with weaker effects than those published in the group intervention [mindfulness training] literature. Additionally, it was expected that beneficial state [mindfulness training] effects would be observed on mood, heart rate, and perceived stress, suggesting the immediate benefits of brief mindfulness meditation."



# 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

"Undergraduate students were recruited from the University of Toronto Mississauga and randomly assigned to train with one of two smartphone applications: Wildflowers, a mindfulness training (MT) application, or 2048, a mathematical training application that was used as an active control condition. ...Upon recruitment, each participant was asked to come in to the laboratory to complete self-report questionnaires of well-being through an online survey platform called qualtrics.com, and complete behavioural measures of attentional and interoceptive integration on a computer in the laboratory. ...After 3-weeks of training, using their assigned application for at least 10-minutes per day, each participant returned to the laboratory to re-take the self-report questionnaires and behavioural measures of attentional control and interoceptive integration."

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



### Does your paper address CONSORT subitem 3b? \*

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

No important changes to methods were made after the trial started.

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

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

### Does your paper address subitem 3b-i?

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

There was one bug fix that occurred when participant data being recorded in the app was not being saved and sent to the experimenters. However, this only affected a couple of participants, which were excluded from the analyses of this data.

4a) Eligibility criteria for participants



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

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

"To be eligible to participate in the current study, participants were expected to: (a) have normal or corrected-to-normal vision and hearing, (b) be 18 years of age or older, (c) be fluent in English, and (d) own an iPhone, iPad, or iPod with access to internet."

Computer / Internet li explicitly clarified.	teracy is o	ften an impl	icit "de facto	o" eligibility o	riterion - this	s should be
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subitem not at all important	0	0	0	0	•	essential
Does your pap					es in quotat	ion marks "like thi

4a-i) Computer / Internet literacy

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

Access to the internet was required to use the mobile app, and as such was part of the stated eligibility criteria, "(d) own an iPhone, iPad, or iPod with access to internet". Additionally, "participants downloaded their assigned application and made sure it was working on their phone and they knew how to use it" before continuing on in the study.

### 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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subitem not at all important	$\bigcirc$	0	$\circ$	0		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

"Undergraduate students were recruited from the University of Toronto Mississauga." The recruitment of undergraduate students at the University of Toronto is typically conducted via flyers around campus or through an online participant recruitment system. Additionally, "[u]pon recruitment, each participant was asked to come in to the laboratory to complete self-report questionnaires of well-being through an online survey platform called qualtrics.com, and complete behavioural measures of attentional and interoceptive integration on a computer in the laboratory. ... After 3-weeks of training, using their assigned application for at least 10-minutes per day, each participant returned to the laboratory...".

### 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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subitem not at all important	0	$\bigcirc$		$\circ$	$\circ$	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

"Before participating in the study, undergraduate students gave written informed consent."

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

"Undergraduate students were recruited from the University of Toronto Mississauga..."

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

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in webbased 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

Subjective well-being was self-assessed through "self-report questionnaires of well-being through an online survey platform called qualtrics.com" completed on a computer in the lab, and "behavioural measures of attentional control and interoceptive integration" were also completed "on a computer in the laboratory". "Ratings of current mood, stress level, and heart rate were recorded within each app before and after each training session".

### 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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subitem not at all important	0	$\circ$		$\circ$	$\circ$	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

Undergraduate students were recruited from the University of Toronto Mississauga knowing that they were participating in a study being conducted at the University of Toronto Mississauga.

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).

### 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

Wildflowers Mindfulness was co-developed with our lab at the University of Toronto Mississauga and Mobio Interactive. The control math training condition was a popular open source game on the apple app store called 2048.

### 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.

### 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

This is not applicable to the present study.

### 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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### 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

No major changes on the intervention were made during the trial.

# 5-iv) Quality assurance methods Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable. 1 2 3 4 5 subitem not at all important 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

The intervention was relatively simple to use. Additionally, "participants downloaded their assigned application and made sure it was working on their phone and they knew how to use it" before they continued on with the study.

# 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.



### 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

This is not relevant for our trial as Wildflowers is freely available for download on the apple app store. Screenshots are provided in the multimedia appendix.

