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

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

The goal of the CONSORT EHEALTH checklist and guideline is to be a) a guide for reporting for authors of RCTs, b) to form a basis for appraisal of an ehealth trial (in terms of validity)

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

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (nonpharmacologic treatment) items. Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

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

Mandatory reporting items are marked with a red *.

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

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED). Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

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

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

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

Mobile Health Interventions J Med Internet Res 2011;13(4):e126 URL: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name *

First Last

Vess Stamenova

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

Toronto

Your e-mail address * abc@gmail.com

vess.stamenova@wchospital.ca

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

Technology-enabled self-management of Chronic Obstructive Pulmonary Disease (COPD) with or without asynchronous remote monitoring: 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.

Cloud Dx Connected Health Kit

Evaluated Version (if any)

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

3.11

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://www.clouddx.com/#/healthkittelemedi

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?



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

Primary Medical Indication/Disease/Condition *

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

COPD

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Partners in Health (PIH) scale

Secondary/other outcomes

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

St. George's Respiratory Questionnaire (SGRQ), Bristol COPD Knowledge Questionnaire , Health Utilization

Recommended "Dose" * What do the instructions for users say	y on how often the app should be used?
• Approximately Daily	
O Approximately Weekly	
O Approximately Monthly	
Approximately Yearly	
O "as needed"	
O Other:	

Approx. Percentage of Users (starters) still using the app as recommended after 3 months * unknown / not evaluated 0-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71%-80% 81-90% 91-100% Other:

Overall, was the app/intervention effective? *	
O yes: all primary outcomes were significantly better in intervention group vs control	
O partly: SOME primary outcomes were significantly better in intervention group vs control	
• no statistically significant difference between control and intervention	
O potentially harmful: control was significantly better than intervention in one or more outcomes	
O inconclusive: more research is needed	
O Other:	
Article Preparation Status/Stage *	
At which stage in your article preparation are you currently (at the time you fill in this form)	

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

Journal *

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

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

Is this a full powere	d effectivenes	s trial or a	nilot/feasibility	trial? *
is this a full powere	enectivenes	ร เมลา 01 ส	pilotreasipility	y u lai:

- Pilot/feasibility
- Fully powered

Manuscript tracking number *

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

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

) Other:

TITLE AND ABSTRACT

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

1a)	Does	vour	paper	address	CONSORT	item '	1a? *
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I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

🌒 yes

) Other:

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

Technology-enabled self-management of Chronic Obstructive Pulmonary Disease (COPD) with or without asynchronous remote monitoring: a randomized controlled trial

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	0	۲	0	0	0	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

Technology-enabled self-management of Chronic Obstructive Pulmonary Disease (COPD) with or without asynchronous remote monitoring: a randomized controlled trial

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	٢	essential

Does your paper address subitem 1a-iii? *

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

Technology-enabled self-management of Chronic Obstructive Pulmonary Disease (COPD) with or without asynchronous remote monitoring: a randomized controlled trial

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

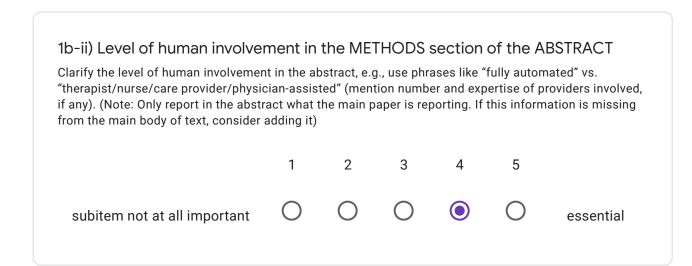
Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)



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

"We conducted a 3-arm randomized controlled trial evaluating the effectiveness of a RM and a SM program relative to standard care. "



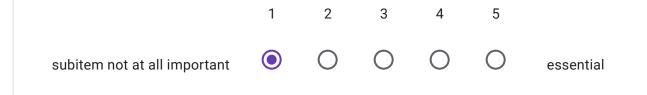
Does your paper address subitem 1b-ii?

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

"only patients in the RM group were monitored by a respiratory therapist. "

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)



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

It's in the main body of the paper.

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential

Does your paper address subitem 1b-iv?

