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 (non-pharmacologic treatment) items.

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

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

Mandatory reporting items are marked with a red *.

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

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

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

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

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

Eysenbach G, CONSORT-EHEALTH Group

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

J Med Internet Res 2011;13(4):e126 URL: 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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subitem not at all important \bigcirc \bigcirc \bigcirc \bigcirc essential

Does your paper address subitem 1b-i? *

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

"Methods: 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 univariate comparisons, Generalized Estimating Equations

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)

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

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. 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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Does your paper address subitem 1b-iii?

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

Participants were approached and enrolled in person during their emergency department visit, and those who enrolled and randomized to the HERA intervention condition completed the self administered web-based assessment. All received minimal treatment counseling from clinicians as typical treatment in addition to randomization into the HERA intervention.

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

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

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INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

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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

"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]. While the HERA assesses and refers patients to treatment for multiple substances, only results pertaining to alcohol are reported and discussed in this paper. A previous publication reported results for tobacco use [23], and a subsequent paper will address the results pertaining to illicit drug use. This clinical trial was registered with ClinicalTrials.gov as the

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, but due to the complex nature of a multi-substance screening and intervention program, a detailed description of the methods was previously published as a separate methods paper [26, 34].

26. Boudreaux ED, Abar B, Baumann BM, Grissom G. A randomized clinical trial of the health evaluation and referral assistant (HERA): research methods. Contemp Clin Trials. 2013

3b-i) Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2]. 1 2 3 4 5 subitem not at all important • • • • • • • • essential Does your paper address subitem 3b-i?

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26. Boudreaux ED, Abar B, Baumann BM, Grissom G. A randomized clinical trial of the health evaluation and referral assistant (HERA): research methods. Contemp Clin Trials. 2013

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

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

"Patients were enrolled from four EDs (see Table 1) between 8 AM and 7 PM, with shifts occurring every day of the week. 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."

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?

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Interviews were also conducted with 65 healthcare professionals from a variety of medical specialties to represent a range of provider types, as well as 13 tobacco, alcohol, and drug-using 5-iii) Revisions and updating Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b). 1 2 3 4 5 Subitem not at all important • • • essential Does your paper address subitem 5-iii? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study N/A 5-iv) Quality assurance methods	in the cited, previously publ						
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5-vii) Access	
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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

"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.

Does your paper address subitem 5-ix?

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

Participants meeting eligibility criteria and who consented to participate were offered the HERA service once during their ED visit.

"Research assistants (RAs) approached all adult patients at their bedside during their ED visit."

"Patients 18 years and older with risky alcohol use were

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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

Does your paper address subitem 5-x?

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

Designed as a stand-alone, automated, SBIRT system, clinician involvement was kept to a minimum. Research assistants introduced the service, obtained informed consent, and were present to troubleshoot any technical or user difficulties with the system. Providers were also encouraged, but not required, to counsel patients in response to their feedback report, for the intervention condition, and provided minimal treatment for the control condition.

~

5-xi) Report any prompts/reminders used

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

Does your paper address subitem 5-xi? *

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

For those who accepted a faxed referral to treatment, the treatment provider called the patient to initiate treatment within 48 hours of receiving the faxed referral. Follow-up calls were also performed by trained research assistants.

"If accepted by the patient, the dynamic referral was faxed by the HERA to a matched treatment facility, along with a brief assessment summary and the patient's contact information. The

•

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

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

Does your paper address subitem 5-xii? *

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

"...the HERA is designed to offer brief intervention and referral to treatment as a stand-alone service."

"Intervention and control conditions were treated the same in all aspects of the study procedures; however the groups differed on the type of referral and availability of reports. Participants in the intervention condition (HERA) (1) were offered a dynamic referral, (2) received the Patient Feedback Report with a tailored referral

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

"Post-visit interview. Immediately after patients were discharged/transferred from the ED, the enrolling RA completed a brief interview to establish whether the treating clinicians provided alcohol treatment counseling, education materials, or referrals for alcohol use treatment. Chart review was not used because of unreliability associated with documentation.

Follow-up assessment. All participants were phoned by an RA

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Online questionnaires were not used to obtain outcomes.

