

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/>

doi: 10.2196/jmir.1923

PMID: 22209829

* Required

Your name *

First Last

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Your e-mail address *

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linda.dimeff@jasprhealth.com

Title of your manuscript *

Provide the (draft) title of your manuscript.

Using a Tablet-Based App to Deliver Evidence-Based Practices for Suicidal Patients in the Emergency Department: Pilot Randomized Controlled Trial



Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Jaspr [Jaspr Health]

Evaluated Version (if any)

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

Your answer

Language(s) *

What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

Your answer

URL of an image/screenshot (optional)

Your answer



Accessibility *

Can an enduser access the intervention presently?

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

Primary Medical Indication/Disease/Condition *

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

Suicidality

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Suicide-related coping, Capacity to cope with c

Secondary/other outcomes

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

Interventions received, Patient satisfaction



Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- Other: When in the Emergency Department

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- Other: App is meant for use only when in the Emergency Department for suic



Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Other:

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

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



Journal *

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

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

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- Pilot/feasibility
- Fully powered

Manuscript tracking number *

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

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Other: 23022



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.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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 Tablet-Based App"



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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Does your paper address subitem 1a-ii?

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

No important co-interventions present

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

"for Suicidal Patients in the Emergency Department"



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

"Participants were randomly assigned to Jaspr Health (n=14) or care as usual (control; n=17) groups." Other key features are mentioned in the BACKGROUND section of the abstract; "we developed Jaspr Health, a tablet-based app for direct use by such patients, which enables the delivery of 4 evidence-based practices."

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

"direct use by such patients"

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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subitem not at all important essential

Does your paper address subitem 1b-iii?

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

"Patients who were acutely suicidal and seeking psychiatric crisis services participated in an unblinded pilot randomized controlled trial while in the ED."



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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subitem not at all important essential

Does your paper address subitem 1b-iv?

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

"All established feasibility and acceptability criteria were met: no adverse events occurred, participants' app use was high, Jaspr Health app user satisfaction ratings were high, and all participants using Jaspr Health recommended its use for other suicidal ED patients."

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

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

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subitem not at all important essential



Does your paper address subitem 1b-v?

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

"Even with limited statistical power, the results showed that Jaspr Health is feasible, acceptable, and clinically effective for use by ED patients who are acutely suicidal and seeking ED-based psychiatric crisis services." This is also addressed in the RESULTS section of the abstract; "significant decreases in distress and agitation, along with significant increases in learning to cope more effectively with current and future suicidal thoughts, were observed among participants using Jaspr Health compared with those receiving care as usual."

INTRODUCTION

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

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

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

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subitem not at all important essential



Does your paper address subitem 2a-i? *

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

"Moreover, suicide rates have significantly increased over the past two decades, making suicide one of the few health outcomes proving difficult to impact", "On average, these patients wait for care more than 3 times longer than those with medical emergencies, which leads to the problem of boarding where the patient is waiting (and still under observational status) in the ED for an inpatient or residential bed to become available", "Boarding then leads to crowding, poor patient experience, lower quality care, delays in treatment, and morbidity and mortality as beds that might otherwise be used to treat patients with life-threatening medical conditions are used for patients who are suicidal while they await treatment or transfer to an inpatient unit or a residential facility"

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 appropriate), 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.

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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

"For these reasons, a number of public health policy initiatives have recommended increased delivery of suicide prevention efforts during ED visits. Accordingly, in recent years, The Joint Commission has required improved screening for suicidality. By July 2021, The Joint Commission will also require EDs to create suicide crisis safety plans for all patients who are acutely suicidal", "The use of electronic tablets in health care by providers and patients has exponentially increased over the past decade because of their portability, efficiency, and range of functionality.", "We sought to create a digital technology for use in EDs to increase the delivery of suicide prevention evidence-based practices without adding to personnel needs in an effort to reduce suicidal behavior with an ultimate goal of saving lives while also improving the quality of ED care delivered to those who are suicidal."