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

"A total of 122 patients participated in the study, 40 in the SC, 41 in the SM, and 41 in the RM groups. "

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

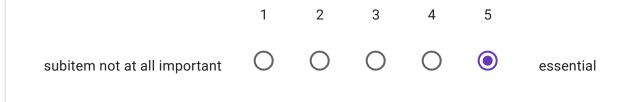
"Despite regular use of the technology, patients with COPD assigned to remote monitoring or self-monitoring did not have any improvement in patient outcomes like self-management skills, knowledge or symptoms or healthcare utilization compared to each other or to a standard care group. This may be due to low health utilization at baseline, the lack of structured educational components in the intervention groups, and the lack of integration of the action plan with the technology. "

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)



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

"Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of mortality worldwide [1] with 65 million people having moderate to severe COPD worldwide [2]. In Ontario, Canada, COPD accounts for 24% of hospital admissions and 24% of emergency department (ED) visits and is responsible for the highest percentage (18.8%) of 30-day ED readmissions [3]. Reducing the frequency of COPD exacerbations is an important patient outcome and could result in significant cost savings.

One approach to reducing exacerbations is to provide regular remote monitoring of patients from their home. "

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

"One approach to reducing exacerbations is to provide regular remote monitoring of patients from their home. This approach has been used in the past with patients taking measurements of their vital signs (oxygen, blood pressure, symptoms) and recording them manually on paper [4] or transmitting them with devices through a phone or internet line [5-7]. Recent developments such as Bluetooth technology, cloud based storage, and WiFi enabled tablets have allowed data from remote devices to be uploaded automatically to a database accessible by patients, caregivers and healthcare providers either periodically or on an "as needed" basis [8-10]. Remote monitoring programs are always monitored by a healthcare provider, even though they are sometimes referred to as "self-management" programs, as the recordings are taken by the patients [10]. Some remote monitoring programs also often have an educational component [11,12], such as coaching sessions to support self-management. COPD self-management behaviors include self-recognition and self-treatment of exacerbations (e.g. taking medications), coping with breathlessness and lifestyle changes such as quitting smoking, eating healthy and exercising[13]. Selfmanagement COPD interventions have generally been shown to be effective in improving quality of life measures [13,14], but a recent meta-analysis failed to show significant improvements in health-related quality of life [15].

There is a large body of literature on COPD reporting on the effects of remote monitoring on patient outcomes and health care utilization, and several recent reviews have summarized these findings [16–18]. Kruse et al. [16] reported that the number of articles stating that patient outcomes were improved overall with telemonitoring was about equal to those showing no improvement. Another review [17] reported that remote monitoring decreased ED admissions and hospitalizations, but failed to impact on other patient outcomes. Hong and Lee suggested that "integrated remote monitoring" programs (those that have educational components) may be more effective, especially when they target patients with more advanced disease [17].

Educational components come at an additional cost to these programs and even the simple act of monitoring patients remotely and connecting with them only when alerts are received requires dedicated staff. Few studies have looked at the effectiveness of "self-monitoring" programs, where patients take their readings and receive automated feedback based on these readings without being actively monitored [4,19]. These studies have shown some promise in improving patient outcomes, but they were feasibility trials that require larger samples and control group designs. A self-monitoring program, if non-inferior to a RM program, would provide the opportunity for significant cost savings without compromising patient outcomes. To our knowledge, no studies to date have directly compared a remote monitoring program with a self-monitoring program for COPD patients. "

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

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

"The objective of our study was to compare the effectiveness of implementing a technologyenabled self-monitoring (SM) program versus a technology-enabled self- and remote monitoring program, from here on called remote monitoring (RM), in a COPD patient population compared to a standard care (SC) group. "

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 an open-label randomized controlled trial (RCT) comparing two technologyenabled interventions, a self-monitoring group (SM) and a remote monitoring group (RM), relative to standard care. Patients were randomized in a 1:1:1 ratio to one of the three groups. "

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

Does your paper address CONSORT subitem 3b? *

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

N/A. We have the protocol published in JMIR Research Protocols. Any deviations (only in data analysis) are described in the paper.

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential

Does your paper address subitem 3b-i?

