# 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: http://www.jmir.org/2011/4/e126/

doi: 10.2196/jmir.1923

PMID: 22209829

\* Required

Your name \*

Carmel Martin

Your answer

Primary Affiliation (short), City, Country \*

Monash University, Clayton, Victoria, Australia

Your answer

Your e-mail address \*

carmelmarymartin@gmail.com carmel.martin@monash.edu

Your answer

Title of your manuscript \*

Provide the (draft) title of your manuscript.

Pragmatic controlled evaluation of MonashWatch: an outreach telehealth/coaching value-based hospital admission innovation in Victoria, Australia

Name of your App/Software/Intervention \* Patient Journey Record System (PaJR)

Evaluated Version (if any)

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

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

https://monashhealth.org/services/monashwatch/

URL of an image/screenshot (optional)

Your answer

Accessibility * Can an enduser access the intervention presently?
0
O access is open to everyone, but requires payment/subscription/in-app
Opurchases
0
Primary Medical Indication/Disease/Condition *  DVMVSFAcute Non-Surgical 3V_ [ee[a`e
Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial
Bed Days during hospital admissions of intervention vs control group
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?
Your answer Satisfaction, Numbers of admissions per person per month

Recommended "Dose" *
What do the instructions for users say on how often the app should be used?
Approximately Weekly
"as needed"
Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
unknown / not evaluated
0-10%
O 11-20%
21-30%
31-40%
41-50%
51-60%
61-70%
71%-80%
81-90%
91-100%
Other:

H

Overall, was the app/intervention effective? *
yes: all primary outcomes were significantly better in intervention group vs control
partly: SOME primary outcomes were significantly better in intervention group vs control
on statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other:
Article Preparation Status/Stage *  At which stage in your article preparation are you currently (at the time you fill in this form)
onot submitted yet - in early draft status
onot 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

Journal *  If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")
not submitted yet / unclear where I will submit this
Journal of Medical Internet Research (JMIR)
JMIR mHealth and UHealth
JMIR Serious Games
JMIR Mental Health
JMIR Public Health
JMIR Formative Research
Other JMIR sister journal
Other:
Is this a full powered effectiveness trial or a pilot/feasibility trial? *
O 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)  On ms number (yet) / not (yet) submitted to / published in JMIR  Other: (ms #18046) to the Journal of Medical Internet Research (JMIR).

!

#### TITLE AND ABSTRACT

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

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

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

yes

Other: No because it it a controlled evaluation of the implementation of a model of care in a living complex system that has already passed proof of concept

#### 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.

5

subitem not at all important essential

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

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

Your answer

	1	2	3	4	5	
subitem not at all important	O	O	O	O	O	essential
Does your paper address sul	oitem 1a	a-ii?				
Copy and paste relevant sections from indicate direct quotes from your man information not in the ms, or briefly e	uscript), c	or elaborat	e on this i	tem by pro	viding add	itional
Your answer						
Mention primary condition or target g Example: A Web-based and Mobile In	roup in th	e title, if a	ny (e.g., "f			
Mention primary condition or target g Example: A Web-based and Mobile In	roup in th	e title, if a	ny (e.g., "f			
Mention primary condition or target g Example: A Web-based and Mobile In	roup in th	ne title, if a n with Tele	ny (e.g., "f phone Sup	port for C	hildren wit	
Mention primary condition or target g Example: A Web-based and Mobile In Randomized Controlled Trial	roup in th	ne title, if a n with Tele	ny (e.g., "f phone Sup	port for C	hildren wit	h Type I Diabet
1a-iii) Primary condition or ta Mention primary condition or target g Example: A Web-based and Mobile In Randomized Controlled Trial subitem not at all important	rroup in the tervention	e title, if an with Tele	ny (e.g., "f phone Sup	port for C	hildren wit	h Type I Diabeto

### 1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status. This was not a RCT

The ITT AT group provided consent to being recruited. GPs, health and social services were aware of their pilot service status - blinding was not possible. Controls had no contact by the MW team, GPs, health and social services were unaware that they were controls.

