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

rhianmale15@gmail.com (not shared) Switch account

Draft saved

* Required

Your name *

First Last

Rhian Male

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Unmind Ltd, London, United Kingdom

Your e-mail address *

abc@gmail.com

rhian.male@unmind.com

Title of your manuscript *

Provide the (draft) title of your manuscript.

Feasibility and preliminary efficacy of digital interventions for depressive symptoms in working adults: a multi-arm randomized pilot 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.

Unmind

Evaluated Version (if any)

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

Versions 2.90.0 - 2.92.0

Language(s) *

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

English

URL of your Intervention Website or App

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

https://unmind.com/

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?

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

Primary Medical Indication/Disease/Condition *

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

Depressive symptoms

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Feasibility, Acceptability, Engagement, Transfe

Secondary/other outcomes

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

Patient Health Questionnaire-8 (PHQ-8), Generalized Anxiety Disorder-7 (GAD-7), Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS), the Unmind Index, Work Productivity and Activity Impairment (WPAI) questionnaire

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: Participants had three weeks to complete their allocated intervention,

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: This was a pilot RCT, so was not powered for formal hypothesis testin

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: ms #41590

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

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 title identifies the mode of delivery as "digital interventions"

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”).

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 1a-ii?

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

This item is not applicable because this study did not include any non-web-based components or co-interventions

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

subitem not at all important

1 ◯

2 ◯

3 ◯

4 ◯

5 ◯

essential

Does your paper address subitem 1a-iii? *

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

The title identifies that the intervention is targeted for "depressive symptoms in working adults"

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

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 Abstract states that this study was a "parallel, multi-arm, pilot randomized controlled trial" in which "participants were allocated to one of three digital interventions or a wait list control group and had 3 weeks to complete 6-8 short self-guided sessions. The three interventions are available on the Unmind mental health app for working adults, and draw on Behavioural Activation (BA), Cognitive Behavioural Therapy (CBT), and Acceptance and Commitment Therapy (ACT), respectively."

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)

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

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

Your answer

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)

subitem not at all important

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essential

Does your paper address subitem 1b-iii?

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

The Methods section of the Abstract state that "Participants were recruited from the Prolific web-based recruitment platform, and the study was conducted entirely online. Feasibility and acceptability were assessed using objective engagement data and self-reported feedback. Efficacy outcomes were assessed using validated self-report measures of mental health and functioning, and linear mixed models with intention-to-treat principles".

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)

subitem not at all important

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- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 1b-iv?

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

"2003 individuals were screened for participation, and 405 were randomized. 92% of participants were retained in the study, 97% initiated their allocated intervention, and 67% completed all sessions".

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)

subitem not at all important

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- 2 ○
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- 5 ○

essential

Does your paper address subitem 1b-v?

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

Your answer

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)

subitem not at all important

- 1 ◯
- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem 2a-i? *

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

This is addressed in the introduction. For example:

"Whilst major depression has been the focus of much previous research, mild to moderate depressive symptoms are highly prevalent."

"Traditional face-to-face or therapist-guided psychological interventions, though effective, are not easily scalable in a workplace context and are subject to stigma and a perception of inefficacy". "Digital interventions can be scaled at low cost, and smartphone-based applications (‘apps’) delivering content designed to alleviate the symptoms of common mental health problems are now widely available, though only a small proportion have established efficacy".
A meta-analysis of digital interventions for depression included programmes "predominantly based on cognitive behavioral therapy techniques (CBT), while other evidence-based therapeutic models for depression (e.g. Acceptance and Commitment Therapy; ACT) were underrepresented and require more thorough evaluation". "Digital mental health interventions for working adults have also not been widely evaluated."