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

"Throughout the trial there were 3 releases, and 1 service pack installed in the platform as well as 2 release, 5 hotfixes and 1 service pack released for the companion application. (see Metafile 2 for details)"

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

"Patients were included if they were 18 years of age or older and had an established clinical diagnosis of Chronic Obstructive Pulmonary Disease (COPD) by a respirologist as per clinical guidelines [21]"

4a-i) Computer / Internet literacy

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

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential

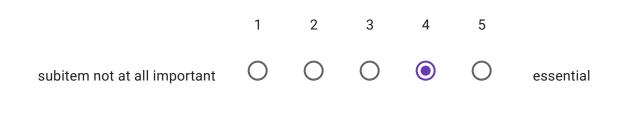
Does your paper address subitem 4a-i?

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

"Exclusion criteria included a diagnosis of other significant lung disease (e.g. interstitial lung disease), patients without Wi-Fi internet access in their home, inability to read English (required for filling out the questionnaires), participation in other remote monitoring programs or inability to use the technology due to physical or cognitive impairment. "

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 webbased 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.



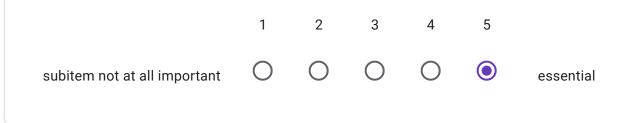
Does your paper address subitem 4a-ii? *

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

"All patients completed 3 assessments: at baseline, 3 months, and 6 months on a series of questionnaires. Visit 1 (baseline) was in person and Visit 2 (3 months) and 3 (6 months) could be done in-person or remotely (online through REDCap [26,27] or over the phone). "

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.



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

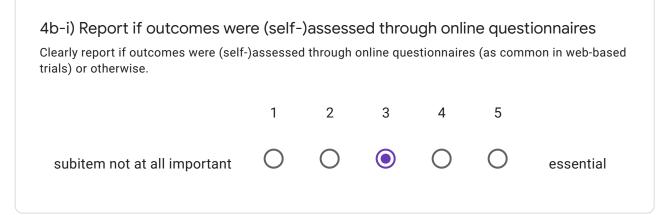
"The main site of recruitment was through the hospital-based outpatient clinic, where all eligible patients seen within the past year were contacted for participation. Patients could also be referred to the study from outside the clinic, though the private practice of hospital-affiliated respirologists and through an outpatient COPD rehabilitation program. Patients were either contacted by phone or directly approached at an appointment or at the hospital's exercise rehab program by a clinical staff member (respirologist or respiratory therapist (RT)). Those who were interested were referred to the clinical project specialist and scheduled for a baseline evaluation, at which time informed consent was obtained, group allocation was revealed, and the kit was provided (if in SM or RM group). "

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 main site of recruitment was through the hospital-based outpatient clinic, where all eligible patients seen within the past year were contacted for participation. Patients could also be referred to the study from outside the clinic, though the private practice of hospital-affiliated respirologists and through an outpatient COPD rehabilitation program. Patients were either contacted by phone or directly approached at an appointment or at the hospital's exercise rehab program by a clinical staff member (respirologist or respiratory therapist (RT)). Those who were interested were referred to the clinical project specialist and scheduled for a baseline evaluation, at which time informed consent was obtained, group allocation was revealed, and the kit was provided (if in SM or RM group). "



Does your paper address subitem 4b-i? *

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

"All patients completed 3 assessments: at baseline, 3 months, and 6 months on a series of questionnaires. Visit 1 (baseline) was in person and Visit 2 (3 months) and 3 (6 months) could be done in-person or remotely (online through REDCap [26,27] or over the phone). "

4b-ii) Report how institutional affiliations are displayed

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

	1	2	3	4	5	
subitem not at all important	٢	0	0	0	0	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

Patients were recruited through the hospital and as such they knew that the hospital supports the technology.

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

We have provided the name of the technology and details can be found online for those that are interested.

5-ii) Describe the history/development process

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

	1	2	3	4	5	
subitem not at all important	0	۲	0	0	0	essential

Does your paper address subitem 5-ii?

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

This is an established product already on the market.

5-iii) Revisions and updating

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

"Throughout the trial there were 3 releases, and 1 service pack installed in the platform as well as 2 release, 5 hotfixes and 1 service pack released for the companion application. (see Metafile 2 for details)"

5-iv) Quality assurance methods								
Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.								
	1	2	3	4	5			
subitem not at all important	0	0	۲	0	0	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

Seems not applicable. Product is already developed and available on the market.

