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

kateellenloveys@gmail.com (not shared) Switch account

* Required

Your name *
First Last
Kate Loveys

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
The University of Auckland, Auckland, New Zealand

Your e-mail address *

abc@gmail.com
k.loveys@auckland.ac.nz

Title of your manuscript *
Provide the (draft) title of your manuscript.

Effects of Emotional Expressiveness of a Female Digital Human on Loneliness, Stress, Perceived Support, and Closeness Across Genders: 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.

Digital human

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

2019 version

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.

https://www.soulmachines.com/

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)"

Loneliness

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

Loneliness

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

Stress (subjective and physiological), social support, social closeness, caring perceptions
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: A one-off 15-minute interaction was used in this study

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:
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: The effects of emotional expressiveness in a female digital human vary by user gender.

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: 30624
1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *
I.e. does the title contain the phrase "Randomized Controlled Trial"? (If not, explain the reason under 'other')

- [ ] yes
- [ ] Other:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

1 2 3 4 5

- [ ] subitem not at all important
- [ ] essential

1a-i) 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

Effects of Emotional Expressiveness of a Female Digital Human on Loneliness, Stress, Perceived Support, and Closeness Across Genders: Randomized Controlled Trial
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").

|   | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| subitem not at all important | ☐ | ☐ | ☐ | ☐ | ☐ |
| essential | ☐ | ☐ | ☐ | ☐ | ☐ |

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

Not applicable- this study compared the effects of digital humans of different designs (i.e., that varied in their degree of emotional expressiveness)

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

|   | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| subitem not at all important | ☐ | ☐ | ☐ | ☐ | ☐ |
| essential | ☐ | ☐ | ☐ | ☐ | ☐ |

Does your paper address subitem 1a-iii? *

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

A community sample of adults (an equal number of women and men) were the target group. This is alluded to in the title ("across genders").
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)

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

"...complete a 15-minute self-disclosure conversation with a female digital human in 1 of 6 conditions. In these conditions, the digital human varied in modality richness and emotional expression on the face and in the voice (emotional, neutral, or no face; emotional or neutral voice)."

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)
The digital human was fully automated. The interaction took place in a private room with only the participant and the digital human. A researcher was available in a separate room and could be called on by the participant to help should they encounter any technical issues that they couldn't resolve.

Participants were recruited online and offline via flyers at the university campuses and in university email lists. Participants interacted with the digital human in a private room at a clinical research centre during one 45-minute appointment. Measures were administered in two paper questionnaires completed independently by the participant at the beginning and end of the appointment. Objective data were collected during the participant's interaction with the digital human via a wrist-worn sensor and an audiovisual recording.
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

"A community sample of 198 adults (101 women, 95 men, and 2 gender-diverse individuals) was block-randomized by gender to complete a 15-minute self-disclosure conversation with a female digital human in 1 of 6 conditions." There were on average 32 participants per condition (see Figure 1- CONSORT Flow diagram). "Emotional expression in the voice was associated with greater perceptions of caring and physiological arousal during the interaction, and unexpectedly, with lower feelings of support. User gender moderated the effect of emotional expressiveness on several outcomes. For women, an emotional voice was associated with increased closeness, social support, and caring perceptions, whereas for men, a neutral voice increased these outcomes. For women, interacting with a neutral face was associated with lower loneliness and subjective stress compared with no face. Interacting with no face (ie, a voice-only black screen) resulted in lower loneliness and subjective stress for men, compared with a neutral or emotional face. No significant results were found for heart rate or skin temperature. However, average electrodermal activity was significantly higher for men while interacting with an emotional voice."
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)

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

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

"Emotional expressiveness in a female digital human has different effects on loneliness, social, and physiological outcomes for men and women. The results inform the design of digital human support persons and have theoretical implications. Further research is needed to evaluate how more pronounced emotional facial expressions in a digital human might affect the results."

