## 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/

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The title does include target group: "Health Evaluation and Referral Assistant: a randomized controlled trial of a web-based screening, brief intervention and referral to treatment system to reduce risky alcohol use among emergency department 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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#### 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

"Alcohol users (n=319) presenting to an emergency department were considered for enrollment. Those enrolled (n=212) were	^
randomly assigned to the HERA, to complete a patient-	
administered assessment using a tablet computer, or a minimal-	
treatment Control, and were followed for three months. Analyses	
compared alcohol treatment provider contact, treatment initiation,	
treatment completion, and alcohol use across condition using	$\checkmark$
univariate comparisons, Generalized Estimating Equations (GEE),	

#### 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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your study The HERA is a stand-alone, self-administered, web-based assessment completed by the patients. "Alcohol users (n=319) presenting to an emergency department were considered for enrollment. Those enrolled (n=212) were randomly assigned to the HERA, to complete a patient-administered assessment using a tablet computer, or a minimal-treatment Control, and were followed for three months."	~
1b-iii) Open vs. closed, web-based (self-assessment) vs. fac METHODS section of the ABSTRACT	e-to-face assessments in the
Mention how participants were recruited (online vs. offline), e.g., fr from a clinic or a closed online user group (closed usergroup trial), web-based trial, or there were face-to-face components (as part of assessment). Clearly say if outcomes were self-assessed through web-based trials). Note: In traditional offline trials, an open trial (op trial in which both the researchers and participants know which tre avoid confusion, use "blinded" or "unblinded" to indicated the level "open" in web-based trials usually refers to "open access" (i.e. part Only report in the abstract what the main paper is reporting. If this main body of text, consider adding it)	and clarify if this was a purely the intervention or for questionnaires (as common in pen-label trial) is a type of clinica atment is being administered. To of blinding instead of "open", as icipants can self-enrol). (Note:
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differ between conc treatment provider, change in risky alco HERA participants to initiate contact w for risky alcohol use engaging in treatme	s (n=212: control=115; intervention=97) did not ditions on initial contact with an alcohol treatment initiation, treatment completion, or ohol use behavior. Subanalyses indicated who accepted a faxed referral were more likely vith a treatment provider and initiate treatment e, but were not more likely to continue ent, or to complete treatment and change risky
1b-v) CONCLUSION	NS/DISCUSSION in abstract for negative trials
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#### Does your paper address CONSORT subitem 2b? \*

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

"This study hypothesized that the HERA would improve initiation of specialized outpatient treatment for risky alcohol use, and reduce risky alcohol use among ED patients at three months post visit

as compared with a minimal intervention control condition."

### 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

A complete description of the HERA development and randomized controlled trial (RCT) methods were previously published [26, 34]. Only results pertaining to alcohol are presented here.

26. Boudreaux ED, et al. A randomized clinical trial of the health evaluation and referral assistant (HERA): research methods. Contemp Clin Trials. 2013 Jul; 35(2):87-96. PMID: 23665335

# 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

A brief overview of the methods is included, a detailed description of the methods was previously published [26, 34].	^	
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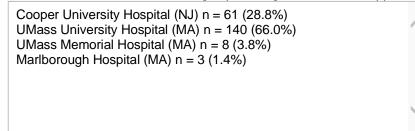
"Research assistants (RAs) approached all adult patients at their bedside during their ED visit. Patients 18 years and older with risky alcohol use were considered."

"All participants gave their informed consent and signed a written consent form prior to inclusion in the study."

### 4b) Settings and locations where the data were collected

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

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

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

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#### Does your paper address subitem 4b-ii?

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

Institutional affiliations were disclosed as part of the informed consent process.

# 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).

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 Does your paper address subitem 5-i?

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Developers are not discussed in this paper, but are discussed in the previously published papers detailing the methods of this study [26, 34].

The prototype of the HERA was called the Dynamic Assessment and Referral System for Substance Abuse (DARSSA). The name was changed to reflect long-term plans to expand the system to provide SBIRT for other non-substance problems.

5-ii) Describe the history/development process

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#### 5-iv) Quality assurance methods

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

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Does your paper address subitem 5-viii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like th to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
"Participants in the intervention condition (HERA) (1) were offered a dynamic referral, (2) their treating physician received the Healthcare Provider Report, and (3) the patient received the Patient Feedback Report with a tailored referral list. Participants assigned to the minimal intervention control condition (Control) were given a standardized, printed list of local treatment providers instead of dynamic referrals and Healthcare Provider Reports were not made available."
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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subitem not at all important 🔿 🔿 💽 🔿 essential
participate were offered the HERA service once during their ED visit.
5-x) Clarify the level of human involvement
<b>5-x) Clarify the level of human involvement</b> 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 professiona 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).
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 professiona 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 –
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 professiona involved, if any, as well as "type of assistance offered, the timing and frequency of the support, ho it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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aspects of the stu	idy procedures; how	vever the groups		
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6a) Compl	etely define	ed pre-sp	pecified	primary and
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7a) How sa	nple size was	s determined
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#### Does your paper address CONSORT subitem 9? \*

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Software used a random number generator that was embedded, and occurred after the patient consented and completed the assessment.