To address this, this study was a "pilot RCT evaluating the feasibility, acceptability and preliminary efficacy of three brief, self-guided, stand-alone digital interventions for low mood and depressive symptoms available on the Unmind mental health platform. Unmind is a web and mobile app for working adults, and features a range of content designed to help employees measure, manage and improve their mental health and wellbeing. Although employees are granted access to Unmind via their employer, it can be used both within and outside of the workplace. The Unmind interventions evaluated in this study are underpinned by either Behavioural Activation (BA), CBT, or ACT; three evidence-based psychological therapies for low mood and depression. The Unmind app deliberately includes interventions for depression that use different therapeutic modalities, giving the user free choice over which modality feels most relevant and

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 appropiate), 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

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

This is addressed in the Introduction. For example:

Regarding "smartphone-based applications ('apps') delivering content designed to alleviate the symptoms of common mental health problems", "only a small proportion have established efficacy." "Mild to moderate depressive symptoms are highly prevalent" and "can result in both presenteeism and absenteeism in the workplace". A meta-analysis of digital interventions for depression, which "reported moderate symptom reduction vs control" included programmes "predominantly based on cognitive behavioral therapy techniques (CBT), while other evidence-based therapeutic models for depression (e.g. Acceptance and Commitment Therapy; ACT) were underrepresented and require more thorough evaluation". "Digital mental health interventions for working adults have also not been widely evaluated."

The "need for broader evaluation of digital interventions for depression is further demonstrated by the reportedly low user adherence to such programmes, and mixed findings for the acceptability of web-based mental health interventions in the workplace. Given the association between adherence to digital interventions for depression and clinical outcome, it is important that feasibility and acceptability are established".

To address this, this study was a "pilot RCT evaluating the feasibility, acceptability and preliminary efficacy of three brief, self-guided, stand-alone digital interventions for low mood and depressive symptoms available on the Unmind mental health platform. Unmind is a web and mobile app for working adults". "The Unmind interventions evaluated in this study are underpinned by either Behavioural Activation (BA), CBT, or (ACT); three evidence-based psychological therapies for low mood and depression. The Unmind app deliberately includes interventions for depression that use different therapeutic modalities, giving the user free choice over which modality feels most relevant and appealing to them". The interventions were assessed "in a community-based sample of working adults experiencing mild-moderate low mood and depressive symptoms."

Participants were randomized to one of the three interventions or to a waitlist control group. A waitlist design was selected to ensure all participants were provided with access to the evidence-based interventions evaluated. This approach was deemed most appropriate for establishing intervention feasibility and acceptability, the primary aim of this study, as this does not require use of an active control comparator. The study was not powered for the evaluation of efficacy outcomes, and so a passive

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

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

"This study is therefore a pilot RCT evaluating the feasibility, acceptability and preliminary efficacy of three brief, self-guided, stand-alone digital interventions for low mood and depressive symptoms available on the Unmind mental health platform." The interventions are "underpinned by either Behavioural Activation (BA), CBT, or (ACT); three evidence-based psychological therapies for low mood and depression".
"Each intervention was assessed according to predefined progression criteria for a definitive trial, in a community-based sample of working adults experiencing mild-moderate low mood and depressive symptoms".

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 Methods state that "This study was "a parallel, multi-arm, pilot RCT with pre (t0), post (t1, week 3) and follow-up (t2, week 7) assessments. Participants were randomly allocated to 1 of 3 brief self-guided psychological interventions for low mood and depressive symptoms on the Unmind platform or to a waitlist control group in a 1:1:1:1 allocation ratio without stratification."

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

There were no other changes to methods after trial commencement.

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

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

subitem not at all important

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- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem 3b-i?

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

Your answer

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

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

"Eligible participants were (1) aged 18+, (2) UK based, (3) fluent in English, (4) currently in full or part time employment, (5) had access to the internet (6) had an active Prolific account, and (7) scored between 5 and 14 on The Patient Health Questionnaire-8 (PHQ-8; see Secondary Outcome Measures), indicating mild to moderate depressive symptoms. Additional criteria included interest in, and willingness to use, the study interventions, and willingness to be randomized. Individuals reporting a diagnosis of bipolar disorder, schizophrenia or other psychotic spectrum disorder, alcohol or substance use disorder, or neurocognitive disorder were excluded. Current engagement with psychological therapy for low mood or depression via a health care professional, and current or previous engagement with the Unmind platform or an Unmind study were

4a-i) Computer / Internet literacy

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

subitem not at all important

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essential

Does your paper address subitem 4a-i?