### 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	0	0	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

Your answer

#### 1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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

Your answerThe web-based Patient Journey Record System (PaJR) supports frequent telephone calls by lay Telecare Guides (TCG) to track risk with a clinical algorithm, in line with the dynamic unstable health states typically observed in HLCC-identified patients. Health Coaches (HC) triage, navigate, and support MW participants in a reactive and anticipatory manner bridging GP, hospital, pharmacy, social welfare, housing and legal services.

### 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)

5 subitem not at all important essential

### Does your paper address subitem 1b-iii?

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

Your answer this is a telehealth call based intervention operated by clinical team

#### 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)

subitem not at all important

essential

### Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Your answer Findings: MW identified 1373 suitable HLCC patients: UC (293) and ITT (1080: 471 AT (44%); 485 declined; 178 lost to follow up and 8 died). ITT and UC had similar conditions profiles. Age, MW exposure and ITT/UC status independently predicted BD. Reduction in BD in ITT vs UC was 1.14 days per patient, with 1,236 BD savings (p. Both groups demonstrated regression-to-the-mean. Negative trends were greater in ITT -406 vs -104 downward Sen slopes. NPS was 95% compared with typical hospital scores of 77%.

### 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

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

Your answer Clinically and statistically meaningful reductions in acute hospital bed days in ITT vs UC cohorts is demonstrated, although admission frequency (secondary outcome) was unchanged.

#### 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)

subitem not at all important essential

### Does your paper address subitem 2a-i? \*

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

Your answer Health Links: Chronic Care (HLCC) is a funding-neutral reform to better identify patients at-risk of hospitalisation and respond to their care needs earlier. Monash Health is the largest hospital group in Victoria, Australia. It participated in the new HLCC funding model with a service called MonashWatch (MW) to optimise bed days.

### 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.

subitem not at all important essential

#### Does your paper address subitem 2a-ii? \*

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study in the past 20 years, there have been multiple initiatives to address PPH and costs across the multiple jurisdictions. There have been two waves of coordinated care trials which pooled Federal and State resources (and private health resources) in local geographic deployments which have not improved Bed Days or health outcomes[2]. Significantly higher health service use and costs were incurred in the absence of clear evidence of improved health outcomes. Many clients did not require care coordination. Funds pooling arrangements contributed to limited possibilities for service substitution and training of GP care coordinators was inadequate[2]. Ongoing and continually changing Federal, State 'integrated care' initiatives have similarly failed to document improvements for BD and costs

#### 2b) In INTRODUCTION: Specific objectives or hypotheses

#### Your answer yes

#### 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 primary outcome metric is Bed Days i.e. length of stay related to emergency non-surgical admissions derived from the Victorian Admitted Episode Data/Victorian Emergency Minimum Dataset 2016-12-23 - 2019-6-23.

#### **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 Patients were considered candidates to be entered into MW evaluation pool before allocation on the basis of 4:1, following pragmatic screening by coaches to exclude those who were not suited to a self-rated health phone-based model i.e. nursing home, necessitated use of an interpreter, and patients that would pose a high risk to staff visiting at home.

### 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

Your answer Nil

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

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

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subitem not at all important

essential

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

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

Your answer. The web-based telehealth/coaching system ran throughout the duration of the evaluation

### 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

Your answer. Residents in a hospital geographic catchment area, identified independently by a hospital data algorithm, screened for suitability and then systematically (blindly) allocated into intervention and control. All intervention were invited to participate and acceptors were participants

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

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

essential

essential

subitem not at all important

subitem not at all important

Does your paper address subitem 4a-i?