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

#### Does your paper address CONSORT subitem 10? \*

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

A random number generator was used to randomize. Research assistants enrolled the patients, but the assignment was done by the random number generator programmed into the HERA.

# 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 wa	isn't
Specify who was blinded,	and who wasn't. Usua	lly, in web-based trial

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

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

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

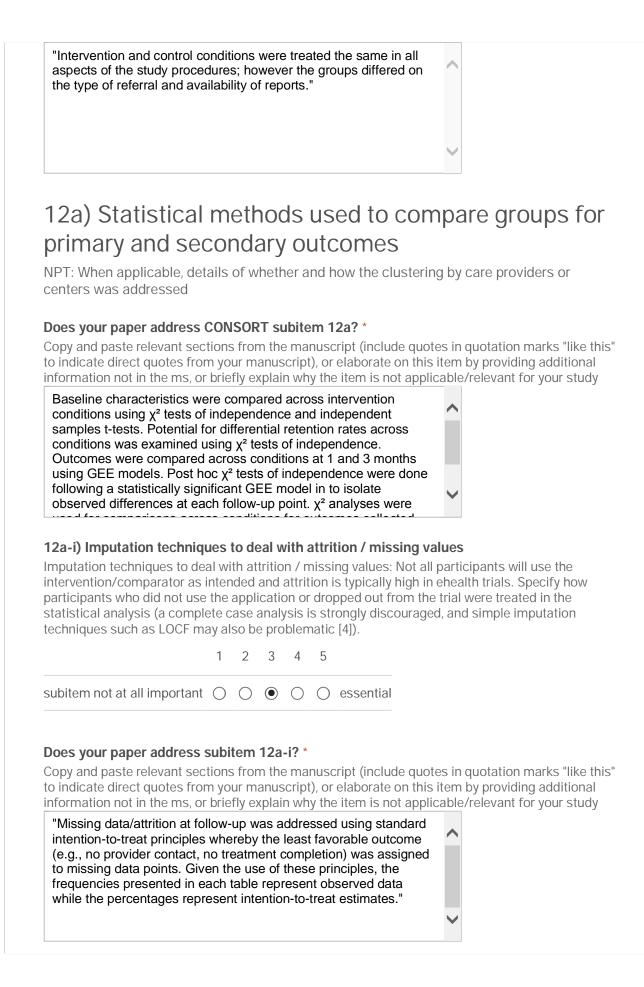
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12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses
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"We then performed a series of analyses comparing participants in three distinct groups: the control condition, the intervention condition that declined a dynamic referral to providers (Tailored List Only), and the intervention condition that accepted a dynamic referral (Dynamic Referral)"
X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (ne a CONSORT item)
X26-i) Comment on ethics committee approval
1 2 3 4 5
subitem not at all important 🔿 🔿 💽 🔿 essential
<b>Does your paper address subitem X26-i?</b> Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like
to indicate direct quotes from your manuscript), or elaborate on this item by providing addition information not in the ms, or briefly explain why the item is not applicable/relevant for your stu
"This study was approved by the Institutional Review Boards for all data collection sites, in accordance with the ethical standards of the Helsinki Declaration of 1975. All participants gave their informed consent and signed a written consent form prior to inclusion in the study."
<b>x26-ii) Outline informed consent procedures</b> Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.
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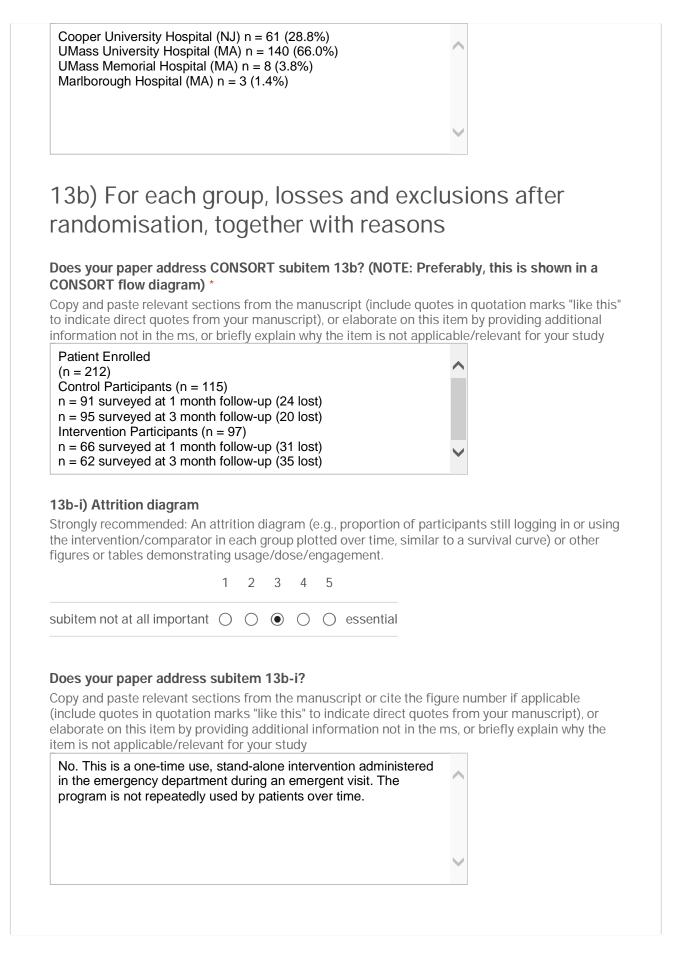
for eligibility. If the substance exam criteria, willing to	nods of this study [26, 34]. as first obtained to complete the rapid screener e individual tested positive for at least one ned by the study, and was eligible by all other participate in the clinical trial as explained, ras then obtained [26].
Safety and securit	<b>Id security procedures</b> procedures, incl. privacy considerations, and any steps taken to reduce the tion of harm (e.g., education and training, availability of a hotline)
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#### Does your paper address CONSORT subitem 13a? \*