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

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

	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential

Does your paper address subitem 5-v?

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

This is proprietary I imagine.We don't have access to it.

5-vi) Digital preservation

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

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

We had problems doing that for the protocol paper.Some of these sites do not exist anymore I believe.We have included a picture of the devices in the supplement.

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	٢	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

Patients received the equipment free and did not pay monthly charges and "patients in the SC were told that they will receive the equipment at the end of the trial."

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	0	0	0	۲	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

"Intervention Procedures

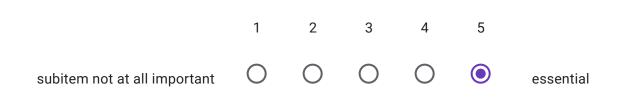
The intervention lasted for 6-months during which patients in the intervention groups were asked to record their vitals (oximetry and blood pressure were required, whereas temperature and weight were optional) and symptoms (CAT, MRC) with the Cloud DX platform every day and were provided with a written version of a personalized COPD action plan which instructed patients on what to do if their readings fell outside pre-determined thresholds (Figure 2, Supplement). Individual patient thresholds were determined by the clinical project specialist (also an RT) in consultation with the patient's respirologist. Patients in the SM and RM groups were also contacted by the clinical project specialist 2 weeks after receiving their kit to re-assess the appropriateness of the thresholds. All patients also had the option to email or call the clinic with any non-emergency questions they may have. All patients were advised to go to the emergency department if they deemed it necessary, at any point in the study. Patients were also informed that data was not monitored 24hrs/7 days a week and to respond to their clinical needs as they would normally do outside of the study.

When a patient's readings fell outside the pre-determined thresholds, a notification was sent to both the clinical project specialist and to the patient through email. The clinical project specialist reviewed the readings and responded when clinically indicated only for the RM group. Follow-up calls were made only when readings exceeded thresholds twice or more within two days and were made only on weekdays. An attempt to complete the follow-up call was done within 24 hours of receiving the notification. If the patient was unavailable, a message was left to return the call. The RT also called patients in the RM group once a week irrespective of the value of the vitals. The purpose of the call was to check on the patients, prompt action plan use as needed, and provide education to patients about their COPD as needed. The clinical project specialist received the readings for the SM group, but they were not actively monitored and no follow-up calls were made in this group. Patients in the SM group were informed that their data was not actively monitored by the clinic. Patients in both intervention groups had secondary threshold levels (extreme measures) preset by the site investigator. Cloud DX staff monitored these levels and contacted the patients when necessary. For details, please refer to the protocol [20].

Patients in the SC group were not provided with a technology or an action plan. This group received otherwise standard care from the respiratory clinic including routine in-person follow-up appointments and access to a certified respiratory educator. Patients in the SC were told that they will receive the equipment at the end of the trial."

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.



Does your paper address subitem 5-ix?

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

"The intervention lasted for 6-months during which patients in the intervention groups were asked to record their vitals (oximetry and blood pressure were required, whereas temperature and weight were optional) and symptoms (CAT, MRC) with the Cloud DX platform every day and were provided with a written version of a personalized COPD action plan which instructed patients on what to do if their readings fell outside pre-determined thresholds (Figure 2, Supplement). "

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	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

"Patients in the SM and RM groups were also contacted by the clinical project specialist 2 weeks after receiving their kit to re-assess the appropriateness of the thresholds. All patients also had the option to email or call the clinic with any non-emergency questions they may have. "

"When a patient's readings fell outside the pre-determined thresholds, a notification was sent to both the clinical project specialist and to the patient through email. The clinical project specialist reviewed the readings and responded when clinically indicated only for the RM group. "

"The RT also called patients in the RM group once a week irrespective of the value of the vitals."

5-xi) Report any prompts/reminders used

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

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential

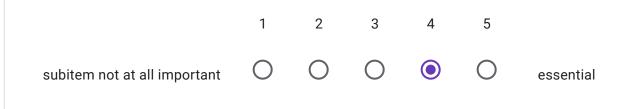
Does your paper address subitem 5-xi? *

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

"When a patient's readings fell outside the pre-determined thresholds, a notification was sent to both the clinical project specialist and to the patient through email. The clinical project specialist reviewed the readings and responded when clinically indicated only for the RM group. "

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.