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

"We conducted this preliminary RCT in EDs to examine the feasibility, acceptability, and effectiveness of Jaspr Health for adults who were acutely suicidal in the ED.", "We predicted that, compared with care as usual (CAU) control participants, Jaspr Health participants would receive more evidence-based suicide prevention interventions, report greater reductions in their agitation and distress, indicate superior capacity for coping with their suicidal ideation over time, and exhibit higher patient satisfaction with their overall ED experience."

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 minimization randomization procedure was used to match participants to condition based on suicide severity and earlier history of ED visits for suicidal behavior."

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 RESULTS section: "Unfortunately, the rapid spread of COVID-19 required the suspension of recruitment efforts at participating health care organizations, thus ending this phase of research earlier than planned and with a significantly smaller sample size than originally planned (N=90)."

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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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

Not applicable, no major changes were made during the trial.

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

"Eligible participants were English-speaking adults, 18 years or older, and acutely suicidal in the ED. Patients who were actively psychotic, severely agitated, and/or significantly impaired by alcohol or drugs were excluded from participating because they would be unable to provide informed consent and participate meaningfully in a behavioral intervention and/or because of safety concerns involving access to a tablet that could be weaponized.

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 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; internet literacy was not necessary for the intervention

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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subitem not at all important essential

Does your paper address subitem 4a-ii? *

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

"Potentially eligible participants were identified by a member of the medical team or behavioral health specialists who initially approached each patient to briefly describe the study and assess their interest in participating. A researcher then met with the patient, provided a high-level summary of the project to determine the patient's interest, and conducted an eligibility screen to verify that the patient met the study criteria.", "To ensure safety while using the tablet-based app, the researcher remained in the patient's room during their use and sat on a chair in the corner of the room. Researchers told patients that they would be focusing on their own work to minimize the impact of their presence. Researchers were allowed to answer specific questions asked by the patient about Jasp Health use but did not speak to the patient during the study session."



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

"Potentially eligible participants were identified by a member of the medical team or behavioral health specialists who initially approached each patient to briefly describe the study and assess their interest in participating. A researcher then met with the patient, provided a high-level summary of the project to determine the patient's interest, and conducted an eligibility screen to verify that the patient met the study criteria. As patients who are suicidal are a vulnerable population, great care was taken to ensure that before providing consent, eligible participants had a thorough understanding of the study procedure, including its risks and benefits. To standardize the informed consent process and ensure that all information was reliably, simply, and succinctly delivered, all eligible participants watched a brief 5-min video in which the study's Director of Lived Experience Integration walked through all study procedures aided by a simple PowerPoint illustrating the key points. Eligible participants were offered the opportunity to review the written informed consent form and/or to have the researcher review other specific sections.", "To guard against bias or possible disappointment caused by not being randomly assigned to the Jaspr Health condition, specific details about Jaspr Health were contained in a separate supplemental 2-min video, and consent was provided to those assigned to Jaspr Health following the randomization procedure."

4b) Settings and locations where the data were collected



Does your paper address CONSORT subitem 4b? *

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

"We recruited individuals who were acutely suicidal and seeking ED-based psychiatric crisis services from 2 EDs located in the Midwest.", "All study procedures took place in the patient's ED room."

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

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

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subitem not at all important essential

Does your paper address subitem 4b-i? *

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

"Study data were collected using SurveyMonkey, a Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant secure web-based assessment tool and were stored in a HIPAA-compliant cloud-based server. Participants completed self-report questionnaires on an Apple iPad tablet. Researchers entered additional data (eg, time spent using Jaspr Health and answers to semistructured interview questions) onto laptops where content was saved and stored on the cloud-based server."



4b-ii) Report how institutional affiliations are displayed

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

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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

Your answer

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?

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

"At [Jaspr Health's] core is the Collaborative Assessment and Management of Suicidality (CAMS), a highly adaptable evidence-based suicide prevention intervention developed by Jobes", a conflict of interest section is also included at the end of the manuscript.

5-ii) Describe the history/development process

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

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Does your paper address subitem 5-ii?

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

"Jaspr Health was developed over a span of several years using an iterative process of development and best practices in user-centered design. Extensive feedback was sought from ED patients who were suicidal (n=89) and their ED-based care team (n=105) from 4 large health care systems across the United States."



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).

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Does your paper address subitem 5-iii?

