

# 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



**mahed.mousavi@unitn.it** (not shared) [Switch account](#)



Draft saved

\* Required

Your name \*

First Last

Seyed Mahed Mousavi

Primary Affiliation (short), City, Country \*

University of Toronto, Toronto, Canada

University of Trento, Trento, Italy

Your e-mail address \*

[abc@gmail.com](mailto:abc@gmail.com)

mahed.mousavi@unitn.it

Title of your manuscript \*

Provide the (draft) title of your manuscript.

Assessing the Impact of Conversational Artificial Intelligence in  
the Treatment of Stress and Anxiety in Aging Adults: 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.

TEO - Therapy Empowerment Opportunity

Evaluated Version (if any)

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

v1.5 - 2021

Language(s) \*

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

Italian

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.linkedin.com/company/coadapt-personal-agent/>

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)"

Stress, Anxiety,

### Primary Outcomes measured in trial \*

comma-separated list of primary outcomes reported in the trial

Stress Level, Anxiety Level

### Secondary/other outcomes

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

Reduction of stress-related Anxiety Symptoms, depression,



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:

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:

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: 38067



## 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.

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

#### 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

The mode of delivery is not identified in the title





### 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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

### 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

The non-web-based components are not identified in the title

### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection



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

"Assessing the Impact of Conversational Artificial Intelligence in the Treatment of Stress and Anxiety in Aging Adults: Randomized Controlled Trial"

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)

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

" The study was based on a protocolized intervention for stress and anxiety management. Participants with stress symptoms and mild-to-moderate anxiety received an 8-week cognitive behavioral therapy (CBT) intervention delivered remotely.

A group of participants also interacted with the agent TEO. The participants were active workers aged over 55 years. The experimental groups were as follows: group 1, traditional therapy; group 2, traditional therapy and mobile health (mHealth) agent; group 3, mHealth agent; and group 4, no treatment (assigned to a waiting list). "

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)

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection

Does your paper address subitem 1b-ii?

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

"The study was based on a protocolized intervention for stress and anxiety management. Participants with stress

symptoms and mild-to-moderate anxiety received an 8-week cognitive behavioral therapy (CBT) intervention delivered remotely.

A group of participants also interacted with the agent TEO. The participants were active workers aged over 55 years."



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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

" The participants were active workers aged over 55 years. The experimental groups were as follows: group 1, traditional therapy; group 2, traditional therapy and mobile health (mHealth) agent; group 3, mHealth agent; and group 4, no treatment (assigned to a waiting list)"



#### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

#### 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

"Despite randomization, statistically significant differences between groups were present at T1. Group 4 showed lower levels of anxiety and depression compared with group 1, and lower levels of stress compared with group 2. Comparisons between groups at T2 and T3 did not show significant differences in outcomes. Analyses conducted within groups showed significant differences between times in group 2, with greater improvements in the levels of stress and scores related to overall well-being."

#### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection



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

"No statistically significant differences could be observed between participants who used the mHealth app alone or within the traditional CBT setting. However, the results indicated significant differences within the groups that received treatment and a stable tendency toward improvement, which was limited to individual perceptions of stress-related symptoms."

## 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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Clear selection



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

"TEO (Therapy Empowerment Opportunity) is a mobile personal health care agent (m-PHA) designed to provide CBT support for the prevention and treatment of stress and anxiety [12]. It has been designed and developed in collaboration with CBT therapists [12]."

"The observational study discussed in this paper was designed for evaluating the impact of introducing AI technology in the psychological treatment of aging workers presenting a variety of stress symptoms hypothetically related with moderate to high levels of perceived stress in the workplace."

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.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"The demand for accessible and large-scale mental health care support has been previously pointed out [8] and aggravated by the COVID-19 pandemic and its consequences [9,10]. A growing number of studies have indicated that the development of conversational AI systems (also known as chatbots) as applications in the mental health domain can improve access to mental health care support in an easy and inexpensive manner [8,11,12]."