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

Your answer

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 ○

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essential

Does your paper address subitem 4a-ii? *

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

"Participants were recruited via Prolific and all study assessments were completed online via Qualtrics. Prolific is an online recruitment platform that has been empirically tested across key attributes such as response rates and data quality. It allows researchers to advertise studies to a large and diverse participant pool (>119,000 as of February 2023), with existing demographic information per individual that can be used for initial screening. Prolific is available for individuals aged at least 18 years, from most Organisation for Economic Co-operation and Development (OECD) countries, and participants undergo various verification and technical (e.g. Internet Protocol (IP) address) checks prior to acceptance on the platform".
"Individuals who met Prolific's automated initial screening criteria (UK-based, fluent in English, employed, having not participated in previous studies assessing the Unmind platform) were invited to take part in a study to evaluate the impact of completing one of several interventions (of between 6-8 sessions) for symptoms of low mood, featured on the Unmind mental health app. Following informed consent, participants were directed to a brief screening questionnaire to assess for study-specific eligibility criteria. Study screening was separated by sex and age bracket with the aim of recruiting a sample demographically similar to the UK working population. Eligibility was assessed via a script programmed by the authors that checked all participant responses against eligibility criteria automatically".

Information regarding measures taken to ensure participant anonymity was included in the study protocol, which was pre-registered on Open Science Framework (OSF). In brief, Prolific
assigns a unique identifier (the 'Prolific ID') to each individual in their participant pool. Prolific IDs were automatically recorded alongside survey responses to allow matching of

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 ○

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essential

Does your paper address subitem 4a-iii?

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

Your answer

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 Methods state that "All study procedures were conducted online in the UK". "Participants were recruited via Prolific and all study assessments were completed online via Qualtrics".

In order to be eligible to take part in the study, participants were required to be residing in the UK, as stated in the Participants and procedure section of the Methods - "Eligible participants were" "UK based."

The Results section states that "Recruitment and data collection took place between September and November 2021".

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.

subitem not at all important

1 ○

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essential

Does your paper address subitem 4b-i? *

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

All pre-registered secondary outcomes were self-report measures administered online.

"All study assessments were completed online via Qualtrics."

The Outcomes section of the Methods states that:
"To determine the preliminary efficacy of each intervention, changes in depression and anxiety symptoms, wellbeing, and health-related productivity loss were assessed as secondary outcomes using data collected at t0, t1 (primary end-point) and t2 via the following validated questionnaires..." (information about each of the 5 questionnaires is then provided).

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 ○

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3 ○

4 ○

5 ○

essential

Does your paper address subitem 4b-ii?

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

Your answer

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

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

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

subitem not at all important

1 ○

2 ○

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4 ○

5 ○

essential

Does your paper address subitem 5-i?

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

Your answer

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.

subitem not at all important

1 ◯

2 ◯

3 ◯

4 ◯

5 ◯

essential

Does your paper address subitem 5-ii?

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

Your answer

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

Does your paper address subitem 5-iii?

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

"The versions of the Unmind app that were live during the 3-week intervention period were 2.90.0 - 2.92.0, and no major app changes or updates were launched. Participants had access to a modified version of the Unmind platform with only their allocated intervention available."

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 ◯

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4 ◯

5 ◯

essential

Does your paper address subitem 5-iv?

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

Your answer

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

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5 ○

essential

Does your paper address subitem 5-v?

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

Your answer

5-vi) Digital preservation

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

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 5-vi?

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

Your answer

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

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4 ○

5 ○

essential

Does your paper address subitem 5-vii? *

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

"Participants were then randomized to one of the four groups via the Qualtrics "randomiser" feature which uses block randomisation with variable block sizes to generate balanced groups". "At the end of the baseline assessment, participants assigned to the intervention arms were presented with an instruction video explaining how to access their intervention, including using a unique anonymous ID to sign up to the Unmind Platform. A written version of these instructions was also provided via Prolific".

The interventions were "available on the Unmind platform, accessible via web or mobile app."
"At the end of the intervention period access to the Unmind platform was withdrawn."