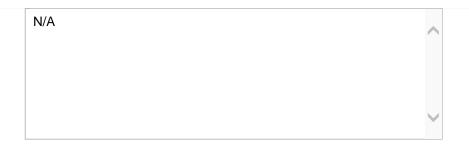
6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

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7a) How sample size was de	etermined
NPT: When applicable, details of whether and howas addressed	w the clustering by care provides or centers
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7b) When applicable, explana	ation of any interim
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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



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

N/A	^
	<u> </u>

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

Does your paper address CONSORT subitem 8b? *

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

"Participants were randomized to either the intervention or control condition by a random number generator from the Java programming language standard library embedded within the HERA."

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? *
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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 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).

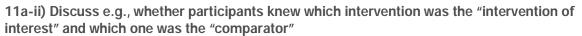
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Does your paper address subitem 11a-i? *

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

This is discussed briefly in the paper and more in depth in the cited, previously published papers detailing the methods of this study [26, 34].

"The RA who performed the outcome assessments was partially blinded. Because the HERA is heavily focused on the referral process, and not all patients received the same type of referrals, to avoid confusion, the follow-up questions were tailored to the



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".

Does your paper address subitem 11a-ii?

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

This is discussed in the cited, previously published papers detailing the methods of this study [26, 34].

Patients were partially blinded to group assignment in order to minimize bias

26. Boudreaux ED, Abar B, Baumann BM, Grissom G. A randomized clinical trial of the health evaluation and referral

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

"Study Conditions

Intervention and control conditions were treated the same in all aspects of the study procedures; however the groups differed on the type of referral and availability of reports. Participants in the intervention condition (HERA) (1) were offered a dynamic referral, (2) received the Patient Feedback Report with a tailored referral list, and (3) their treating physician received the Healthcare Provider Report. Participants assigned to the minimal intervention

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

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

Does your paper address CONSORT subitem 12a? *

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

"Data Analyses

Baseline characteristics (e.g., demographics, alcohol use) were compared across intervention conditions using χ^2 tests of independence and independent samples t-tests to confirm randomization success, and the potential for differential retention rates across conditions was examined using χ^2 tests of independence. Our primary outcomes (i.e., alcohol treatment provider contact, treatment initiation, alcohol use) were then

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

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

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

Does your paper address subitem 12a-i? *

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

"Missing data/attrition at follow-up was addressed using standard intention-to-treat principles whereby the least favorable outcome (e.g., no provider contact, no treatment completion) was assigned to missing data points. Given the use of these principles, the frequencies presented in each table represent observed data while the percentages represent intention-to-treat estimates."

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

"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). Because this categorization allows for preexisting differences across groups (particularly between the Tailored List and Dynamic Referral groups), these models included theoretically relevant covariates that might impact the

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

X26-i) Comment on ethics committee approval

Does your paper address subitem X26-i?

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

"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."

x26-ii) Outline informed consent procedures

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

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

Does your paper address subitem X26-ii?

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

This is discussed in the cited, previously published papers detailing the methods of this study [26, 34].

Verbal consent was first obtained to complete the rapid screener for eligibility. If the individual tested positive for at least one substance examined by the study, and was eligible by all other criteria, willing to participate in the clinical trial as explained, written consent was then obtained [26].

X26-iii) Safety and security procedures

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

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

Does your paper address subitem X26-iii?

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

Standard procedures surrounding data confidentiality and safety were used, such as storage on secure servers, and all research staff were trained and certified on human subjects protections procedures.

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? *

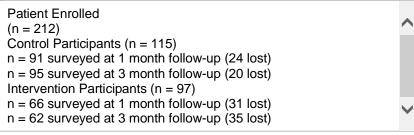
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Cooper University Hospital (NJ) n = 61 (28.8%)
UMass University Hospital (MA) n = 140 (66.0%)
UMass Memorial Hospital (MA) n = 8 (3.8%)
Marlborough Hospital (MA) n = 3 (1.4%)

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



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.

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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

No. This is a one-time use, stand-alone intervention administered in the emergency department during an emergent visit. The program is not repeatedly used by patients over time.

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"

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

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

None noted.