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

"The observational study discussed in this paper was designed for evaluating the impact of introducing AI technology in the psychological treatment of aging workers presenting a variety of stress symptoms hypothetically related with moderate to high levels of perceived stress in the workplace."

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

"The experimental design included comparison of the presence of several different symptoms, like anxiety and depression, and psychological attitudes, measured by standardized self-assessed psychological questionnaires. We applied these metrics before treatment (T1) and at the end of treatment (T2). An additional measurement was performed 3 months after the end of treatment to longitudinally assess the effects (T3)."

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

No changes were applied in our methods

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].

1 2 3 4 5

subitem not at all important ☒ ☐ ☐ ☐ ☐ essential

Clear selection



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

No changes were applied in our methods

#### 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

"we designed new strategies on social media with recruiting campaigns involving engaging posts and graphics. Comparing the usage statistics of the 2 social networks Facebook and Instagram, Facebook provided the highest percentage of users in our target group (21.3% and 11.7% for Facebook and Instagram, respectively) [16]. The campaigns were widespread throughout Italy, with the goal to motivate people to reach our website [17] and enroll in our research."

#### 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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Clear selection



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

this criterion is not relevant to our participant recruitment method

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.

subitem not at all important      1      2      3      4      5      essential

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Clear selection



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

"we designed new strategies on social media with recruiting campaigns involving engaging posts and graphics. Comparing the usage statistics of the 2 social networks Facebook and Instagram, Facebook provided the highest percentage of users in our target group (21.3% and 11.7% for Facebook and Instagram, respectively) [16]. The campaigns were widespread throughout Italy, with the goal to motivate people to reach our website [17] and enroll in our research. The site included all the information about the research and a form where the users could request to participate. Moreover, the users could ask for more information, resulting in one-to-one interviews to answer all the questions."

#### 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.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"we designed new strategies on social media with recruiting campaigns involving engaging posts and graphics. Comparing the usage statistics of the 2 social networks Facebook and Instagram, Facebook provided the highest percentage of users in our target group (21.3% and 11.7% for Facebook and Instagram, respectively) [16]. The campaigns were widespread throughout Italy, with the goal to motivate people to reach our website [17] and enroll in our research. The site included all the information about the research and a form where the users could request to participate. Moreover, the users could ask for more information, resulting in one-to-one interviews to answer all the questions."

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

"The campaigns were widespread throughout Italy, with the goal to motivate people to reach our website [17] and enroll in our research."



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

Clear selection

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

"The self-assessment scales we applied were Symptom Checklist-90-Revised (SCL-90-R), Occupational Stress Indicator (OSI), and Perceived Stress Scale (PSS). SCL-90-R is a self-administered questionnaire that assesses a broad spectrum of psychopathological symptoms like depression, anxiety, psychoticism, and others. OSI is a questionnaire for the evaluation of psychosocial stress in organizations. PSS is a brief questionnaire for the detection of generalized psychological stress. In addition, 2 brief versions of Patient Health Questionnaire-8 (PHQ-8) and General Anxiety Disorders-7 (GAD-7) were administered at the beginning of treatment (T1), after 4 weeks (T2), at the end of treatment (T3), and after 3 months (T4). PHQ-8 is an 8-item questionnaire for assessing and monitoring depression severity [14], while GAD-7 is a short questionnaire for assessing and monitoring generalized anxiety disorders [15]."



#### 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)

subitem not at all important      1      2      3      4      5      essential

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Clear selection

#### 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

subitem 4b-ii is not relevant to your study

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

#### 5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

subitem not at all important      1      2      3      4      5      essential

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Clear selection



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

"IDEGO (Digital Psychology srl, Rome, Italy) carried out the psychometric tests and their data analysis. The experimental design of the RCT, training, and evaluation of the AI algorithms and systems were performed by the University of Trento."