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

The intervention did not undergo major changes during the evaluation process and there were no dynamic components

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-iv?

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

Not very applicable; manuscript briefly describes the validity and soundness of primary outcome measures



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

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

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subitem not at all important essential

Does your paper address subitem 5-v?

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

More info about Jaspr Health can be found at <https://jasprhealth.com/> and demos can be requested through the same link

5-vi) Digital preservation

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

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subitem not at all important essential



Does your paper address subitem 5-vi?

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

There is no URL for this application

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

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subitem not at all important essential

Does your paper address subitem 5-vii? *

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

"Following the completion of the informed consent and randomization process, participants completed a baseline assessment using a tablet. In the CAU condition, participants completed the posttest assessment 2 hours after the baseline assessment. In the Jaspr Health condition, participants were given up to 2 hours to use the app and then administered the posttest assessment.", "All study procedures took place in the patient's ED room."



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

"At [Jaspr Health's] core is the Collaborative Assessment and Management of Suicidality (CAMS), a highly adaptable evidence-based suicide prevention intervention developed by Jobes, for use by clinicians in engaging, assessing, and treating patients who are suicidal. CAMS uses a chart-ready documentation tool, the Suicide Status Form, to serve as a clinical roadmap guiding assessment, treatment planning, and ongoing tracking of risk and care disposition.", "Guided by the CAMS Suicide Status Interview, as adaptation of the Suicide Status Form, Jaspr Health includes an artificial intelligence-powered virtual guide chatbot that gathers patient self-report: the guide conducts the comprehensive suicide assessment, discusses the importance of lethal means safety management, and collaboratively generates a plan to reduce or eliminate access during the high-risk period, and generates a crisis stabilization plan with the patient. Content from these chatbot-driven discussions are then summarized in a clinical decision support guide for use by the care team in deriving an evidence-based discharge disposition.", "In light of the increased awareness of the power of imparting messages of hope and insights by PLEs, Jaspr Health also includes psychoeducation videos delivered by PLEs on what to expect in the ED, how to survive the first days after returning home from the hospital, coping with shame, strategies for staying well, and inspiring messages to generate hope (eg, My Wish for You). Efficacious behavioral skills from Dialectical Behavior Therapy, a recognized gold standard in the treatment of suicidal behavior, are also included to teach users how to tolerate distress, change unwanted negative emotions, distract from painful cues, better manage their thoughts with mindfulness, and radically accept that which cannot be changed."



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?

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 Jaspr Health condition, participants were given up to 2 hours to use the app and then administered the posttest assessment. The 2-hour study time and app use were paused when Jaspr Health participants met with a member of their care team and then resumed when done.", "Jaspr Health participants used Jaspr Health for an average of 80 min (SD 33 min; median 85 min)."

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).

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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

"The 2-hour study time and app use were paused when Jaspr Health participants met with a member of their care team and then resumed when done. To ensure safety while using the tablet-based app, the researcher remained in the patient's room during their use and sat on a chair in the corner of the room. Researchers told patients that they would be focusing on their own work to minimize the impact of their presence. Researchers were allowed to answer specific questions asked by the patient about Jaspr Health use but did not speak to the patient during the study session. Jaspr Health participants also received access to usual care."

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).

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subitem not at all important essential

Does your paper address subitem 5-xi? *

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

Not applicable



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).

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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

No co-interventions

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

"Key domains assessed among those in the Jaspr Health group included feasibility and acceptability. Feasibility was measured by the absence of negative or adverse events, the premature stopping of a test session by medical personnel concerned about the patient's welfare, or the premature disengagement of use (requesting to stop after 20 min, the average length of an ED-based clinical interview). Acceptability was measured by the total number of minutes used, whether the patient would recommend Jaspr Health to others in their situation, and satisfaction.