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# 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

Recruitment period was from 5/17/2010-5/27/2011 and follow up period was 8/23/2010-09/16/2011.	^
	~

#### 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"

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subitem not at all important	$\bigcirc$	$\bigcirc$	$oldsymbol{O}$	$\bigcirc$	$\bigcirc$	essentia
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#### Does your paper address subitem 14a-i?

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

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

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A table showing baseline demographic and chiral content of the particularly inportant to report demographics associated with digital divide such as age, education gender, social-economic status, computer/Internet/elealth literacts		rget.
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 subtem 15? *         Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" o indicate direct quotes from your manuscript), or elaborate on this item by providing additional normation not in the ms, or briefly explain why the item is not applicable/relevant for your study         Table 2 features demographic characteristics of the analyzed sample.         Is-1) Report demographics associated with digital divide issues         n ehealth trials it is particularly important to report demographics associated with digital divide ssues, 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       Important       Important       Important       Important         Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" o indicate direct quotes from your manuscript), or elaborate on this item by providing additional normation not in the ms, or briefly explain why the item is not applicable/relevant for your study         Does your paper address subitem 15-i? *       Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" o indicate direct quotes from your manuscript), or elaborate on this item by providing additional norormation not in the ms, or briefly explain w		
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females (78/10 $\chi^2$ (1) = 5.87, P average, (M = 3 non-enrolled in 2.63, P = .009. enrolled eligible and insurance	et eligibility criteria, 212 were enrolled. More eligible 33; 76.7%) enrolled than males (134/216, 62.0%), P = .015, and enrolled individuals were younger, on 38.1 years; standard deviation (SD) = 13.4) than individuals (M = 42.3 years; SD = 13.9), t (317) = There were no differences in percentage of e patients across sites, concomitant tobacco use, status. Of the 212 enrolled, 115 were control and analysis should be intent-to-treat is should be intent-to-treat, secondary analyses could include comparing only
Primary analysis	appropriate caveats that this is no longer a randomized sample (see 18-i). 1 2 3 4 5
Primary analysis "users", with the	

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### 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? \*

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This was reported.	~	
	$\checkmark$	

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

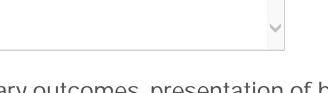
In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous 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).