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

"The RT also called patients in the RM group once a week irrespective of the value of the vitals. The purpose of the call was to check on the patients, prompt action plan use as needed, and provide education to patients about their COPD as needed."

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

The primary outcome for the trial was the Partners in Health (PIH) scale [28], a validated scale measuring the current status of self-management, with items on knowledge of the condition and skills to monitor and respond to symptoms. This scale was selected as a primary outcome, as we believed that both interventions could lead to self-management improvement.

Secondary Outcomes

The secondary outcomes included the St. George's Respiratory Questionnaire (SGRQ) [29] and The Bristol COPD Knowledge Questionnaire [30]. SGRQ contains subsections on respiratory symptoms, activities that are limited because of breathlessness, and impacts on daily life. The Bristol COPD Knowledge Questionnaire [30] is a measurement of COPD patients' disease knowledge level. Patients were also asked to self-report at baseline, 3 months and 6 months, COPD-related ED presentations, hospital admissions, and length of hospital stay, number of exacerbations (episodes in which antibiotics or steroids were prescribed or hospital/clinic visit due to a respiratory issue), number of COPD-related visits to a family doctor, number of COPD-related nurse contacts, self-reported use of medication, and self-reported smoking cessation. The number of contacts/calls to the outpatient clinic and deaths were tracked and reported by the clinical project specialist. In addition, hospital admission data and ED use from the local hospital were also obtained."

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	0	0	۲	0	essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Not validated, but transferred on redcap without any changes (or very few), no changes to the questions were made.

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Vendor recorded usage data was also documented and sent for analysis at the end of the trial. This included frequency of recordings for oxygen, blood pressure, temperature, weight, MRC and CAT scores and the number of times thresholds were exceeded.

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	0	0	0	0	۲	essential		

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

This report is only quantitative The qualitative paper is published separately and currently submitted to JMIR.

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

Only in data analysis, which is described.

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	0	0	0	٢	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

Described in the protocol paper

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

N/A

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

"We used an online random number generator [22] to allocate patients to groups as described in the trial protocol [20]. Sequential patient group allocation was placed in a sealed envelope and revealed to the patient by the clinical project specialist after consent was obtained. "

8b) Type of randomisation; details of any restriction (such as blocking and block size)

В

Does your paper address CONSORT subitem 8b? *

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

"We used an online random number generator [22] to allocate patients to groups as described in the trial protocol [20]. Sequential patient group allocation was placed in a sealed envelope and revealed to the patient by the clinical project specialist after consent was obtained. "

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

"We used an online random number generator [22] to allocate patients to groups as described in the trial protocol [20]. Sequential patient group allocation was placed in a sealed envelope and revealed to the patient by the clinical project specialist after consent was obtained. "

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

A postdoc and first author generated the sequence (VS)

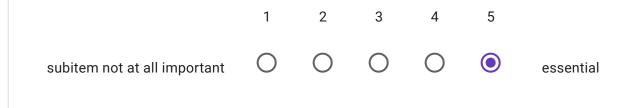
11a) If done, who was blinded after assignment to interventions (for example,

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).



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

We conducted an open-label randomized controlled trial (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".

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

We conducted an open-label randomized controlled trial (RCT)

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

Patients in the SC group were not provided with a technology or an action plan. This group received otherwise standard care from the respiratory clinic including routine in-person follow-up appointments and access to a certified respiratory educator. Patients in the SC were told that they will receive the equipment at the end of the trial.

12a) Statistical methods used to compare groups for primary and secondary

outcomes

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

Does your paper address CONSORT subitem 12a? *

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

"All quantitative continuous data were analyzed by conducting a between-group repeatedmeasures ANOVA analysis comparing the scores at baseline versus 3 months and baseline versus 6 months follow-up assessments. This deviation from the original protocol (where we had planned to include all three timepoints in each analysis) was done to maximize the data and avoid excluding participants who did not have data on all three time points. Kruskal-Wallis tests were used where data was not normally distributed or group variances were heterogenous. "

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential

Does your paper address subitem 12a-i? *

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

Not 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

"Post-hoc comparisons showed that the SC group made significantly fewer calls (Mean= 0.13) than the SM (Mean=4) (p<0.001) and the RM group (Mean=3.3) (p<0.001). "

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



Does your paper address subitem X26-i?