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

Clear selection

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

the development process is not relevant to your 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).

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

### 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

subitem 5-iii is not relevant to our study

### 5-iv) Quality assurance methods

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

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection



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

subitem 5-iv is not relevant to our study

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.

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

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

subitem 5-v is not relevant to our study



### 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](http://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.

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

### 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

subitem 5-vi is not relevant to our study

### 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).

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☒      ☐      ☐

Clear selection



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

"The experimental design included 4 groups of subjects as follows: group 1 received traditional psychotherapy from CBT therapists in a remote setting; group 2 received both traditional therapy and the support of the conversational AI agent; group 3 received only the support of the conversational AI agent; and group 4 was the control group not receiving any treatment. Participants assigned to group 4 were also assigned to a waiting list and received treatment at the end of the 8 weeks of the experiment"

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].

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection



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

"TEO is an m-PHA [19], a type of AI conversational agent, in the form of a mobile app that supports input/output interactions with users via natural language. Many PHAs currently developed for the mental health domain demonstrate limited flexibility of interactions with users, with system-directed interactions and a predefined dialogue flow [11]. As a result, the user has no control over the flow of the conversation and can only follow the system directives throughout the conversation. These limitations lead to shallow conversations and weak user engagement [8]."

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.

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

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

subitem 5-ix is not relevant to our study



### 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).

subitem not at all important      1      2      3      4      5      essential

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Clear selection

### 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 experimental design included 4 groups of subjects as follows: group 1 received traditional psychotherapy from CBT therapists in a remote setting; group 2 received both traditional therapy and the support of the conversational AI agent; group 3 received only the support of the conversational AI agent; and group 4 was the control group not receiving any treatment. Participants assigned to group 4 were also assigned to a waiting list and received treatment at the end of the 8 weeks of the experiment."



### 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).

subitem not at all important      1      2      3      4      5      essential

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Clear selection

### Does your paper address subitem 5-xi? \*

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

"For the second type of dialogue (follow-up),  
TEO notifies the user about the ABC note written the day before  
and asks the user how he/she feels about the events, whether  
the issue is resolved, or whether the user is experiencing a  
different emotion [20]."

### 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).

subitem not at all important      1      2      3      4      5      essential

☐   ☐   ☐   ☒   ☐

Clear selection



Does your paper address subitem 5-xii? \*

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

"The experimental design included 4 groups of subjects as follows: group 1 received traditional psychotherapy from CBT therapists in a remote setting; group 2 received both traditional therapy and the support of the conversational AI agent; group 3 received only the support of the conversational AI agent; and group 4 was the control group not receiving any treatment. Participants assigned to group 4 were also assigned to a waiting list and received treatment at the end of the 8 weeks of the experiment."

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

"According to the findings by Sullivan and Artino [22] about the power of parametric versus nonparametric tests to detect differences between small-size samples, parametric analysis with repeated measures ANOVA (with a mixed within and between-subjects design) was performed to assess the differences between times (T1, T2, and T3) and groups (group 1, group 2, group 3, and group 4), and their interaction effect related to the results obtained in the PSS, SCL-90-R, and OSI tests. Multiple comparisons were corrected by using Bonferroni adjustment. The same analysis was conducted on PHQ-8 and GAD-7, which were administered before the intervention (T1), at mid-term (T2), at the end of the intervention (T3), and after 3 months (T4) to assess the differences between times (T1, T2, T3, and T4) and groups (group 1, group 2, group 3, and group 4). Regarding the OSI test, only a few scales were considered for the analysis, that is, the ones regarding coping strategies (social support, home-work relationship, task oriented, logic, time, and involvement), mental health, and physical health."

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].

1 2 3 4 5

subitem not at all important ☒ ☐ ☐ ☐ ☐ essential

Clear selection



Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

subitem 6a-i not relevant to our study

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.

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

subitem 6a-ii not relevant to our study

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).

