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

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

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

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

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

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

Mandatory reporting items are marked with a red *.

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

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

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

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

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Eysenbach G, CONSORT-EHEALTH Group

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

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doi: 10.2196/jmir.1923 PMID: 22209829

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TITLE AND ABSTRACT
1a) TITLE: Identification as a randomized trial in the title
 1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other") yes Other:
1a-i) Identify the mode of delivery in the title Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.
1 2 3 4 5 subitem not at all important • • • • 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 "A Randomized Controlled Trial Comparing Web-Based Provider-initiated and Patient-Initiated Survivorship Care Planning for Cancer Patients"
1a-ii) Non-web-based components or important co-interventions in title Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").
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NA		

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

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

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Does your paper address subitem 1a-iii? *

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

"A Randomized Controlled Trial Comparing Web-Based Provider- initiated and Patient-Initiated Survivorship Care Planning for Cancer
Patients"

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

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

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

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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

"Patients were randomized 1:1 to either a provider-initiated or patient-initiated SCPs – both are web-based tools. We conducted qualitative interviews with providers at baseline and follow-up, and with patients 2 months after enrollment. In addition, patients were administered the Preparing for Life as a (New) Survivor (PLANS) and Cancer Survivors' Unmet Needs (CaSUN) surveys at baseline and 2-months."

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

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

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Does your paper address subitem 1b-ii?

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

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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INTRODUCTION
2a) In INTRODUCTION: Scientific background and explanation of rationale
2a-i) Problem and the type of system/solution Describe the problem and the type of system/solution that is object of the study: intended as standalone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5) 1 2 3 4 5
subitem not at all important O • O O essential
Does your paper address subitem 2a-i? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study "The 2005 Institute of Medicine report 'From Cancer Patient to Cancer Survivor: Lost in Transition' [1] highlighted the difficulty that many cancer patients face when transitioning from acute treatment. The IOM report recommended that patients completing treatment receive a summary of the treatments received and a plan for follow-up care. These materials have become known as a 'Survivorship Care Plan' (SCP). The concept of SCPs has been widely accepted [2], but the literature on their implementation and impact remains sparse and inconclusive [3-6]."
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 \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc essential

Does your paper address subitem 2a-ii? *

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

designed with the intention of oncology providers initiating the survivorship care planning process. Uptake of survivorship care planning has, however, been slow and limited [7]. There are now several initiatives underway that are reconsidering survivorship care planning approaches, updating available templates, or both. Webbased, patient-initiated SCPs are one alternative whereby the patient is empowered to at least begin completion of a treatment summary and care plan at home. The idea behind the patient-initiated approach is that this may serve to reduce barriers related to available time and

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

"In the current study (ClinicalTrials.gov NCT02405819), we sought to compare the feasibility and value of the two Journey Forward models of survivorship care plan provision. This study was designed to provide initial evidence of comparative effectiveness, as well as to inform future, larger studies."

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

"This mixed-methods study comparing two modalities of survivorship care plans ("Care Plan Builder" and "My Care Plan") used a randomized design and was conducted in two community-based, academically affiliated hospitals."

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

"In the initial month of the study it became clear that oncologists and their staff were experiencing considerable difficulty in identifying eligible patients for study purposes. As a result, the research team played an active role in recruiting patients, but such approaches are not sustainable for real-word applications."

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 \(\cap \) \(\cap \) \(\cap \) 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

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4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

"Patient eligibility was not, however, limited to breast, prostate and colorectal cancer; patient participants were recruited through the participating clinicians, and were adults (21 years and older) diagnosed
with any non-metastatic cancer."
4a-i) Computer / Internet literacy Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.
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Does your paper address subitem 4a-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
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4a-ii) Open vs. closed, web-based vs. face-to-face assessments:
Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.
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Does your paper address subitem 4a-ii? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
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"patient participants were recruited through the participating clinicians, and were adults (21 years and older) diagnosed with any non-metastatic cancerPatient participants were identified in the clinic by clinic staff, and a member of the research team oversaw consent procedures."
4a-iii) Information giving during recruitment
Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.
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Does your paper address subitem 4a-iii? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
4b) Settings and locations where the data were
collected
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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
"Patient participants were identified in the clinic by clinic staff, and a member of the research team oversaw consent procedures. Eligible patients who agreed to participate provided written informed consent and were randomized 1:1"

 $https://docs.google.com/forms/d/1KIxFI4iTrxRIWADX-jCukJwHv4...I=en_US\&formkey=dGIKd2Z2Q1INSGQ0THI1azM5MS1aWWc6MA\&rm=fullowers.$