RCT measures were developed in collaboration with the Emergency Department Safety Assessment and Follow-up Evaluation principal investigator and Jaspr Health consultant (Dr Boudreaux), reviewed with PLEs, and selected for their brevity and simplicity for use with individuals who are suicidal and seeking psychiatric crisis services in an ED. The Safety and Imminent Distress Questionnaire is a 4-item, face-valid self-report survey based on Dr Boudreaux's Keeping Myself Safe Subject Usability Survey. Participants rated their feelings in the present moment using a 10-point scale. The following items were included: intensity of emotional distress (1=no distress; 10=highest distress ever felt), the extent to which they felt calm or agitated (1=very calm; 10=very frustrated or agitated), their ability to cope with thoughts of killing themselves (1=no ability to cope; 10=strong ability to cope), and their ability to go home safely (1=not able; 10=very able). The Suicide-Related Coping Scale (SRCS) is a 17-item psychometrically sound self-report measure of coping with suicidal thoughts, urges, and crises. The SRCS uses a 5-point rating scale (0=strongly disagree; 4=strongly agree). The Emergency Room-Patient Satisfaction Survey (ER-PSS) is a 7-item measure used to assess patient experience in the ED. The measure was developed in consultation with the patient experience division of a large reputable health care organization. The initial 6 items used a 5-point rating scale (1=poor; 5=excellent). Items included the helpfulness of ED visit, the degree to which the patient felt listened to and cared about by their care team, the likelihood that they would recommend the ED to others in their situation, and their overall rating of care they received. A final item involves rating their overall ED experience from 1 (worst) to 100 (best). The Jaspr Health Patient Satisfaction Questionnaire is an 8-item survey that adapts the ER-PSS to evaluate Jaspr Health, including its ease of use and helpfulness to patients. Patients also rate Jaspr Health on a 100-point scale and indicate whether they would recommend Jaspr Health to others in their situation. A brief semistructured interview was conducted at the end of the posttest session and sought to identify what, if any, suicide prevention best practices the participant received while in the ED. When they positively affirmed receiving an intervention, patients were asked to subjectively rate the thoroughness with which they received best practices using a 5-point Likert scale (1=not very thorough; 5=very thorough). They were also asked who delivered the best practice (a member of their care team, Jaspr Health, or both)."



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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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

"Study data were collected using SurveyMonkey, a Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant secure web-based assessment tool and were stored in a HIPAA-compliant cloud-based server. Participants completed self-report questionnaires on an Apple iPad tablet.", also see section 6A for discussion of validity.

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

"Feasibility was measured by the absence of negative or adverse events, the premature stopping of a test session by medical personnel concerned about the patient's welfare, or the premature disengagement of use (requesting to stop after 20 min, the average length of an ED-based clinical interview). Acceptability was measured by the total number of minutes used,"

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

"A brief semistructured interview was conducted at the end of the posttest session and sought to identify what, if any, suicide prevention best practices the participant received while in the ED. When they positively affirmed receiving an intervention, patients were asked to subjectively rate the thoroughness with which they received best practices using a 5-point Likert scale (1=not very thorough; 5=very thorough). They were also asked who delivered the best practice (a member of their care team, Jaspr Health, or both)."

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, there were no changes to trial outcomes after the trial was commenced

7a) How sample size was determined

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

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 7a-i?

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

Not relevant since sample size was much smaller than planned due to the onset of COVID-19

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

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

Not applicable

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

Not applicable for care providers.

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

"A minimization randomization procedure was used to match participants to condition based on suicide severity and earlier history of ED visits for suicidal behavior." No blocking occurred in this study.

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

"To minimize enrollment bias, randomization to either Jaspr Health or the CAU condition occurred after the process of informed consent was performed.", "To guard against bias or possible disappointment caused by not being randomly assigned to the Jaspr Health condition, specific details about Jaspr Health were contained in a separate supplemental 2-min video, and consent was provided to those assigned to Jaspr Health following the randomization procedure."

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

"Potentially eligible participants were identified by a member of the medical team or behavioral health specialists who initially approached each patient to briefly describe the study and assess their interest in participating. A researcher then met with the patient, provided a high-level summary of the project to determine the patient's interest, and conducted an eligibility screen to verify that the patient met the study criteria."

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

"an unblinded pilot randomized controlled trial", "Third, the assessors were not blinded to the patients' study condition."

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?

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

"To minimize enrollment bias, randomization to either Jaspr Health or the CAU condition occurred after the process of informed consent was performed.", "To guard against bias or possible disappointment caused by not being randomly assigned to the Jaspr Health condition, specific details about Jaspr Health were contained in a separate supplemental 2-min video, and consent was provided to those assigned to Jaspr Health following the randomization procedure."