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

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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.

subitem not at all important \bigcirc \bigcirc \bigcirc \bigcirc 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 319 alcohol users who met eligibility criteria and did not report any drug use, 212 individuals were enrolled (see Figure 1). A greater proportion of eligible females (78/103; 76.7%) enrolled in the study than males (134/216, 62.0%), χ^2 (1) = 5.87, P = .015, and enrolled individuals were younger, on average, (M = 38.1) years; standard deviation (SD) = 13.4) than non-enrolled individuals (M = 42.3 years; SD = 13.9), t (317) = 2.63, P = .009. There were no differences in percentage of enrolled eligible

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).

2 3 4 5 subitem not at all important \(\cap \) \(\cap \) \(\cap \) essential

Does your paper address subitem 16-ii?

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

Yes, this was done.

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

This was reported.		^
		~

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?

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

N/A	^
	\

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

Does your paper address CONSORT subitem 17b? *

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 "Of the analyzed participants, 196 out of 212 (74.1%) completed the one-month follow-up, and 157 out of 212 (74.1%) completed the one-month follow-up, and 157 out of 212 (74.1%) completed the present of the complete of the post-visit interview, 157 out of 212 (74.1%) completed the present of the complete of the post-visit interview, 157 out of 212 (74.1%) completed the three-month follow-up, case Figure 1). There were no differences between retained individuals and those lost to follow-up on age (P = .99, .17 respectively), baseline AUDIT scores (P = .62, .34), mental health diagnoses (P = .2781; .0974), or readiness to change (P = .58; 2.1). However, at the three-month follow-up, case of the complete of the co	information not in the ms, or Done	ושות	ny e	хріаі	11 001	iy ciiv		посары	ioabio,			,	,
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Does your paper address subitem 22-ii?	
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"Future research should examine the efficacy of automated referral systems for alcohol treatment among all alcohol users."	^
"Barriers to patient follow-through in systems like the HERA should be explored in future studies."	
should be explored in future studies.	

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

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Does your paper address subitem 20-i? *

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

"Limitations

Firstly, because a minimal treatment control group was used, rather than true treatment as usual, the assessment and resource list provided to the minimal treatment control group may have had an intervention effect and artificially inflated treatment contact and behavior change in the control group. Secondly, the use of a modified AUDIT allowed for time-sensitive brief assessment of alcohol use, but assessed use over a shorter time period than

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

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

21-i) Generalizability to other populations

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

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

Does your paper address subitem 21-i?

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

"By focusing solely on alcohol users who used alcohol above the AUDIT quantity/frequency guidelines and who had not used illicit drug in the past 12 months, the generalizability of the results is limited. Future research should examine the efficacy of automated referral systems for alcohol treatment among all alcohol users."



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

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

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Does your paper address subitem 21-ii?

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

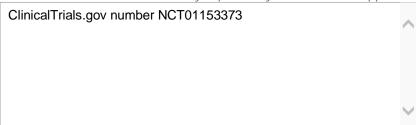
"The HERA was designed as a one-time, brief interaction due to the fast-paced ED environment filled with competing demands for time and resources. Minimizing the intervention for this purpose could have adversely affected the HERA's potential for clinical impact. The brief encounter with the HERA, while efficient and time-saving for clinicians, may not be powerful enough to support long-term changes in alcohol use behavior. Future technology-facilitated interventions may need to integrate motivational tools

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



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

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Visit the website clinicaltrials.gov	^
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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."

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.

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

An agreement related to technology used in this study exists between the University of Massachusetts Medical School and Polaris Health Directions. Dr. Boudreaux is an employee of the University of Massachusetts Medical School and receives consulting income from Polaris Health Directions. In addition, if the aforementioned technology should be licensed and result in licensing-related income, Dr. Boudreaux would receive a share under the University's allocation policy to inventors. Dr. Harralson

About the CONSORT EHEALTH checklist

As a result of	of using this	checklist, d	did you make d	changes in v	our manuscript? *
A3 a l C3alt	or asing ans	CHCCKH3t, u	aid you illake t		your manuscript.

yes, major changes

yes, minor changes

 \bigcirc no

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

Adding details to the abstract, including standard language with respect to consent and ethical standards.

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

8 hours

As a result of using this checklist, do you think your manuscript has improved? *

○ yes	
○ no	
Other: only slightly	
Would you like to become involved in the This would involve for example becoming involve "Explanation and Elaboration" document	CONSORT EHEALTH group? Colved in participating in a workshop and writing an
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Any other comments or questions on CON	ISORT EHEALTH
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