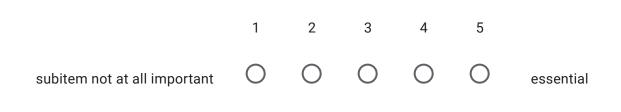
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Ethics and dissemination

The study was approved by the Markham Stouffville Hospital and Women's College Hospital Research Ethics Boards in Ontario, Canada (Protocol version: 1.8, 07 December 2018). The study was also retrospectively registered with clinicaltrials.gov (NCT03741855). "

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.



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

"Those who were interested were referred to the clinical project specialist and scheduled for a baseline evaluation, at which time informed consent was obtained, group allocation was revealed, and the kit was provided (if in SM or RM group). "

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	۲	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

This was all evaluated and approved by the board.

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

"A total of 122 patients participated in the study, 40 in the SC, 41 in the SM, and 41 in the RM groups. Out of those patients, 7 in the SC, 5 in the SM, and 6 in the RM group did not complete the study due to various reasons (8 withdrew from the trial for various reasons, 6 were non-compliant with their readings, 4 died (one from a COPD exacerbation, one from complications of co-morbid conditions, one from cardiac arrest and one from unknown causes), and 1 dropped out due to difficulty using the technology (Figure 1). "

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

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

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

"There were no significant differences in the rates of study completion among the groups (P=.80). "

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.



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

Figure 1

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 recruitment started in April, 2018 and was completed in September, 2019. "

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	0	0	0	۲	0	essential

E

Does your paper address subitem 14a-i?

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

N/A

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

N/A

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

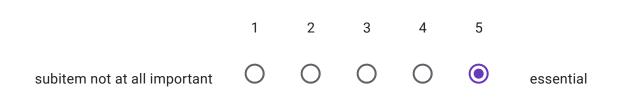
Does your paper address CONSORT subitem 15? *

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

Table 1

15-i) Report demographics associated with digital divide issues

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



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

"Unfortunately, we don't have detailed SES data"

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	0	0	0	0	۲	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

n's provided in tables.

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	۲	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

lt is.

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

"Primary and Secondary Outcomes

A repeated-measures ANOVA showed a significant improvement in PIH scores from baseline to 3 months (p=0.001) and from baseline to 6 months (p=0.008), but no group effects or interactions, suggesting no differential effect among the groups. Figure 2: PIH at baseline and 3 months and baseline and 6 months for each group.

A repeated-measures ANOVA showed a significant improvement in BCKQ scores from baseline to 3 months (p<0.001) and from baseline to 6 months (p<0.001) (Figure 6, Supplement). Steeper gains were observed in the RM group compared to the SM and SC group both from baseline to 3 months and from baseline to 6 months, but the interaction effect did not reach statistical significance (p=0.13 and p=0.07, respectively). The gains made were in magnitude of less than 10% and all groups had initial scores of just above 30%, which is lower than the average of 54% reported by the original BCKQ study [30]. No group main effects were observed either.

A repeated-measures ANOVA showed no changes in SGRQ Activity scores (Figure 7, Supplement). from baseline to 3 months (p=0.49) or from baseline to 6 months (p=0.76), and no group effects or interactions.

A repeated-measures ANOVA showed a significant improvement in SGRQ Impact scores (Figure 8, Supplement) from baseline to 3 months (p=0.047), but no significant group effect or interaction, suggesting no differential effect among the groups. When comparing baseline to 6 months, a repeated-measures ANOVA showed a significant effect of time (p=0.006) and a significant interaction effect (p=0.005). Separate pairwise comparison analyses were run to examine the interaction effect. The SC group improved from baseline to 6 months, while the RM group scores deteriorated (higher score), as demonstrated by a significant interaction effect (p=0.015). A significant interaction effect (p=0.003) was also observed when the SM and RM groups were analyzed separately, showing the SM group improved, while the RM group worsened. Both SC and SM groups improved significantly with time in their SGRQ Impact scores (p=0.0002) and there was no interaction or group effect. A repeated-measures ANOVA showed no changes in SGRQ Symptoms scores from baseline to 3 months (p=0.56) or from baseline to 6 months (p=0.62), and no group effects or interactions (Figure 9, Supplement).