### 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, <a href="webcitation.org">webcitation.org</a>, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

	1	2	3	4	5	
subitem not at all important	0	$\bigcirc$		$\bigcirc$	$\bigcirc$	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

This is an un-archived link: https://itunes.apple.com/ca/app/wildflowers-mindfulness/id988835763?mt=8.

### 5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

	1	2	3	4	5	
subitem not at all important	0	0	0	0		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 did not have to pay to download the intervention. However, they were given a special code to download the intervention from the apple app store so their data recorded in the app could be tracked by the experimenters.

### 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	0	$\circ$	$\bigcirc$	$\bigcirc$		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

"Mindfulness training in the study was performed using a new app called Wildflowers (Mobio Inc., Toronto), that was developed in collaboration with our lab. This smartphone app incorporates features that have been deemed to be important to include in smartphone MT, as suggested by Mani and colleagues [27]. For example, Wildflowers includes guided meditations such as breathing, body scans, and open monitoring practices, and also provides didactic content in the form of lessons and information about the benefits of MT. Additionally, the app was designed to collect user's ratings of current mood and stress level, as well as heart rate, before and after each guided meditation session. This feedback is aggregated and provided to the user, and may be useful in providing the user with helpful insights into the physiological and psychological benefits of MT. Using the Wildflowers application (Multimedia Appendix 1), participants were able to choose and complete a variety of guided meditations. Participants could decide on a certain mindfulness meditation through different avenues. First, they could complete a lesson on a certain type of meditation (e.g., mindfulness of breath, mindfulness of body). Each lesson included: (a) a fact about the particular meditation, (b) teaching the user about 'snapshots' to record current mood, stress level, and heart rate, (c) a minute of flow where the participant was asked to connect with the present moment, (d) the meditation, (e) a fact on how to increase resilience, such as practicing being nonjudgemental, and (f) ending with another snapshot. Instead of a lesson, participants could also choose from a library of guided meditations that are each unlocked after completing a certain number of meditations. Lastly, participants could also have a guided meditation suggested to them based on their current mood and stress level."

"The training app for the control condition was based on open source code for a very popular mathematical game, called 2048 (Multimedia Appendix 2), where participants had to slide tiles around with numbers on them. If two tiles with the same value touched, they combined to create a tile with a larger value. The object of the game is to combine tiles until a tile with the value of 2048 is created. The same ratings of mood, stress, and heart rate before and after each training session were also built into this redesigned app to provide parity in measurement of state effects between the two training conditions."

# 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

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

subitem not at

all important

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

essential

Participants were asked to use their assigned app for 10 minutes every day. "Minimal adherence was defined as 10 minutes of practice per day, missing no more than 4 of the 21 days".

### 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	0	0	0	0		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 research assistants helped participants to download the app, and were available to answer any technologically related questions.

# 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

essential

### Does your paper address subitem 5-xi? \*

all important

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

The research assistants tracked when participants logged in and used the app. If a participant had not used the app for 3 days, they were contacted to be reminded to use the app. "Minimal adherence was defined as 10 minutes of practice per day, missing no more than 4 of the 21 days".

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

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

	1	2	3	4	5	
subitem not at all important	0	$\bigcirc$	$\bigcirc$	$\circ$		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

No other 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

"[E]ach participant was asked to come in to the laboratory to complete self-report questionnaires of well-being through an online survey platform called qualtrics.com, and complete behavioural measures of attentional and interoceptive integration on a computer in the laboratory. ...Ratings of current mood, stress level, and heart rate were recorded within each app before and after each training session. After 3-weeks of training, using their assigned application for at least 10-minutes per day, each participant returned to the laboratory to re-take the self-report questionnaires and behavioural measures of attentional control and interoceptive integration."

# 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	0	$\circ$	$\circ$	$\circ$		essential

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

Copy and paste relevant sections from manuscript text

Questionnaires used have previously demonstrated evidence of validity and reliability in the literature, reported within the manuscript. Participants completed the questionnaires via an online survey platform called qualtrics.com.