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

"Loneliness is a growing public health issue that has been exacerbated in vulnerable groups during the COVID-19 pandemic [1]...Interventions are needed to alleviate the burden of loneliness on population health and health care systems." "Digital humans are a new form of computer agent that show promise for applications in health care, including acting as a supportive peer... Digital humans (and computer agents in general) are a new technology, and research is needed to understand how to design them in a way that is conducive to providing support to people."

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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subitem not at all important  ○  ○  ○  ○  ○ essential
"Research has increasingly shown that social robots and computer agents may help to reduce loneliness and improve health outcomes for people by providing functional social support... There is limited research investigating the effect of support from a computer agent on loneliness [31]. However, 1 study found that companionship from an animal-like conversational agent reduced loneliness in hospitalized older adults [32]. Other studies have found that Tanya, a humanlike computer agent companion for older adults at home, was effective at improving loneliness and was highly acceptable to users [33,34]. Similarly, studies in young adult populations have found that computer agents show promise for improving loneliness [35,36]... Digital humans (and computer agents in general) are a new technology, and research is needed to understand how to design them in a way that is conducive to providing support to people. Research has shown that the perceived effectiveness of social support interventions may be influenced by how socially close people feel to the support partner [39]. This suggests that it may be important to design digital humans to engage in behaviors that build closeness with people while providing support. However, there is limited research on which behaviors increase closeness with computer agents [40]... Research has yet to investigate the effects of emotional expressiveness in a digital human's face and voice on user outcomes, and how emotional expressiveness interacts with user gender during a supportive interaction."
The aim of this study is to investigate the effect of emotional expressiveness in a digital human on loneliness, closeness, caring perceptions, social support, stress, and physiological arousal in a community sample. It was hypothesized that there would be gender differences in the effect of emotional expressiveness in a digital human on outcomes. Particularly, it was anticipated that women would report the greatest reductions in loneliness, stress, and physiological arousal and the greatest increases in social support, closeness, and caring perceptions in response to a digital human with an emotional face and an emotional voice. In contrast, it was predicted that men would report better outcomes in response to a digital human with a neutral face and a neutral voice.

A between-group experimental study was conducted... Participants were then block-randomized by gender to interact with 1 of 6 versions of a digital human.
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.

There were no important changes to the methods after trial commencement.

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

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

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subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 3b-i?

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

"At times, errors with the conversation engine meant that the digital human occasionally interrupted the participants during their speech. However, interruptions were equally likely across the experimental conditions (F5,179=1.11; P=.36)." "Data from 1.5% (3/198) of participants were excluded from analyses for the following reasons: the software would not start (1/198, 0.5%)."

There were no content changes nor bug fixes 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

"Participants were considered eligible if they were aged ≥18 years and were fluent in English."

4a-i) Computer / Internet literacy

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

1 2 3 4 5

subitem not at all important  ○  ○  ○  ○  ○  essential

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

Computer/internet literacy was not part of the eligibility criterion.

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.

"The study was advertised using flyers distributed in the University of Auckland campuses and through Facebook advertising to the Auckland city area. "Participants attended a 45-minute experimental session at the University of Auckland Clinical Research Centre. After providing written informed consent, participants secured an Empatica E4 sensor to their wrist and completed a baseline questionnaire on paper... The researcher provided the participant with verbal and written instructions for interacting with the digital human, started the digital human program on the laptop computer, then closed the door, and exited the room for the duration of the interaction. Participants were instructed to call on the researcher (who was sitting on a chair down the hallway) by ringing a loud desk bell if they encountered any technical difficulties that they could not resolve. Participants completed the RCIT with a digital human... Once the RCIT was completed, the participant rang the desk bell, and the researcher returned to the room. The participant removed the wrist sensor and completed a second paper questionnaire on perceived loneliness, closeness, caring perceptions, social support, and stress.”

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.