Finally, for the RM and SM group, a repeated-measures ANOVA comparing the second CAT readings to their last CAT reading, with time as a within-subject variable and group as a between-subject variable, showed no significant main effects or interactions. The same was observed with MRC scores. Therefore, there were no changes in CAT and MRC scores from the start of the intervention until the end. "

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	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

"We ran a series of Pearson correlations between the number of readings (CAT, MRC, and SpO2) and the change in score from baseline to 6 months for the participants in the SM and RM group. There were no correlations observed on any of these analyses."

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

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

n/a

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

Does your paper address CONSORT subitem 18?*

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

n/a

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	٢	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

n/a

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

n/a

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].



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

None

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	0	0	0	0	۲	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

Will be presented in another paper

DISCUSSION

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

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

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

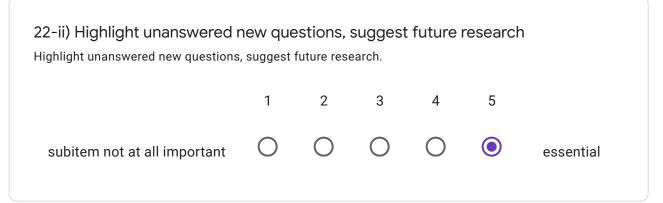
Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	٢	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 study compared the effectiveness of a technology-enabled self-monitoring program to a remote monitoring program and to standard care in a COPD patient population. Despite high adherence to the intervention and a low rate of dropout, the study found no difference in self-efficacy or disease knowledge and disease severity measures between the groups. All three groups, including the standard care group, improved in self-efficacy and disease knowledge measures. These changes were significant over time and were evident both at 3 months and 6 months evaluations. The SC and SM group, but not the RM group, also reported lower impact of COPD on their life when comparing baseline to 6 months evaluations. There were no changes in symptoms or activity scores in any of the groups. There were also no differences (increases or decreases) in patient healthcare utilization including ED visits, hospital admissions, primary care visits or nursing visits, during participants' participation in the trial relative to the 6 months preceding the trial, though these were secondary outcomes that the study was not powered for. "



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

"Future studies should focus on patients with higher healthcare system use and with moderate to severe disease. We also recommend including structured educational components (potentially both in remote and self-monitoring programs) and predictive analytics of vitals data that detect relative, rather than absolute changes in vitals. "

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	0	٢	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

"Despite this, our design suffered from drawbacks, such as a relatively short intervention period (6 months) and inclusion criteria that allowed any patients with a diagnosis of COPD, irrespective of disease severity, to participate. Some of these decisions were made due to time constraints surrounding the trial funding and associated recruitment challenges. Many studies in the literature have disease severity inclusion criteria that often require patients to be admitted at least once and often twice in the previous year[8,40,45]. With respect to intervention duration, a full year intervention seems to be the most common, but we noted interventions ranging from 3 to 24 months. While our intervention was only 6 months, it is worth noting that some 6 month interventions have shown positive effects [7,32,33]. "

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

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

21-i) Generalizability to other populations

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential

Does your paper address subitem 21-i?

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

Your answer

21-ii) Discuss if there were el routine application setting	ements	in the R	CT that	would k	be differ	ent in a
Discuss if there were elements in the prompts/reminders, more human invo impact the omission of these elemen applied outside of a RCT setting.	olvement,	training se	essions or	other co-i	nterventior	ns) and what
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	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

We believe the elements will be the same

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: ClinicalTrials.gov NCT03741855; https://clinicaltrials.gov/ct2/show/ NCT03741855.

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

Multimedia appendix

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

Does your paper address CONSORT subitem 25? *

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

The project was funded by a provincial grant.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential

Does your paper address subitem X27-i?

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

The study was designed and evaluated by an independent team.

About the CONSORT EHEALTH checklist

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

yes, major changes



🔵 no

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

Your answer

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

4

As a result of using this checklist, do you think your manuscript has improved? *				
🔘 yes				
O no				
Other: I did not make any changes, but I had followed the recommendations and find				
Mould you like to be some involved in the CONSORT FUE ALTU snown?				
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				

_	
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) Other:

Any other comments or questions on CONSORT EHEALTH

I find the process of filling this form quite burdensome and time consuming. I think a checklist should be completed in order to jot people's memory on including certain details, but copying and pasting all the information here is very time consuming. I love the Ehealth consort components though, as they highlight details that are unique to ehealth research.

STOP - Save this form as PDF before you click submit

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