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"At the end of treatment, feedback was collected from all the participants through the administration of a satisfaction questionnaire conceived for this study. For each item of the questionnaire, users were asked to indicate their degree of agreement on a 5-point Likert scale, from 1 (strongly disagree) to 5 (strongly agree)."

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

subitem 6b is not relevant to our study

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.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"After the assignment, 2 subjects (1 in group 3 and 1 in group 4) showed mental health issues that made it necessary to reassign them to groups 1 and 2 to provide more accurate monitoring, where they could receive psychological support throughout the experiment. Other subjects showed a critical profile during the experiment, and they were directed to a standard psychological support service. Subsequently, these subjects were excluded from the analyses (Figure 1). Only 45 subjects were considered for the analysis."

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

"According to the findings by Sullivan and Artino [22] about the power of parametric versus nonparametric tests to detect differences between small-size samples, parametric analysis with repeated measures ANOVA (with a mixed within and between-subjects design) was performed to assess the differences between times (T1, T2, and T3) and groups (group 1, group 2, group 3, and group 4), and their interaction effect related to the results obtained in the PSS, SCL-90-R, and OSI tests. Multiple comparisons were corrected by using Bonferroni adjustment. The same analysis was conducted on PHQ-8 and GAD-7, which were administered before the intervention (T1), at mid-term (T2), at the end of the intervention (T3), and after 3 months (T4) to assess the differences between times (T1, T2, T3, and T4) and groups (group 1, group 2, group 3, and group 4). Regarding the OSI test, only a few scales were considered for the analysis, that is, the ones regarding coping strategies (social support, home-work relationship, task oriented, logic, time, and involvement), mental health, and physical health."



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

"A code was assigned to each participant, and through a random generator of numbers, the selected subjects were distributed into 4 groups."

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

subitem 8b is not relevant to 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

"A code was assigned to each participant, and through a random generator of numbers, the selected subjects were distributed into 4 groups."

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

"IDEGO (Digital Psychology srl, Rome, Italy) carried out the psychometric tests and their data analysis. The experimental design of the RCT, training, and evaluation of the AI algorithms and systems were performed by the University of Trento."

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).

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

### 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

11a-i is not relevant to our study

### 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".

subitem not at all important      1      2      3      4      5      essential

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Clear selection



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

11a-ii is not relevant to our study

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

11b is not relevant to our study

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

"According to the findings by Sullivan and Artino [22] about the power of parametric versus nonparametric tests to detect differences between small-size samples, parametric analysis with repeated measures ANOVA (with a mixed within and between-subjects design) was performed to assess the differences between times (T1, T2, and T3) and groups (group 1, group 2, group 3, and group 4), and their interaction effect related to the results obtained in the PSS, SCL-90-R, and OSI tests. Multiple comparisons were corrected by using Bonferroni adjustment."

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

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

subitem not at all important      1      2      3      4      5      essential

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Clear selection



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

"After the assignment, 2 subjects (1 in group 3 and 1 in group 4) showed mental health issues that made it necessary to reassign them to groups 1 and 2 to provide more accurate monitoring, where they could receive psychological support throughout the experiment. Other subjects showed a critical profile during the experiment, and they were directed to a standard psychological support service. Subsequently, these subjects were excluded from the analyses (Figure 1)."

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

"Multiple comparisons were corrected by using Bonferroni adjustment."

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



### X26-i) Comment on ethics committee approval

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection

### Does your paper address subitem X26-i?

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

"This methodology was approved by the Ethics Committee of the University of Trento within the context of the research activities of the HORIZON2020 CO-ADAPT project, and the experimental protocol has been registered on ClinicalTrials.gov (NCT04809090)."

### 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.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection



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

"The site included all the information about the research and a form where the users could request to participate. Moreover, the users could ask for more information, resulting in one-to-one interviews to answer all the questions. In order to select eligible participants, several questionnaires and a clinical interview with each subject were conducted."