"Participants received £10 for completing each study assessment and £1 for

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

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

The Interventions section of the Methods states that:

"Unmind is a digital platform designed to help working adults measure, manage and improve their mental health and wellbeing, and has previously been described in full." The manuscript directs the reader here to the reference of a previously published study which describes the Unmind platform in full, so the full details were not replicated in the current manuscript.

The Unmind platform is "accessible via web or mobile app."

"This study evaluated three brief interventions (known as Courses) available on the Unmind platform" which are "intended to help users manage and improve low mood and depressive symptoms and designed to be completed over the course of several days or weeks (Figure 1)". (Figure 1 provides screenshots of the Finding Happiness Course on the Unmind platform).

Further information is provided about each of the three interventions, for example:

"Activate Your Mood (AYM)
AYM is a BA-based Course consisting of eight 10-minute sessions designed to help the user understand the links between their behavior and mood, and to increase their levels of activity, with the aim of improving mood. Activities encouraged between sessions include a mood diary, activity monitoring and activity scheduling, and participants are advised to complete one session every other day".

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

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

Your answer

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

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

Your answer

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 ○

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essential

Does your paper address subitem 5-xi? *

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

"Participants then had three weeks to complete their allocated intervention, and were sent a weekly intervention reminder message via Prolific's anonymous messaging

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

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

Each intervention was designed to be a stand-alone intervention, and therefore the study did not include any co-interventions.

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

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

All primary and secondary outcomes are detailed in the Methods section.

"The following primary outcomes were assessed via a combination of objective data (including app usage data) and self-report feedback data collected at t1 and t2. Feedback data was largely based on questions adapted from the MARS, the most widely used, validated scale for evaluating the quality and content of mental health apps.

- Feasibility: recruitment rate, intervention uptake and retention (at t1 and t2)
- Acceptability: intervention adherence (completion rate, defined as the proportion of participants completing all sessions of their allocated Course within the intervention period), activity adherence (the self-reported completion rate for all additional intervention activities to be completed between sessions), participant satisfaction ("How satisfied are you with the Unmind Course you were asked to complete overall?"; see Table 3), and reasons for non-adherence (two multi-select questions; see Multimedia Appendix 3)
- Engagement: average intervention sessions completed in each group, average number of between-session activities completed, and select questions adapted from sections A and B of the MARS, at t1
- Transferability of the intervention to other settings or populations: assessed via select questions adapted from section E of the MARS at t1
- Relevance: assessed via subjective feedback data gathered at t1 ("Would you agree that the Unmind Course was relevant to your personal experience?")
- Bad effects: the proportion of participants who reported experienced lasting bad effects from the intervention, as per [30], and the proportion of participants whose PHQ-8 scores increased above the minimally clinically important difference for the PHQ-8 (an increase of >5 points [32]), assessed at t1 and t2.

"To determine the preliminary efficacy of each intervention, changes in depression and anxiety symptoms, wellbeing, and health-related productivity loss were assessed as secondary outcomes using data collected at t0, t1 (primary end-point) and t2 via the following validated questionnaires":
- The PHQ-8
- Generalized Anxiety Disorder-7 (GAD-7) scale
- Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
- The Unmind Index
- Work Productivity and Activity Impairment (WPAI) questionnaire

(Further details on each of the above validated questionnaires is provided in the

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].

subitem not at all important

1 ○

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essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer

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

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Your answer

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

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

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

"Due to a technical error, planned per protocol analyses of secondary outcomes could not be conducted. All other pre-registered primary and secondary outcomes are reported, except for analysis of qualitative feedback. Protocol deviations are detailed in Multimedia Appendix 1".
Thus secondary efficacy outcomes were assessed using an intention to treat (ITT) approach only.

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

Does your paper address subitem 7a-i?

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

"A sample size calculation indicated that ~100 participants per group were required to estimate feasibility outcomes with a margin of error <10%, based on a conservative estimate of 50% for retention and/or adherence. This is consistent with guidelines suggesting that 60-100 participants per intervention arm is optimal for estimating binary outcomes in pilot studies, such as the recruitment and completion rate progression criteria outlined in section 3.6 [42]. We therefore aimed to recruit 400 participants. The PHQ score distribution of a previous UK study sample recruited via Prolific was used as reference to estimate the appropriate number of participants required for screening (n = 2000)."