# 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.

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

Copy and paste relevant sections from manuscript text

The self-report questionnaires and behavioural measures of attentional control and interoceptive integration were assessed in the lab, which allowed research assistants to monitor participants progress. Subjective self-reports of mood, stress, and heart rate were recorded in the app and the responses emailed to the experimenters. "Minimal adherence was defined as 10 minutes of practice per day, missing no more than 4 of the 21 days". Experimenters could see when participants logged in to use their assigned app, and for how long they used the app.

# 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 O o essential

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

Copy and paste relevant sections from manuscript text

Qualitative data on participants evaluating their experience with the intervention was collected at the end of the trial in the lab during post-self-report questionnaires.

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

### Does your paper address CONSORT subitem 6b? \*

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

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

### 7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

# 7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

	1	2	3	4	5	
subitem not at all important	0	$\circ$	$\circ$	$\circ$		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

"An a priori power analysis for the group-specific training effects were modelled as the interaction of the within-subjects factor of time (pre vs. post) and the between-subjects factor of group (MT vs. Control). The power analysis was conducted using the G\*Power software application to determine how much power would be needed to find weak to moderate interaction effects in the present study. A moderate effect, eta-squared of .06, or Cohen's F of .25, was assumed. It was also assumed that repeated measures scores had a moderate to strong correlation of 0.5. The analysis suggested a total N = 34 for 80% power. A weaker effect of Cohen's F = .15 would require 90 participants, and so the study was powered conservatively for this effect, i.e., we attempted to recruit approximately 45 participants in each group."

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

Does not apply.

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

Participants were randomized through a computer generated random sequence using excel.

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

A simple randomization method was used.

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

Subject numbers were first randomized, then group labels were randomized, and then these two columns were put together to create a list of subject codes and group assignments. Participants were then sequentially assigned to their subject number and group.

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

Tha randomization was completed by the authors of the manuscript, and participants were sequentially assigned to the intervention groups by the research assistants.

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 O O 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

Participants were aware of their group assignment after completing preintervention self-report and behavioural measures.

### 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	$\circ$	$\bigcirc$	0	0		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

Participants did not know which was the "intervention of interest" and which was the "comparator".

### 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 same ratings of mood, stress, and heart rate before and after each training session were also built into this redesigned app [comparator] to provide parity in measurement of state effects between the two training conditions."

# 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

### "Data Reduction

An exploratory factor analysis (EFA) was conducted upon the scale measures listed above in the R statistical computing environment [54]. The number of factors required was first estimated using the paran library for performing Horn's parallel analysis of Principal Components/Factors [56].

### **Group Comparisons**

All statistical analyses were conducted using the statistical platform R 3.4.3 [54] with an alpha level of .05 for all tests. Demographics between groups were compared using a t test and a chi-squared test. Prior to group comparisons, the questionnaire data was reduced using EFA to increase ease of interpretability and minimize type I error. Multilevel models were used to compare both state and trait measures of well-being between groups over time. Lastly, the relationship between the state and trait measures of well-being were investigated through correlations."

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

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

	1	2	3	4	5	
subitem not at all important	0	$\bigcirc$	$\circ$	$\circ$		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

No imputation techniques were used.

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

Follow-up ANOVAs were conducted to explain observed three-way interactions, and "...pairwise follow-up comparisons, Tukey HSD corrected for multiple comparisons, using least-squares means were conducted using the Ismeans function from the Ismeans package [59] in R." No other additional analyses were 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	0	0	0	0		essential

#### Does your paper address subitem X26-i?

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

"The research protocol was approved by the University of Toronto Social Sciences, Humanities, and Education Research Ethics Board."

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	$\circ$		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

"Before participating in the study, undergraduate students gave written informed consent."

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

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

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

Potential risks were explained in the informed consent. Participants were assigned a subject number and non-identifying emails were created in the lab and used for each participant to allow them confidential downloading and use of the intervention and comparator apps.



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

"As shown in the participant flow diagram for the study (Figure 1), the final sample included 41 participants in the math training group (mean age = 19.78, SD = 2.43, 88% female), and 45 participants in the MT group (mean age = 20.24, SD = 2.63, 80% female)." The participant flow diagram shows who received treatment and who were analyzed for the primary outcome.