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

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

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Does your paper address subitem 4b-i? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this' indicate direct quotes from your manuscript), or elaborate on this item by providing additional
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this indicate direct quotes from your manuscript), or elaborate on this item by providing additional
"Data collection occurred at two-time points: baseline and two-month follow-up. The primary outcome was receipt of an SCP by the two-month follow-up. Specifically, at the two-month follow-up contact, we determined whether the patient had a partially or fully completed survivorship care plan versus no plan at all, as well as whether the patient's primary care provider had received a copy of the SCP.
Secondary outcomes included supportive care needs assessed by
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
Does your paper address subitem 4b-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this' indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

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).

indicate direct quotes	Iress subitem 5-i? nt sections from the manuscript (include quotes in quotation marks "like this" to from your manuscript), or elaborate on this item by providing additional ms, or briefly explain why the item is not applicable/relevant for your study
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Does your paper add Copy and paste releva ndicate direct quotes	
5-iii) Revisions and of Revisions and updating (and comparator, if apchanges during the evithe trial. Describe dynamical comparator, and the evithe trial.	Iress subitem 5-ii? nt sections from the manuscript (include quotes in quotation marks "like this" to from your manuscript), or elaborate on this item by providing additional ms, or briefly explain why the item is not applicable/relevant for your study

Copy and paste relevant sections from the manuscript (include quotes in or ndicate direct quotes from your manuscript), or elaborate on this item by participation not in the ms, or briefly explain why the item is not applicable. 5-iv) Quality assurance methods Provide information on quality assurance methods to ensure accuracy and provided [1], if applicable.	providing additional relevant for your study
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5-vi) Digital preservation Digital preservation: Provide the URL of the application, but as the intervention is likely disappear over the course of the years; also make sure the intervention is archived (Intervention.org, and/or publishing the source code or screenshots/videos alongside the pages behind login screens cannot be archived, consider creating demo pages which a without login.	ernet Archive, ne article). As
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Does your paper address subitem 5-vi? Copy and paste relevant sections from the manuscript (include quotes in quotation maindicate direct quotes from your manuscript), or elaborate on this item by providing addinformation not in the ms, or briefly explain why the item is not applicable/relevant for your manuscript). 5-vii) Access Access: Describe how participants accessed the application, in what setting/context, if (or were paid) or not, whether they had to be a member of specific group. If known, desparticipants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mo reviewers/readers to explore the application (also important for archiving purposes, se	ditional your study f they had to pa scribe how ode for
Copy and paste relevant sections from the manuscript (include quotes in quotation maindicate direct quotes from your manuscript), or elaborate on this item by providing addinformation not in the ms, or briefly explain why the item is not applicable/relevant for your manuscript). 5-vii) Access Access: Describe how participants accessed the application, in what setting/context, if (or were paid) or not, whether they had to be a member of specific group. If known, desparticipants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mo	ditional your study f they had to pa scribe how ode for

For participants randomized to the patient-initiated My Care Plan group, the research team directed patients to the web address for the appropriate tool and provided an instructional hand-out for reference. For participants randomized to the provider-initiated Survivorship Care Plan Builder, the provider was made aware of their randomization and was responsible for completing the survivorship care plan. The clinicians were all given information on the SCP Builder website/tool and were also familiarized with the patient-

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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Does your paper address subitem 5-viii? *

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

"The Journey Forward collaboration has developed both the "Survivorship Care Plan Builder" (provider-initiated) and "My Care Plan" (patient-initiated) web-based templates, and has made these tools freely available online. It is also possible to print the forms and fill them out by hand."

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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Does your paper address subitem 5-ix?

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5-x) Clarify the level o	f human involvement			
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There were no calls or reminders provided other than the knowledge that there would be a follow up interview after approximately 2 months	

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 standalone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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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

"Plan initiation: For participants randomized to the patient-initiated My Care Plan group, the research team directed patients to the web address for the appropriate tool and provided an instructional handout for reference. For participants randomized to the provider-initiated Survivorship Care Plan Builder, the provider was made aware of their randomization and was responsible for completing the survivorship care plan. The clinicians were all given information on the SCP Builder website/tool and were also familiarized with the patient-

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 primary outcome was receipt of an SCP by the two-month follow-up. Specifically, at the two-month follow-up contact, we determined whether the patient had a partially or fully completed survivorship care plan versus no plan at all, as well as whether the patient's primary care provider had received a copy of the SCP.