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

We did not implement any interim analyses or stopping guidelines.

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

"Participants were then randomized to one of the four groups via the Qualtrics "randomiser" feature, which uses block randomisation with variable block sizes to generate balanced 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

"Participants were then randomized to one of the four groups via the Qualtrics "randomiser" feature which uses block randomisation with variable block sizes to generate balanced groups".

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

"Participants were randomized to one of the four groups via the Qualtrics "randomiser" feature, which uses block randomisation with variable block sizes to generate balanced groups." "The research team remained blind to group assignment for the duration of data collection, but were unblinded during analysis".

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

Following the baseline assessment, "Participants were then randomized to one of the four groups via the Qualtrics "randomiser" feature." This in-built Qualtrics feature automatically allocated participants to, and informed participants of, their study group.

"The research team remained blind to group assignment for the duration of data collection".

"At the end of the baseline assessment, participants assigned to the intervention arms were presented with an instruction video explaining how to access their intervention, including using a unique anonymous ID to sign up to the Unmind Platform. A written version of these instructions was also provided via Prolific".

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

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

"It was not possible to blind the participants to group assignments. The research team remained blind to group assignment for the duration of data collection, but were unblinded during analysis".

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

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

Your answer

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

A description of the three intervention arms is included in the Methods section, which allows for a comparison of similarities and differences between them. The study utilised a waitlist control group, and thus any description of similarities between the 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

The Statistical Analyses section of the Methods details all methods used to compare groups for primary and secondary outcomes. For example:

"Primary outcomes were reported using descriptive statistics and appropriate measures of central tendency, and Fisher's exact or one way analysis of variance (ANOVA) tests were used to compare between groups as appropriate. Objective in-app usage data was provided by Unmind, the creator of the interventions evaluated. For simplicity, intervention sessions were only characterized as complete if all components of the session were played. Thus, for each participant, intervention engagement ranged from 0 sessions complete to all sessions complete. Usage data also included the duration of each session completed by each participant. Descriptive statistics were used to characterize engagement and stratify participants according to whether they completed, started but did not complete, or failed to start their allocated intervention.

Secondary efficacy outcomes were assessed using an intention to treat (ITT) approach (where all randomized participants were included in the statistical analysis, regardless of intervention engagement or attrition) and linear mixed effects (LME) models. Each LME included 'timepoint' as a within-subjects factor (levels: t0, t1 and t2), 'group' as a between-subjects factor, and their interaction as fixed effects, with a separate baseline for each participant. Timepoint was coded as a categorical variable so as not to enforce a linear relationship with outcomes."

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

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

"Secondary efficacy outcomes were assessed using an intention to treat (ITT) approach (where all randomized participants were included in the statistical analysis, regardless of intervention engagement or attrition) and linear mixed effects (LME) models".

Analyses were performed using linear mixed effects models (LMMs), which are capable of
handling missing data under the 'missing at random' assumption, and are considered superior to other missing data techniques such as single imputation.

"Due to a technical error, planned per protocol analyses of secondary outcomes could

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

"Exploratory analyses examined the proportion of individuals that experienced a clinically important change in PHQ score, defined according to [43] as a change of >5 from baseline and change in subscale scores for the Unmind Index, as per the study protocol".
For the former, this was applied to the "148 participants" who "had a baseline PHQ score >9 indicating likely caseness for depression"

"The Unmind Index is a measure of mental health and wellbeing comprising 7 subscales. Change in subscale scores were investigated as an exploratory outcome in

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

X26-i) Comment on ethics committee approval

subitem not at all important

1 ○

2 ○

3 ○

4 ○

5 ○

essential

Does your paper address subitem X26-i?

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

Your answer

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.

subitem not at all important

- 1 ◯
- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem X26-ii?

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

Your answer

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)

subitem not at all important

1 ○

2 ○

3 ○

4 ○

5 ○

essential

Does your paper address subitem X26-iii?