1 2 3 4 5

subitem not at all important    ○    ○    ○    ○    ○    essential
Does your paper address subitem 4a-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"A community sample of 198 adults (101 women, 95 men, and 2 gender-diverse individuals) was recruited to participate in a study on relationships with a digital human." "After providing written informed consent, participants secured an Empatica E4 sensor to their wrist and completed a baseline questionnaire on paper."

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.

"Participants attended a 45-minute experimental session at the University of Auckland Clinical Research Centre."

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 0 0 0 0 0 essential
The two questionnaires were administered in paper format. "After providing written informed consent, participants secured an Empatica E4 sensor to their wrist and completed a baseline questionnaire on paper." "The participant removed the wrist sensor and completed a second paper questionnaire on perceived loneliness, closeness, caring perceptions, social support, and stress."

Institutional affiliation was evident on the flyer, participant information sheet and consent form. No logos were present on the technology.

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).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

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

"The authors wish to thank the engineering team at Soul Machines Ltd for their assistance in building the digital human for this experiment."

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.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As described in the 'Digital Human' section, the program was built for the study.
5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

1  2  3  4  5

subitem not at all important ☐  ☐  ☐  ☐  ☐  essential

Does your paper address subitem 5-iii?

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

The intervention did not undergo any changes during the evaluation process (i.e., the content was “frozen” during the trial).

5-iv) Quality assurance methods

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

1  2  3  4  5

subitem not at all important ☐  ☐  ☐  ☐  ☐  essential
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.

The ‘Measures’ section describes how validated measures were used for data collection. A combination of subjective self-report and objective sensor/ audiovisual data were collected to evaluate the intervention. Questionnaires were completed independently by participants in a de-identified booklet (labeled with an ID code, not their names).

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.

1  2  3  4  5

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 5-v?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Not applicable to publish the source code as the digital humans belong to Soul Machines Ltd. Screenshots of the interface are shown in Figure 3.
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.

Does your paper address subitem 5-vi?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as the intervention was not web-based. The source code cannot be shared as it is commercially owned (by Soul Machines Ltd, Auckland, New Zealand).

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).

Does your paper address subitem 5-vii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as the intervention was not web-based. The source code cannot be shared as it is commercially owned (by Soul Machines Ltd, Auckland, New Zealand).
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

"Participants attended a 45-minute experimental session at the University of Auckland Clinical Research Centre... The researcher provided the participant with verbal and written instructions for interacting with the digital human, started the digital human program on the laptop computer, then closed the door, and exited the room for the duration of the interaction." Participants did not pay to access the intervention.

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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].

![Subitem Importance Scale](image)

subitem not at all important ○ ○ ○ ○ ○ essential

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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

See 'Digital Human' section for an in-depth description of the digital human intervention and its functionalities.
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.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-ix?

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

Participants only interacted with the digital human once during an in-person appointment at a clinical research centre. The interaction lasted 15 minutes.

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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subitem not at all important ○ ○ ○ ○ ○ essential
Does your paper address subitem 5-x?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The researcher provided the participant with verbal and written instructions for interacting with the digital human, started the digital human program on the laptop computer, then closed the door, and exited the room for the duration of the interaction. Participants were instructed to call on the researcher (who was sitting on a chair down the hallway) by ringing a loud desk bell if they encountered any technical difficulties that they could not resolve... Once the RCIT was completed, the participant rang the desk bell, and the researcher returned to the room."

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).

![Rating Scale]

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

Participants only received one reminder to attend their appointment at the clinical research centre. No other reminders were provided.
### 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 a 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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| 1 | 2 | 3 | 4 | 5 | essential |

subitem not at all important

#### 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 additional interventions are provided in the study beyond the digital human. The researcher provides brief verbal and written instructions on how to interact with a digital human (for approx. 5 minutes) before setting up the computer program for the participant (who interacts with the digital human independently in private).