Secondary outcomes included supportive care needs assessed by the Cancer Survivors' Unmet Needs (CaSUN) survey [9], and

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Does your paper address subitem 6a-i? Copy and paste relevant sections from manuscript text

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

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

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Does your paper address subitem 6a-ii? Copy and paste relevant sections from manuscript text	

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text
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 No changes made to the outcomes.
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.
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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

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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

No interim analysis were undertaken with this small, exploratory study.

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

"Eligible patients who agreed to participate provided written informed consent and were randomized 1:1 using a random number generator with the condition concealed until randomization; patients and their clinicians were then informed of the randomized condition. Patients were paid \$35 for their participation in the study.

Plan initiation: For participants randomized to the patient-initiated My Care Plan group, the research team directed patients to the web

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

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"Eligible patients who agreed to participate provided written informed consent and were randomized 1:1 using a random number generator with the condition concealed until randomization"

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

Stata was used to produce random numbers.	

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

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

The study analyst produced the random numbers, which were then put into sequentially numbered envelopes. The person consenting was not aware of condition until after consent was complete, at which point the envelope was opened to reveal the condition for the participant.

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

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

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

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

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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

After randomization occurred both patient and provider had to know the condition given the nature of the intervention.	
	//

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

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

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Does your paper address subitem 11a-ii?

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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.			
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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

rank sum tests. We also compared the quantitative data measured at baseline between patients who did versus those who did not return for follow-up using logistic regression models that adjusted for intervention arm. No formal sample size calculations were conducted for the secondary quantitative outcome measures; however, the results here can inform power calculations for future evaluations. Analysis of interview data from clinicians and patients was thematic and summative, with a focus on identification of perceived and

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

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

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Does your paper address subitem 12a-i? *

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

Not relevant given the nature of our analysis.

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

No additional analyses were performed for this small, exploratory stu				
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X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

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Does your paper address subitem X26-i?

Medicine Institution	nal Review Board."
26-ii) Outline info	rmed consent procedures
outline informed cor	nsent procedures e.g., if consent was obtained offline or online (how? Checkbox, rmation was provided (see 4a-ii). See [6] for some items to be included in informed
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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

the provider-initiated Survivorship Care Plan BuilderAfter two months, 25 (61%) of the 41 enrolled patients provided follow-up data. We made repeated attempts to contact enrolled participants, except where early contacts resulted in expressed desire for no further participation. Reasons given for not participating in follow-up included ill health and change of residence. There were no statistically significant differences in the demographics between patients with follow-up vs. patients with baseline-only, adjusted for intervention arm

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

CONSORT diagram included.

"We made repeated attempts to contact enrolled participants, except where early contacts resulted in expressed desire for no further participation. Reasons given for not participating in follow-up included ill health and change of residence."

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

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

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
applicable/relevant for your study
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
"Patients were enrolled in the study for a period of 4 months and were
followed for 2 months."
da :\ lodina : forizina (forizina) (for colon con a forizina also cando a colon di
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 O O O O essential
- Cookertain important Cookertain
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

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

Does your paper address CONSORT subitem 14b? *

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

The trial was not stopped early.	
	//

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

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

Missing		1 0	10 (0070) 20 (10070)	
Compute Regular Occasion Rare Never Missing	35 (8 nal 1 (3%	8%) 18 (90° 3 (8%) 2	,	

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-i? *

Computer Use n(%)
Regular 35 (88%) 18 (90%) 17 (85%)
Occasional 3 (8%) 2 (10%) 1 (5%)
Rare 1 (3%) 0 (0%) 1 (5%)
Never 1 (3%) 0 (0%) 1 (5%)
Missing 1 1 0"

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 \(\cap \) \(\cap \) \(\cap \) 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

"Of the 25 patients who participated in follow-up (13 in the provider-initiated arm, 12 in the patient-initiated arm), 11(44%) had initiated an SCP. In the patient-initiated arm (n=20), 8 initiated a plan, with 5 of these completing the plan and 3 of these 5 reporting that they had given the plan to their PCP. In the provider-initiated arm (n=21), we were not able to assess the number of plans started but not completed or provided to the patient; 3 patients had received a completed SCP by the two month follow-up, and 2 of these patients

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 \(\cap \) \(\cap \) \(\cap \) essential

Does your paper address subitem 16-ii?