### X26-iii) Safety and security procedures

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

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

Clear selection



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

"Exclusion criteria were the presence of severe depression (PHQ-8 score  $\geq 20$ ), suicidal thoughts, substance abuse, and mild cognitive impairment (Montreal Cognitive Assessment score  $< 26$ ) [18]."

"After the assignment, 2 subjects (1 in group 3 and 1 in group 4) showed mental health issues that made it necessary to reassign them to groups 1 and 2 to provide more accurate monitoring, where they could receive psychological support throughout the experiment."

"Other subjects showed a critical profile during the experiment, and they were directed to a standard psychological support service."

## 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

"According to the findings by Sullivan and Artino [22] about the power of parametric versus nonparametric tests to detect differences between small-size samples, parametric analysis with repeated measures ANOVA (with a mixed within and between-subjects design) was performed to assess the differences between times (T1, T2, and T3) and groups (group 1, group 2, group 3, and group 4), and their interaction effect related to the results obtained in the PSS, SCL-90-R, and OSI tests. Multiple comparisons were corrected by using Bonferroni adjustment. The same analysis was conducted on PHQ-8 and GAD-7, which were administered before the intervention (T1), at mid-term (T2), at the end of the intervention (T3), and after 3 months (T4) to assess the differences between times (T1, T2, T3, and T4) and groups (group 1, group 2, group 3, and group 4). Regarding the OSI test, only a few scales were considered for the analysis, that is, the ones regarding coping strategies (social support, home-work relationship, task oriented, logic, time, and involvement), mental health, and physical health."

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

"After the assignment, 2 subjects (1 in group 3 and 1 in group 4) showed mental health issues that made it necessary to reassign them to groups 1 and 2 to provide more accurate monitoring, where they could receive psychological support throughout the experiment. Other subjects showed a critical profile during the experiment, and they were directed to a standard psychological support service. Subsequently, these subjects were excluded from the analyses (Figure 1)."

#### 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.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☒      ☐      ☐

Clear selection

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

Figure 1. The CONSORT (Consolidated Standards of Reporting Trials) diagram shows the flow of the intervention, the enrollment of participants, their allocation to treatment, their follow-up, and data analysis. PHA: personal health care agent; SMT-CBT: stress management training-cognitive behavioral therapy; T2: end of the treatment; T3: 3 months after the treatment.



## 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

"Symptoms related to stress (anxiety, physical disease, and depression) were assessed prior to treatment (T1), at the end (T2), and 3 months after treatment (T3), using standardized psychological questionnaires. Moreover, the Patient Health Questionnaire-8 and General Anxiety Disorders-7 scales were administered before the intervention (T1), at mid-term (T2), at the end of the intervention (T3), and after 3 months (T4). At the end of the intervention, participants in groups 1, 2, and 3 filled in a satisfaction questionnaire."

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

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

14a-i is not relevant to our 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

subitem 14b not relevant to our study

#### 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

"Table 1. Sample characteristics (N=45)."

"Table 2. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Perceived Stress Scale and Symptom Checklist-90-Revised test."

"Table 3. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Occupational Stress Inventory."



### 15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

### 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

"Table 1. Sample characteristics (N=45)."

### 16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

#### 16-i) Report multiple "denominators" and provide definitions

Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection



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

"Figure 1. The CONSORT (Consolidated Standards of Reporting Trials) diagram shows the flow of the intervention, the enrollment of participants, their allocation to treatment, their follow-up, and data analysis. PHA: personal health care agent; SMT-CBT: stress management training-cognitive behavioral therapy; T2: end of the treatment; T3: 3 months after the treatment."

"Table 2. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Perceived Stress Scale and Symptom Checklist-90-Revised test."

"Table 3. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Occupational Stress Inventory."

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

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

1 2 3 4 5

subitem not at all important ☒ ☐ ☐ ☐ ☐ essential

Clear selection

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

subitem 16-ii is not relevant to our 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

"Table 2. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Perceived Stress Scale and Symptom Checklist-90-Revised test."