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 since the comparator was care as usual.

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

"Table 5 shows that Jaspr Health participants had greater improvement than CAU participants from baseline to posttest in suicide-related coping, capacity to cope with distress, and agitation and distress using GEE analysis. Statistically significant time \times condition effects show that during the 2-hour experimental procedure, compared with CAU patients, Jaspr Health patients reported greater decreases in intensity of agitation and distress and greater increases in their ability to cope with thoughts of killing themselves."

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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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

Dealing with attrition is not applicable; "All Jaspr Health participants completed the use of digital technology without any adverse events or premature stopping of the test session either by medical personnel or participants."

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 subgroup analyses present

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

X26-i) Comment on ethics committee approval

subitem not at all important 1 2 3 4 5 essential

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

"All procedures were approved by a full board review by the Sterling Institutional Review Board and the Institutional Review Board at the Catholic University of America. External monitoring was provided by an independent Data Safety Monitoring Board comprising recognized suicide experts. The trial was registered at ClinicalTrials.gov NCT03584386."



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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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

"As patients who are suicidal are a vulnerable population, great care was taken to ensure that before providing consent, eligible participants had a thorough understanding of the study procedure, including its risks and benefits. To standardize the informed consent process and ensure that all information was reliably, simply, and succinctly delivered, all eligible participants watched a brief 5-min video in which the study's Director of Lived Experience Integration walked through all study procedures aided by a simple PowerPoint illustrating the key points. Eligible participants were offered the opportunity to review the written informed consent form and/or to have the researcher review other specific sections.

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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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

"Patients who were actively psychotic, severely agitated, and/or significantly impaired by alcohol or drugs were excluded from participating because they would be unable to provide informed consent and participate meaningfully in a behavioral intervention and/or because of safety concerns involving access to a tablet that could be weaponized.", "To ensure safety while using the tablet-based app, the researcher remained in the patient's room during their use and sat on a chair in the corner of the room."

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

"For approximately 2 months (January through February 2020), 41 patients who were suicidal in the ED were approached, screened, and informed of the study. Of these, 33 consented to being randomized to Jaspr Health (n=16) or CAU (n=17). Two Jaspr Health participants were excluded from participation after randomization (one was transferred to an inpatient unit before beginning the intervention and the other had previously participated in an earlier usability study), resulting in a Jaspr Health sample size of 14."

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

"Two Jaspr Health participants were excluded from participation after randomization (one was transferred to an inpatient unit before beginning the intervention and the other had previously participated in an earlier usability study), resulting in a Jaspr Health sample size of 14." No losses for care as usual condition. Also see consort table for losses and exclusions BEFORE randomization.

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 essential

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

See Figure 1 (Participant enrollment CONSORT (Consolidated Standard of Reporting Trials) flow chart.)

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

"For approximately 2 months (January through February 2020)". Follow up is not relevant for this study.

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 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

"Unfortunately, the rapid spread of COVID-19 required the suspension of recruitment efforts at participating health care organizations, thus ending this phase of research earlier than planned and with a significantly smaller sample size than originally planned (N=90)."

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

"Unfortunately, the rapid spread of COVID-19 required the suspension of recruitment efforts at participating health care organizations, thus ending this phase of research earlier than planned and with a significantly smaller sample size than originally planned (N=90)."

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

See Table 1 (Participants' characteristics by study group (enrollment).)

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.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | essential |



Does your paper address subitem 15-i? *

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

See Table 1 (Participants' characteristics by study group (enrollment).)

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.

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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

See Figure 1. Also, all analyses include N values and effect sizes (where relevant).



16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Not applicable; "All Jaspri Health participants completed the use of digital technology"

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

See Tables 2, 3, 4, and 5.



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

"Jaspr Health participants used Jaspr Health for an average of 80 min (SD 33 min; median 85 min)". Also see Tables 3 and 4 for participant reported exposure to interventions.

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

Does your paper address CONSORT subitem 17b? *

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

Not applicable; no binary outcomes reported.

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, no exploratory results discussed.