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

"As shown in the participant flow diagram for the study (Figure 1), the final sample included 41 participants in the math training group (mean age = 19.78, SD = 2.43, 88% female), and 45 participants in the MT group (mean age = 20.24, SD = 2.63, 80% female)." Exclusions and losses after randomization is shown in the participant flow diagram.

#### 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	0	0	0	$\circ$		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

Not applicable.

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 study trial took place from approximately May 2016 to May 2017.

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

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

subitem not at essential all important

#### 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

No critical events occurred.

14b) Why the trial ended or was stopped (early)



#### Does your paper address CONSORT subitem 14b? \*

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

The trial did not end or stop 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

"41 participants in the math training group (mean age = 19.78, SD = 2.43, 88% female), and 45 participants in the MT group (mean age = 20.24, SD = 2.63, 80% female)." Besides level of education (university), no other baseline demographic characteristics were recorded.

#### 15-i) Report demographics associated with digital divide issues

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

	1	2	3	4	5	
subitem not at all important	0	0	0	$\circ$		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 not applicable as our intervention targeted those who already used electronic devices with access to the internet.

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



#### 

#### Does your paper address subitem 16-i? \*

all important

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

Figure 1 shows the participant flow and number included in each analysis.

#### 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	0	0	0	0		essential

#### Does your paper address subitem 16-ii?

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

All primary analyses were conducted with participants who maintained adequate adherence as shown in the figure 1 participant flow diagram.

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 for each group, effect sizes, and precision are all reported in Tables 1-4 and Figures 2-11.

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

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	0	0		0	$\circ$	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

"A participant was excluded from analysis if they did not adhere to the study protocol. Minimal adherence was defined as 10 minutes of practice per day, missing no more than 4 of the 21 days, and completing both the pre- and post-training assessment measures."

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

In this study, the primary outcomes were continuous.

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

Follow-up ANOVA comparisons were conducted to clarify three-way interactions, and "pairwise follow-up comparisons, Tukey HSD corrected for multiple comparisons, using least-squares means were conducted using the Ismeans function from the Ismeans package [59] in R."

#### 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		0	0	0	0	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

We did not conduct additional analyses from the primary and follow-up analyses.

#### 19) All important harms or unintended effects in each group

#### 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

Unintended effects did not occur.

(for specific guidance see CONSORT for harms)

#### 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	0	$\bigcirc$	$\circ$	$\circ$		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

There were no privacy breaches. The only technical problem was not receiving data recorded in the app from only a couple of the participants, which was promptly fixed.

### 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 O O 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 was gathered at the end of the study. However, this was optional and not many of the participants provided qualitative feedback, thus this was not analyzed or reported in the manuscript.



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



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

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

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

	1	2	3	4	5	
subitem not at all important	0	$\bigcirc$	$\bigcirc$	$\bigcirc$		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 was the first actively-controlled study to investigate whether [mindfulness training] MT apps can promote the therapeutic effects associated with validated group MT interventions, namely subjective well-being, attentional control, and interoceptive integration.

...A trend towards MT-specific changes in acceptance from pre- to post-training was observed, and closer inspection of the data suggested that the MT group may have driven a general increase in acceptance over time.

... [R]elative to the math training group, participants in the MT group demonstrated improved mood and reduced stress following each training session. ...[T]he beneficial impact of MT on subjective stress in the MT group increased overtime; significant reductions in stress were observed over time in the post-training stress levels of the MT group, but not in the math training group.

...Contrary to the study hypotheses, participants in the MT and math training groups reported significant increases in both acceptance and awareness over the study period. One explanation for this finding may be the fact that participants in both groups recorded their mood and stress levels before and after each training session ...a reflective practice which could itself foster awareness and insight around emotional experience. ...There were no training effects for either group observed for the openness factor. This result is not

antirally curreiging in the contact of research that has shown that these who

choose to practice mindfulness demonstrate greater openness [63], and openness was not predicted a priori to emerge as a factor for analysis.

...Analyses revealed training effects specific to MT; relative to the math training group, 3-weeks of MT led to greater improvements in conflict monitoring.

...Interoceptive attention was assessed with the respiration integration task. In terms of interoceptive attention, there were no training effects.