### 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.

See Figure 2 and the Measures section for an in-depth description of the measures used and when they were administered.
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

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

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

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

Not applicable, measures were administered on paper.

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

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

Not applicable- participants only used the intervention once during an in-person appointment
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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subitem not at all important   ○   ○   ○   ○   ○   essential

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

"Participants also answered a series of open-ended, written qualitative questions on their perceptions of the digital human (reported in another paper; Loveys, unpublished data, March 2021)."

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No changes were made to the study methods after trial commencement.

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

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

"A power analysis was conducted using G*Power software to determine the required sample size. This was informed by the results of Brave et al [55], who compared the effects of agent empathy versus no empathy on feelings of support and found an effect size of $f=0.32$. 198 participants would be needed to detect an effect size of $f=0.32$, with 80% power and an $\alpha$ level of .05 for a 3 (face) by 2 (voice) by 2 (gender) analysis of variance (ANOVA). A recruitment target was set for 100 women and 100 men."

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

Recruitment stopped once the participant quota had been met.

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group
#### 8b) Type of randomisation; details of any restriction (such as blocking and block size)

| Does your paper address CONSORT subitem 8b? * |
|-----------------------------------------------|
| Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study |

"Participants were then block-randomized by gender to interact with 1 of 6 versions of a digital human. Block randomization was completed before the session by a member of the research team, who automatically generated a randomization table using Research Randomizer software."

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#### 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 8b? * |
|-----------------------------------------------|
| Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study |

"Participants were then block-randomized by gender to interact with 1 of 6 versions of a digital human."
10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

"Block randomization was completed before the session by a member of the research team, who automatically generated a randomization table using Research Randomizer software. Allocations were concealed from the researcher and the participant in opaque envelopes. The researcher remained blinded to the participant's condition until the envelope was opened immediately before starting the appropriate computer program for the participant. Although the participants were deblinded to their condition upon starting their interaction, they remained unaware of what digital humans in the other experimental conditions were like."

Participants were enrolled by the researcher who ran the appointments who was blinded to their condition until as described above.

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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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 11a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Block randomization was completed before the session by a member of the research team, who automatically generated a randomization table using Research Randomizer software. Allocations were concealed from the researcher and the participant in opaque envelopes. The researcher remained blinded to the participant’s condition until the envelope was opened immediately before starting the appropriate computer program for the participant. Although the participants were deblinded to their condition upon starting their interaction, they remained unaware of what digital humans in the other experimental conditions were like."

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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subitem not at all important ○ ○ ○ ○ ○ essential
Although the participants were deblinded to their condition upon starting their interaction, they remained unaware of what digital humans in the other experimental conditions were like.

Not applicable to this study
"Data were analyzed using SPSS software, version 27 (IBM Corporation). Data were checked for violations of test assumptions, and bootstrapping was applied to tests where data were not normally distributed. Chi-square tests and ANOVA tests were conducted to check for baseline group differences in demographic and psychological variables. As no significant differences were found in the baseline variables, they were not controlled for in subsequent analyses. A series of 3-way factorial ANOVA tests were conducted to evaluate the effect of face type, voice type, and gender on outcomes at time point 2 (T2). Post hoc tests with Sidak correction were applied as follow-up analyses."

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]).

Complete case analysis was used for the relevant variable

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses
Does your paper address CONSORT subitem 12b? *

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

Not applicable to this study

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

X26-i) Comment on ethics committee approval

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subitem not at all important  ○  ○  ○  ○  ○  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

"The study procedures were approved by the University of Auckland Human Participants Ethics Committee on November 1, 2018 (reference number: 022191)."
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.

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

Written informed consent was obtained in-person at the appointment. Participants read the participant information sheet and consent form, and had the opportunity to ask questions about the research prior to signing the form. The researcher also provided a verbal explanation of the research in plain language.