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).

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subitem not at all important essential

Does your paper address subitem 18-i?

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

Not relevant; no subgroup analyses comparing only users was present.

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

Not applicable; no important harms or unintended effects were found.



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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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

Not applicable; no privacy breaches or technical problems occurred.

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.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

Not applicable; no Jaspr Health participants did not use the application.



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 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

"We wondered whether patients who are acutely suicidal would tolerate interacting with an artificial intelligence–powered chatbot designed to deliver evidence-based suicide-focused interventions. Would they also choose to virtually hear from PLE and learn behavioral skills to increase their capacity to cope with distress? If they did, would it produce positive clinical outcomes and improve their overall ED visit experience?

Preliminary findings strongly supported Jaspr Health’s feasibility and acceptability, while also appearing promising as an effective clinical intervention. With respect to feasibility and acceptability, patients who are suicidal in the ED tolerated Jaspr Health and opted to use the app on their own for a median of 85 min. Of 14 Jaspr Health patients, all completed a comprehensive suicide assessment and created a crisis stabilization plan, and 12 (85%) patients engaged in lethal means counseling. Jaspr Health participants also opted to learn 3 behavioral skills and hear from 4 PLEs and gave Jaspr Health high satisfaction ratings—100% recommended it for use by others in their situation. In addition, no adverse events occurred during its use. Jaspr Health appeared clinically effective. In comparison with CAU participants, those receiving Jaspr Health reported statistically significant reductions in agitation and distress over time and improved capacity to cope with current and future suicidal thoughts. They also felt more positively about their overall ED experience."

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

Highlight unanswered new questions, suggest future research.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | essential |



Does your paper address subitem 22-ii?

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

"Future research should focus specifically on ED sites in ethnically and racially diverse regions of the United States to ensure greater sample diversity to address this considerable limitation.", "Future studies should seek to reduce threats to internal validity by building in greater experimental controls while also recruiting participants from more ethnically and racially diverse regions of the country"

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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| subitem not at all important | | | | | | essential |

Does your paper address subitem 20-i? *

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

"Second, a placebo device was not used for the CAU participants. Without controlling for the tablet itself and engagement with it, we cannot know for certain whether the effect achieved was because of Jaspr Health's content or simply the outcome of having access to a tablet. (It is worth noting, however, that all rooms were equipped with a television for patient use). Third, the assessors were not blinded to the patients' study condition." Other non-typical ehealth trial limitations are discussed in the "Limitations" section"



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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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

"Finally, limitations of budget and project scope, complicated further by reducing study length because of COVID-19, resulted in our inability to expand to other ED research sites located in more ethnically and racially diverse regions of the United States. This resulted in another significant study limitation, namely, a predominantly White sample that significantly limits the study's external validity. Future research should focus specifically on ED sites in ethnically and racially diverse regions of the United States to ensure greater sample diversity to address this considerable limitation."



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.

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 21-ii?

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

"First, researchers were only in the room for Jaspr Health, but not CAU, to ensure safe use of the app during initial testing."

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

"The trial was registered at ClinicalTrials.gov NCT03584386."

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 trial was registered at ClinicalTrials.gov NCT03584386."

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 work was supported by the National Institutes of Health or National Institute of Mental Health (R44MH108222). The sponsor had no role in the review or approval of this manuscript."

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.

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| subitem not at all important | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 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

"LD and KK co-own the Evidence-Based Practice Institute, Inc, a for-profit company that owns Jaspr Health. DJ is the treatment developer of CAMS and receives royalties for his books from the American Psychological Association Press and Guilford Press. He is a founder and co-owner of CAMS-care, a limited liability corporation, a for-profit training and consultation organization. Both DJ and PG have equity shares in Jaspr Health. To manage investigators' potential conflicts of interest, statistical consultant BB, independently oversaw all data management, data analyses, and written interpretation of all results and verified the accuracy and validity of all study data before any data have been publicly presented."

About the CONSORT EHEALTH checklist

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

- yes, major changes
- yes, minor changes
- no

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

Your answer



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

Five hours

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

yes

no

Other: no, because we used this checklist after the manuscript was submitte

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

yes

no

Other:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer



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