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

Your answer. Partients did not need internet literacy, but the lay telecare guides were selected on that basis with training for them and coaches

### 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

Telecare guides make regular phone calls for assessments

The Health Coaches in MW, triage, navigate and support MW participants in a reactive and anticipatory manner bridging the GP, hospital, pharmacy, social welfare, housing, legal and other support services. Coaches made telephone contact, home visits, and accompanied participants to GPs, clinics and other services where appropriate.

#### Your answer

#### 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.

subitem not at all important

essential

### Does your paper address subitem 4a-iii?

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

Very detailed informed consent was given to participating in the trial. However, once the pilot started, the team behaved in a typical clinical manner and with no need to revert to care. I will attach linformed consent forms.

### 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 primary outcome metric is Bed Days derived from the Victorian Admitted Episode Data/Victorian Emergency Minimum Dataset 2016-12-23 - 2019-6-23



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

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

subitem not at all important

#### Does your paper address subitem 4b-i? \*

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

The study reported anonymous paper based surveys of the NET Promoter Score - this was secondary outcome

#### 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

essential

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. While Monash Health is alarge network of hospitals, Dandenong Hospital is a typical district hospital of no particular status.

### 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).

essential

subitem not at all important

#### 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.

innovative funding model (HLCC) developed by the Victorian Department of Health and Human Services (DHHS). It acknowledges the stellar work of the MonashWatch clinical team – the Telecare Guides and the Health Coaches who have made the model work to date. It also acknowledges the work of Kevin Smith and John-Paul Smith who own and have implemented and supported the PaJR Application. Carmel Martin was the clinician lead in the development of the PaJR software and a potential conflict of interest is declared. Keith Stockman, co-author, has independently analysed the data, and the DHHS continually tracks the data and has an independent evaluation.

### 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.

subitem not at all important essential

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

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

The PaJR system was initially developed in Ireland and validated in an Irish primary care cohort and the details have been reported in several publications [13-17].

#### 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).

subitem not at all important essential

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

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study. The service is continually adapting to patient, service and treatment needs, but the model called complex adaptive care with the same web-based decision support system operated throughout unchanged. A slightly modified version integrated the Coaching and Telehealth data has now just gone into operation May 2020.

#### 5-iv) Quality assurance methods

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

subitem not at all important essential

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

"Quality assurance of the data analysis was performed in several ways. Carmel Martin analysed the outcome data using ANCOVA using XLSTAT. Keith Stockman and Narelle Hinkley independently analysed the same data set, after rechecking the download from Victorian Admitted Episode Data/Victorian Emergency Minimum Dataset using ANCOVA in r studio. External evaluation is being carried out using external controls with propensity rather than local contemporaneous controls and has not yet formally reported."

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.

5 subitem not at all important essential

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

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

PaJR is not a new software system

#### 5-vi) Digital preservation

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

5

subitem not at all important

essential

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

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

Not relevant

#### 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).

subitem not at all important

essential

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

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

Not relevant

### 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 computermediated 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].

5 subitem not at all important essential

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

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

Not relevant

#### 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.

subitem not at all important essential

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

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

Not relevant

#### 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).

subitem not at all important essential

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

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

This is a human operated system to provide decision support to non-health professionals from the community and this is described in detail in the paper

### 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).

5

subitem not at all important

essential

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

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

Not relevant

#### 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.

subitem not at all important

essential

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

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

The paper does not address the training of telecare guides and coaches, however there is a 2 weeks induction, a training program, supervised use and ongoing audit and feedback on performance

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

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

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

The nature of the evaluation specifically was aimed at containing bed days in a capitated model, this was present before the pilot service started and was never altered.