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)

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

Participants were informed of free university counseling support available to them in the unlikely event they experience any distress from taking part in the research.
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

See Figure 1 (CONSORT flow diagram)

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

See Figure 1 (CONSORT flow diagram)
13b-i) Attrition diagram

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

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subitem not at all important 〇 〇 〇 〇 〇 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.

Not applicable as participants only used the intervention once during an in-person appointment

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.

"Participants were recruited between February 20, 2019, and July 24, 2019."
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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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

Not applicable to this study

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

Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The trial ended once the participant quota had been reached

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 the 'Participants' subsection of the 'Results' section.

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 ○ ○ ○ ○ ○ 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.

These characteristics are reported in the 'Participants' subsection of the 'Results' section.

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.

Does your paper address subitem 16-i? *

Yes, included across the results section

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).

Does your paper address subitem 16-ii?

Not applicable to this study
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

Yes across the results section (see subsections for each outcome)

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).

Does your paper address subitem 17a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable as participants could only access the intervention at the in-person appointment, and the interaction was controlled to finish at 15 minutes.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended
18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

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).

Gender effects are presented throughout the results section

Does your paper address CONSORT 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 applicable to this study
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 to this study

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

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 19-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"...the digital human conversation engine experienced occasional errors with utterance detection and speech-to-text translation during its interactions with people... However, the errors were not more or less frequent in any of the experimental conditions."
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* ○ ○ ○ ○ ○ *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.

"Participants also answered a series of open-ended, written qualitative questions on their perceptions of the digital human (reported in another paper; Loveys, unpublished data, March 2021)."

**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 o o o o o 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

"This is the first study to investigate whether emotional expressiveness in a digital human and user gender interact to affect loneliness, social, and physiological outcomes following a self-disclosure conversation.

Several main effects were found for the impact of emotional expressiveness in a digital human's voice on physiological arousal and social outcomes. Perceived social support was significantly higher for participants after interacting with a neutral voice digital human than after interacting with an emotional voice digital human. However, an emotional voice digital human was perceived as more caring overall than one with a neutral voice. Average electrodermal activity was higher during interactions with an emotional voice digital human than with a neutral voice one. These findings suggest that emotional expression in a digital human's voice can increase physiological arousal and perceptions of caring yet reduce feelings of being supported across both genders.

Gender did impact the effect of emotional expressiveness on loneliness, physiological arousal, and social outcomes. Women benefited more from a digital human with emotional expressions in the voice and with a face. For women, emotional expression in the voice increased closeness with the digital human, caring perceptions, and perceived social support. In addition, for women, the presence of a neutral face was associated with reduced loneliness and subjective stress than a digital human with no face.

In contrast, men had better outcomes for a digital human without emotional expression in the voice and with no face (ie, a black screen). For men, a neutral voice digital human was associated with increased closeness to the digital human, caring perceptions, and perceived social support. A digital human without a face (ie, a black screen) was associated with less loneliness and lower subjective stress in men."
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 ○ ○ ○ ○ ○ 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

Yes see the 'Future Research' subsection

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
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

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

Yes see the 'Limitations' subsection

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

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

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

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

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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

It is possible that ongoing interactions with the digital human over time might improve relationship quality with the digital human and amplify the effects on psychological variables.

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

Retrospective registration was provided by the Australia New Zealand Clinical Trials Registry (registration number: ACTRN12621000865819).
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

Retrospective registration was provided by the Australia New Zealand Clinical Trials Registry (registration number: ACTRN12621000865819).

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

"The authors wish to thank the engineering team at Soul Machines Ltd for their assistance in building the digital human for this experiment."

X27) Conflicts of Interest (not a CONSORT item)
X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

[1 2 3 4 5]

subitem not at all important  ○  ○  ○  ○  ○  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.

"MS is the chief executive officer of Soul Machines (an artificial intelligence company), which supports KL with a PhD stipend, contracts EB for consultancy work, and hired XZ as an engineer at the time of the research."

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

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Approximately 2 hours to complete

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

- [ ] yes
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