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
"Quantitative data (demographics, CaSUN, PLANS) were analyzed descriptively, comparing mean scores at baseline and follow-up between patients using t-tests. Changes from baseline to follow-up were described between patient groups with t-tests and Wilcoxon rank sum tests. We also compared the quantitative data measured at
baseline between patients who did versus those who did not return for follow-up using logistic regression models that adjusted for intervention arm. No formal sample size calculations were conducted
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 O O O O 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

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

"Quantitative data (demographics, CaSUN, PLANS) were analyzed descriptively, comparing mean scores at baseline and follow-up between patients using t-tests. Changes from baseline to follow-up were described between patient groups with t-tests and Wilcoxon rank sum tests. We also compared the quantitative data measured at baseline between patients who did versus those who did not return for follow-up using logistic regression models that adjusted for intervention arm. No formal sample size calculations were conducted

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

Not applicable for this small, exploratory study.	
	//

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

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

Does your paper address subitem 18-i?

10) All important barms or unintended affects in each
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
No harms or unintended effects occurred.
19-i) Include privacy breaches, technical problems
Include privacy breaches, technical problems. This does not only include physical "harm" to participants but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].
1 2 3 4 5
subitem not at all important O O O 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

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 \(\cap \) \(\cap \) \(\cap \) 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

strong patient buy-in for survivorship care planning, such that there was some perception that plans that are patient-initiated might be more successful. Another point raised was that when plans are patient-initiated, there is potential for saving time for the clinician."

From patients:

"In qualitative interviews conducted at follow-up, patients expressed ongoing needs related to information and support, with almost all of those interviewed describing some ongoing negative impact of cancer

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 \(\cap \) \(\cap \) \(\cap \) essential

Does your paper address subitem 22-i? *

"In this mixed-methods study, we evaluated two models of web-based survivorship care planning in the real-world context of two academically-affiliated, community hospitals. This study provides preliminary evidence of the comparative effectiveness of two SCP templates, as well as informing the design and implementation of future, larger studies. The combined qualitative and quantitative data provide important insights regarding the feasibility and value of the two SCP templates tested here, as well as survivorship care planning in general."

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20) Trial lin bias, impre analyses					•			•	ial
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bias, impre analyses 20-i) Typical limita Typical limitations in look at a multiplicity	cision, tions in ehe ehealth trial of outcomes y issues, bias	ealth the sealth the s	rials ticipeasir	f rele	health tria	mult als are rar error. Dis	iplicirely blinded cuss bias	ed. Ehealth tr	ials often on-use of the

indicate direct quotes from your manuscript), or elaborate 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 interpreting these findings, it is important to note that the twomonth follow-up was designed to evaluate delivery of the plan, not the impact of it on the secondary patient-reported outcome measures. This study was intended to provide preliminary evidence of the comparative effectiveness of these two web-based survivorship care planning approaches and to inform the design of larger studies. The sample size was determined based on feasibility, and the analysis of the quantitative data intended to inform power calculations for future

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

population, outside of a RCT setting, and general results for other organizations	patient population, including applicability of the study
1 2 3 4 5	
subitem not at all important \(\cap \) \(\cap \) \(\cap \) es	sential
Does your paper address subitem 21-i? Copy and paste relevant sections from the manus indicate direct quotes from your manuscript), or einformation not in the ms, or briefly explain why the	
21-ii) Discuss if there were elements in the R	CT that would be different in a routine application
setting	
prompts/reminders, more human involvement, tra	uld be different in a routine application setting (e.g., ining sessions or other co-interventions) and what e on use, adoption, or outcomes if the intervention is
1 2 3 4 5	

Does your paper address subitem 21-ii?

subitem not at all important \(\cap \) \(\cap \) \(\cap \) essential

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to

indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
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 NCT02405819"
24) Where the full trial protocol can be accessed, if
available
Does your paper address CONSORT subitem 24? *
Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or
elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
The full protocol is available on request from the corresponding
author/study PI

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

Does your paper address CONSORT subitem 25? *

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

"This study was supported by the Journey Forward consortium with
funding (through contracts to Dr. Smith and Dr. Snyder) from Anthem
and Genentech. All aspects of this research, including the design and
conduct of the study and analysis of resulting data, are solely those of
the authors."

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	0	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

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

0	yes,	major	changes
\odot	yes,	minor	changes

O no

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

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your manuscript *	d you spend on going through the checklist INCLUDING making changes in
20 hours	
As a result of using	this checklist, do you think your manuscript has improved? *
O yes	
○ no	
Other: It is more	compliant with C
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Would you like to b	ecome involved in the CONSORT EHEALTH group?
This would involve fo	or example becoming involved in participating in a workshop and writing an
"Explanation and Elal	boration" document
O yes	
• no	
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