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

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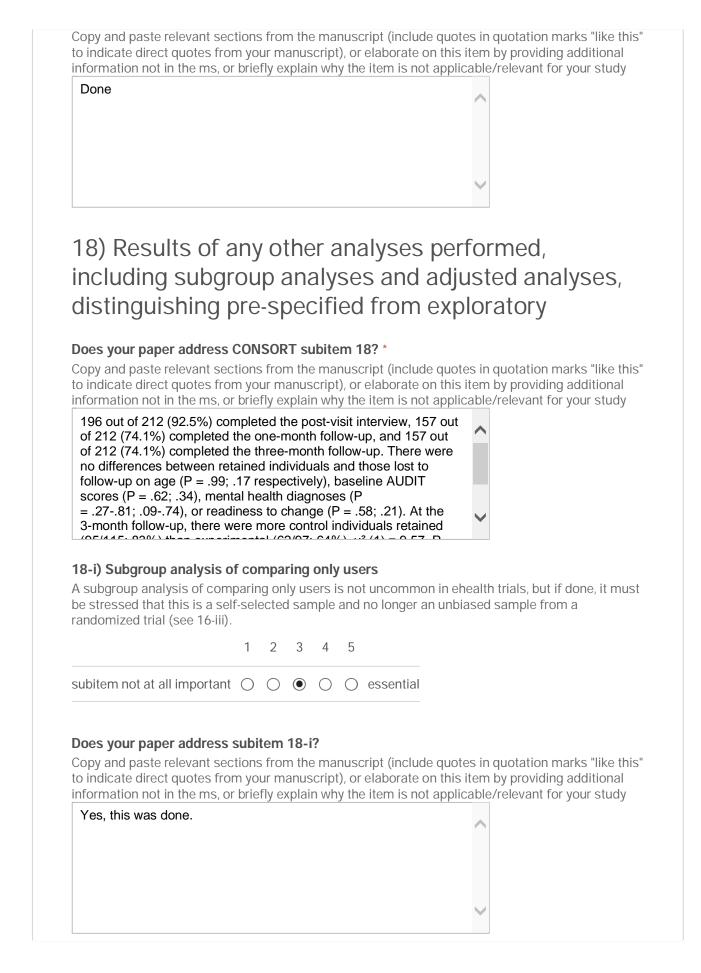


17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? \*

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

(for specific guidance see CONSORT for harms)

#### Does your paper address CONSORT subitem 19? \*

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None noted.		~

#### 19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

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subitem not at all important	$\bigcirc$	$\bigcirc$	0	۲	0	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

None noted.					~	
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#### 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

No, we did not collect it.

### DISCUSSION

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

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

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

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

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subitem not at all important	0	$\bigcirc$	0	$\bigcirc$	۲	essential

#### Does your paper address subitem 22-i? \*

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

The HERA aims to satisfy clinical practice mandates for SBIRT for risky alcohol users in the ED setting. For those who accepted the dynamic referral, the HERA was effective at promoting contact with an alcohol treatment provider and initiating treatment. When employed as a stand-alone intervention, the HERA did not lead to sustained treatment engagement or changes in alcohol use during the 3 months following the ED visit. These results raise two questions: (1) do stand-alone, brief, automated interventions lack

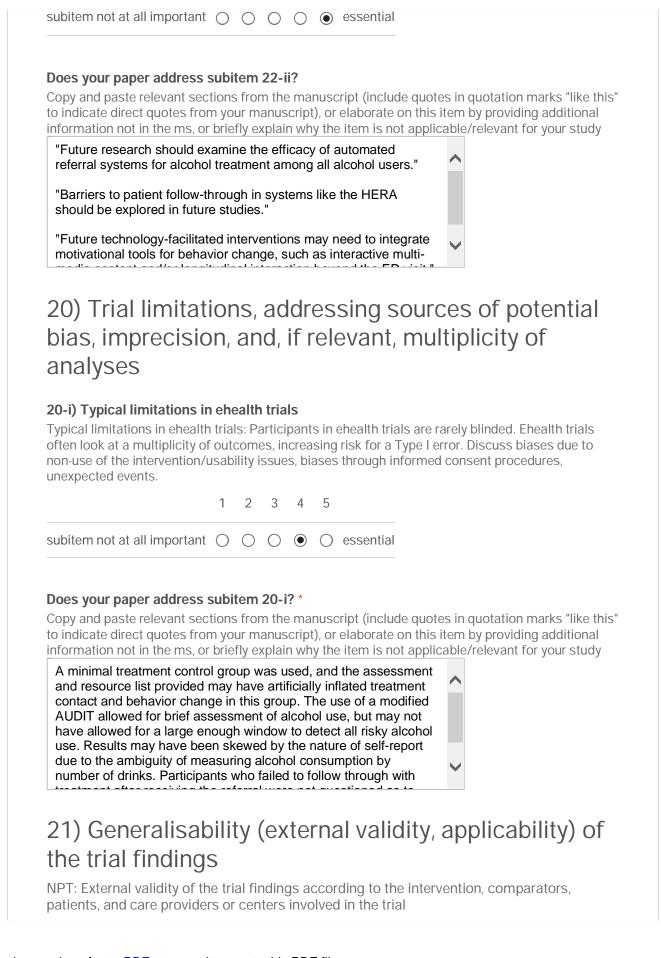
22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

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### 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



# 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



# 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 funded by a Small Business Technology Transfer grant from the National Institutes of Health (R42DA021455) to Polaris Health Directions, Inc."	^	

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