...The results of the present study suggest that MT with a smartphone app may provide immediate effects on mood and stress while also providing long-term benefits for attentional control. Although further investigation is warranted, there is evidence that with continued usage, MT via a smartphone app may provide long-term benefits in changing how one relates to their inner and outer experiences."

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

Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	0	$\bigcirc$	$\circ$	$\circ$		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

"The present work provides preliminary evidence on the benefits of using a [mindfulness training] smartphone application. These findings suggest that future work should continue to investigate the benefits of [mindfulness training] apps in clinical populations. Additionally, future studies should investigate the longitudinal effects of using [mindfulness training] applications. Lastly, the present results on improvements in attention regulation warrant studies exploring neural changes as a result of [mindfulness training] using a smartphone application. For example, Tang and colleagues observed that two weeks of brief mindfulness training altered the resting state functional connectivity of large scale brain networks [73]. Therefore, it may be fruitful for future studies to explore both the self-reported, behavioural, and neural benefits of [mindfulness training] using a smartphone application."

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	0	0	0	$\circ$		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

"While the present study provides evidence for the beneficial effects of [mindfulness training] using a smartphone application, there are several limitations that should be noted. First, although practice was monitored, participants were only reminded to practice if they missed three consecutive days. Therefore, participants did not necessarily practice with their assigned app (Wildflowers or 2048) every day, which might affect the extent of the significant findings observed. On the other hand, this limitation adds more ecological validity to the present study as people in the real world would not be monitored closely to ensure they are practicing every day. Second, state mindfulness was not measured during daily training sessions, so it is hard to know if the benefits to mood and stress observed were a result of transiently increased state mindfulness, or a result of another factor that was not considered in the present study. However, a study design which promotes daily reflection on state mindfulness may have introduced further unintended training effects to the control group. Lastly, although the results strongly support benefits of [mindfulness training] on state measures of subjective well-being, the marginal pre- to post-intervention results around the acceptance factor make it inappropriate to draw strong conclusions about the relative efficacy of [mindfulness training] relative to active control. These marginal results may be due to the power of the present study. While the a priori power analysis suggested adequate power, a post-hoc simulation-based power analysis suggested that the study was underpowered for addressing these group by time interactions. Therefore, a future study with better power should attempt to replicate and extend our understanding of the relationship between the state and trait well-being factors."

## 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

#### 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

The results of the study can be generalized to undergraduate student populations. "The present work provides preliminary evidence on the benefits of using a MT smartphone application. These findings suggest that future work should continue to investigate the benefits of MT apps in clinical populations. Additionally, future studies should investigate the longitudinal effects of using MT applications."

### 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	0	0	$\circ$	$\circ$		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

There are not elements in the RCT that would be different in a routine application setting aside from the fact that research assistants would not be available to assist in downloading the intervention app.

OTHER INFORMATION

23) Registration number and name of trial registry



#### Does your paper address CONSORT subitem 23? \*

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

"The research protocol was approved by the University of Toronto Social Sciences, Humanities, and Education Research Ethics Board. This study was not registered at ClinicalTrials.gov, but the study protocol matches that of the REB approval acquired prior to the study trial."

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 not published.

# 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

Funding: OCE Voucher for Innovation and Productivity I (VIP I)

X27) Conflicts of Interest (not a CONSORT item)

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

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	$\circ$	$\circ$	$\circ$	$\bigcirc$	<b>O</b>	essential

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

being evaluated

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 second author provided his voice for the guided meditations within the intervention app. The first author had no part in the development of the app.

About the CONSORT EHEALTH checklist



As a result of using this checklist, did you make changes in your manuscript? *
yes, major changes
<ul><li>yes, minor changes</li></ul>
O no
What were the most important changes you made as a result of using this checklist?
Title of the manuscript
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript * About 4 hours.
As a result of using this checklist, do you think your manuscript has improved? *
O yes
no
Other:

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

_	•
This	would involve for example becoming involved in participating in a workshop and writing an
"Expl	anation and Elaboration" document
$\bigcirc$	yes

#### Other:

no

#### Any other comments or questions on CONSORT EHEALTH

Your answer

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