"Table 3. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Occupational Stress Inventory."

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).

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☒      ☐

Clear selection



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

"Table 2. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Perceived Stress Scale and Symptom Checklist-90-Revised test."

"Table 3. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Occupational Stress Inventory."

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

subitem 17b since we do not have binary outcome

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

"Table 2. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Perceived Stress Scale and Symptom Checklist-90-Revised test."

"Table 3. Parametric analysis of repeated measures ANOVA for differences between times and groups with regard to the Occupational Stress Inventory."

#### 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).

subitem not at all important      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

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

subitem 18-i is not relevant since we do not have subgroup analysis

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

subitem 19 is not relevant to our analysis

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      1      2      3      4      5      essential

☒      ☐      ☐      ☐      ☐

Clear selection

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

subitem 19-i is not relevant to our analysis



19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection

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

"Table 6. Participants' self-assessments of mobile personal health care agent interactions."

"Table 5. Satisfaction and perceived utility of the treatment."

"Moreover, we observed greater levels of satisfaction and subjective perception of usefulness in participants who were supported by a human therapist as well as the mHealth conversational agent."

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).

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection

Does your paper address subitem 22-i? \*

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

The discussion section addresses principal findings, limitations, and scientific conclusions

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

Highlight unanswered new questions, suggest future research.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"Given the small number of subjects per group, the results concerning the differences between groups and between times within each group are discussed."

"Following the recruitment process, the number of active participants involved in this study was small, and this may weaken the inferences and conclusions. Besides, although the recruitment campaign was conducted through social media platforms to reach out to all Italian regions, the majority of our participants were from the center of Italy. The participants were mainly women, and the fact that women tend to seek psychological help more often than men has been studied previously [23,24]. Nevertheless, the observed gender predominance weakens the generalization of the drawn inferences for both genders."

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.

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"Following the recruitment process, the number of active participants involved in this study was small, and this may weaken the inferences and conclusions. Besides, although the recruitment campaign was conducted through social media platforms to reach out to all Italian regions, the majority of our participants were from the center of Italy. The participants were mainly women, and the fact that women tend to seek psychological help more often than men has been studied previously [23,24]. Nevertheless, the observed gender predominance weakens the generalization of the drawn inferences for both genders."

## 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

subitem not at all important      1      2      3      4      5      essential

☐      ☐      ☐      ☐      ☒

Clear selection



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

"Following the recruitment process, the number of active participants involved in this study was small, and this may weaken the inferences and conclusions. Besides, although the recruitment campaign was conducted through social media platforms to reach out to all Italian regions, the majority of our participants were from the center of Italy. The participants were mainly women, and the fact that women tend to seek psychological help more often than men has been studied previously [23,24]. Nevertheless, the observed gender predominance weakens the generalization of the drawn inferences for both genders."

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

Clear selection

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

subitem 21-ii is not relevant to our study



## OTHER INFORMATION

### 23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? \*

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

"Trial Registration: ClinicalTrials.gov NCT04809090;  
<https://clinicaltrials.gov/ct2/show/NCT04809090>  
International Registered Report Identifier (IRRID): RR2-10.2196/30053"

### 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

"Trial Registration: ClinicalTrials.gov NCT04809090;  
<https://clinicaltrials.gov/ct2/show/NCT04809090>  
International Registered Report Identifier (IRRID): RR2-10.2196/30053"

### 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 methodology was approved by the Ethics Committee of the University of Trento within the context of the research activities of the HORIZON2020 CO-ADAPT project, and the experimental protocol has been registered on ClinicalTrials.gov (NCT04809090)."

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

Clear selection

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

Conflicts of Interest is not declared

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?

no changes made to the manuscript

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

2 hours to answer the question, no changes made to the manuscript

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

☐ yes

☒ no

☐ Other:



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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