## 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].

5

subitem not at all important

essential

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

Copy and paste relevant sections from manuscript text

Not relevant

### 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.

subitem not at all important

essential

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

Copy and paste relevant sections from manuscript text not relevant

### 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).

subitem not at all important

essential

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

Copy and paste relevant sections from manuscript text

The Net Promoter Score with open-ended comments was anonymously administered and evaluated via postal survey. This was administered in accordance with the Australian National Safety and Quality Health Service Standard 2: Partnering with Consumer

#### 6b) Any changes to trial outcomes after the trial commenced, with reasons No

#### 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 studyThe

"HealthLinksChronicCare (HLCC) program was commenced in 2015 in the context of rising demand with constrained resources. The HLCC program employs analytics on hospital data to identify patients predicted to be at-risk of ≥3 repeat hospitalisations and their admission costs in the subsequent 12 months[7] and incentivises hospital systems to improve PPH admission (bed days/costs) and care quality within projected costs to contain expenditures"

#### 7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed not relevnt

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

essential

Two-sided significance level(1-alpha): 95, Power(1-beta, % chance of detecting): 80, Ratio of sample size, Unexposed/Exposed: 0.3 Percent of Unexposed with Outcome: 20 Percent of Exposed with Outcome: 9.9 Odds Ratio: 0.44, Risk/Prevalence Ratio: 0.5Risk/Prevalence difference: -10

Kelsey Fleiss Fleiss with CC

Sample Size - Exposed 359 394 436

Sample SizeNonexposed 108 119 131

Total sample size: 467 513 567

References Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-1Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19CC = contVIPy correction Results rounded up

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

Not relevant

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

Your answer

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.

systematic not random sampling due to clinical service pressures

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

Not relevant

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

Not relevant

### 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).

subitem not at all important

essential

### Does your paper address subitem 11a-i? \*

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

The ITT Active Treatment group provided consent to being recruited, and GPs, health and social services were aware of their pilot service status - blinding was not possible. Controls had no contact by the MW team and GPs, health and social services were unaware that they were controls. Decliners were not identified by any service following their refusal to participate

### 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".

subitem not at all important

essential

#### Does your paper address subitem 11a-ii?

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

Only the active treatment group were aware of 'treatment', refusers had enough information to decide but were had no experience of what the intervention was.

### 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

Not relevant

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

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

Does your paper address	s CONSORT subitem 12a? *
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 relevant

#### 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]).

subitem not at all important

essential

#### Does your paper address subitem 12a-i? \*

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

All participants who were allocated into ITT and UC groups remained in those groups and their outcomes were tracked over time

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

not relevant

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

X26-i) Comment on ethics committee approval

2 3

subitem not at all important

essential

Does your paper address subitem X26-i?

see ethics application

#### 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.

subitem not at all important

essential

Does y	our/	paper	address	subitem	X26-	-ii?
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

see ethics application

#### 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)

subitem not at all important

essential

Does your paper address subitem X26-iii?

see ethics application

#### **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? *
MM : Jantified 1272 anitable III Comption to IIC (202) and ITT (10

MW identified 1373 suitable HLCC patients: UC (293) and ITT (1080: 471 AT (44%); 485 declined; 178 lost to follow up and 8 died).

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) \*

not relevant

#### 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.

subitem not at all important essential

Does your paper address subitem 13b-i? Not relevant								
14a) Dates defining the periods of recruitment and follow-up								
Does your paper address CONSORT subitem 14a? *  2,502 patients were identified by the HLCC clinical algorithm from time period 2016-12-23 - 2019-6-23. Enrolment commenced with a gradual ramp up from December 201								
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	0	0	essential		
Does your paper address subitem 14a-i? not relevant								

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

Not relevant. Pilot service is ongoing amd expanding

# 15) A table showing baseline demographic and clinical characteristics for 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

All patients entered the study with a highbaseline risk with score of 9 on the clinical algorithm of HLCC. Patients who score 9+ based on the DHHS scoring algorithm have a high predicted risk of readmission to hospital and have to have an unplanned admission trigger before being enrolled.

## 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	0	0	essential

Does your paper address subitem '	15-11	^
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 relevant

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.

5

subitem not at all important



# 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

not relevant

#### 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).

subitem not at all important

essential

## Does your paper address subitem 16-ii?

The ITT AT group provided consent to being recruited, and GPs, health and social services were aware of their pilot service status - blinding was not possible. Controls had no contact with the MW team and GPs, health and social services were unaware that they were controls. Once allocated to the ITT and the AT group, patients remained in that group for the duration, even if they dropped out, died or were discharged the treatment group.

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? \*

SECONDARY OUTCOME Control Group UC had 163 (56%) of patients admitted more than once; median admissions/person was 3.0 with 3rd quartile being 5.0; Mean admissions/person was 3.9 with standard deviation admissions/person 4.3 with skewness of admissions/person (Pearson) 3.1. ITT had 549 (50%) of patients admitted more than once; median admissions/person was 2.0 with 3rd quartile being 4.0; mean admissions/person 3.6 and standard deviation admissions/person 4.3 with skewness of admissions/person (Pearson) 6.8. PRIMARY OUTCOME The UC Least Square mean was  $4.52 \pm 0.23$ bed days (4.1- 4.9 95% CI) while the ITT LS mean was 3.4 bed days  $\pm$  0.13 bed days (3.13-3.6 95% CI) (P<.001 and alpha <.5). A statistically significant bed days saving of 1.14 bed days per 1,080 ITT patients (1,236 days) was estimated.

# 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).

5 subitem not at all important essential

## Does your paper address subitem 17a-i?

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

Not Relevant

# 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

not relevant

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? \*

AIHW Potentially Preventable Hospital Admission codes as principal ICD diagnosis, were present for 11% UC vs 13% ITT with a non-significant difference; while 1% in both groups were for vaccine preventable conditions.

## 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).

subitem not at all important







essential

## Does your paper address subitem 18-i?

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

Your answer

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

(for specific guidance see CONSORT for harms)

# Does your paper address CONSORT subitem 19? \*

There were no harms identified and the monash ethic committe recommendations were addressed



	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].

subitem not at all important

5

essential

## Does your paper address subitem 19-i?

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

Your answer

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

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

subitem not at all important

essential

# Does your paper address subitem 19-ii?

Patient satisfaction was very high. Staf satisfaction etc will be reported elsewhere

#### 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).

5

subitem not at all important

## 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

Your answer

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

Highlight unanswered new questions, suggest future research.

subitem not at all important



essential

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

Your answer

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.

5

subitem not at all important







essential

# Does your paper address subitem 20-i? \*

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

Your answer

#### 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

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

5

subitem not at all important

essential

## Does your paper address subitem 21-i?

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

Your answer

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

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

subitem not at all important

essential

Does your paper address subitem 21-ii?

not relevant

#### OTHER INFORMATION

## 23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? \* not relevant

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

not relevant evaluation framework for Monash Watch is closest

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

Does your paper address CC	ONSORT	subiter	n 25? *			
X27) Conflicts of Interest (n	ot a CC	NSORT	item)			
X27-i) State the relation of th	ne study	team to	owards <sup>·</sup>	the syst	em bein	g evaluated
the study team developed the intervention	and conduc	ted the INT	ERNAL eva	luation		
	1	2	3	4	F	
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address su	bitem X	27-i?				
Copy and paste relevant sections fro indicate direct quotes from your man information not in the ms, or briefly e	uscript), c	r elaborat	e on this it	tem by pro	viding add	itional
Your answer						
About the CONSORT EHEA	TH che	ecklist				
About the Consolit Liter		CRIISC				

As a result of using this checklist, did you make changes in your manuscript? *  yes, major changes  yes, minor changes  no
What were the most important changes you made as a result of using this checklist?  It became important to clarify some Consort issues which were buried in the study
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *  Yseveral hours
As a result of using this checklist, do you think your manuscript has improved? *  yes  no Other:

Would you like to become involved in the CONSORT EHEALTH group?  This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document
O yes
O no
Other:
Any other comments or questions on CONSORT EHEALTH
Your answer
STOP - Save this form as PDF before you click submit  To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.
When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.
Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!
Final step: Click submit! Click submit so we have your answers in our database!
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