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

Your answer

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

These figures are included in a detailed CONSORT flow diagram (Figure 2). We also include the following in the results:

"95% (386/405) of participants completed t1 and 92% (373/405) completed t2".
"Objective adherence data obtained from the Unmind platform database is summarized in Table 3. 97% (295/303) of participants started their allocated intervention and 66% (201/303) completed all relevant sessions. Of those that initiated their intervention, 70% (201/295) went on to complete".
"Completion of between-session activities was self-reported (Table 3). 70% (200/284) of participants reported completing all recommended activities between sessions, with no significant difference between groups (P=.304)".

The Methods section states that "Secondary efficacy outcomes were assessed using an intention to treat (ITT) approach (where all randomized participants were included in the statistical analysis, regardless of intervention engagement or attrition).
"Due to a technical error, planned per protocol analyses of secondary outcomes could not be conducted". "Protocol deviations are detailed in Multimedia Appendix 1".

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

A CONSORT flow diagram is included in the manuscript (Figure 2), which reports losses and exclusions after randomisation for each study arm. Reasons were unknown, as is stated in the CONSORT flow diagram.

13b-i) Attrition diagram

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

subitem not at all important

- 1 ◯
- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem 13b-i?

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

Your answer

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

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

"Recruitment and data collection took place between September and November 2021".

This study had "pre (t0), post (t1, week 3) and follow-up (t2, week 7) assessments".

"Participants (then) had three weeks to complete their allocated intervention".

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

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

Your answer

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

Does your paper address CONSORT subitem 14b? *

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

The trial did not stop early.

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 in the manuscript shows demographics and baseline variables for the overall sample and split by study arm.

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.

subitem not at all important

- 1 ◯
- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem 15-i? *

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

As explained in the Methods section, "Study screening was separated by sex and age bracket with the aim of recruiting a sample demographically similar to the UK working population". (50% male, 50% female; 10% 25 years and under, 90% 26 years and over).

In Table 1 in the manuscript, we report on age, sex, ethnicity, education, employment status and workplace industry. We did not collect data on socio-economic status or ehealth literacy, but we did collect data (at baseline) on whether participants had used any mental health apps or accessed psychological therapy in the last 6 months (also reported in Table 1). Participants were required to have access to the internet and to be willing to use the interventions either on the web or by downloading the Unmind mobile

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

16-i) Report multiple “denominators” and provide definitions

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

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 16-i? *

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

All relevant denominators are included in the manuscript figures and tables.

"Objective adherence data obtained from the Unmind platform database is summarized in Table 3". For the study group overall and for each of the three intervention arms, we report on the number of participants who started their intervention, the number of partial completers, and the number of completers. As stated in the Outcomes section of the Methods, the completion rate was "defined as the proportion of participants completing all sessions of their allocated Course within the intervention period".

"Secondary efficacy outcomes were assessed using an intention to treat (ITT) approach (where all randomized participants were included in the statistical analysis, regardless of intervention engagement or attrition)"

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).

subitem not at all important

- 1 ◯
- 2 ◯
- 3 ◯
- 4 ◯
- 5 ◯

essential

Does your paper address subitem 16-ii?

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

Your answer

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

As this was a pilot trial, intervention efficacy was assessed as a secondary outcome, and all results are considered preliminary.
Table 4 in the manuscript reports between-group (Hedge's g) effect sizes and 95% confidence intervals for all secondary outcome measures, for each intervention arm relative to the control group (intention-to-treat (ITT) analysis).

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

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

Your answer

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

None of the intervention outcomes included in this study were binary.

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

Exploratory outcome:
"The Unmind Index is a measure of mental health and wellbeing comprising 7 subscales. Change in subscale scores were investigated as an exploratory outcome in the ITT sample using LMEs". The results are reported in the manuscript, and Multimedia Appendix 4 and 5 reports between-group (Hedge's g) effect sizes and 95% confidence intervals for each of the Unmind Index subscales, for each intervention arm relative to the control group.

Subgroup analysis:
"148 participants had a baseline PHQ score >9 indicating likely caseness for depression, and were therefore evaluated for clinically important change, defined as a

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

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

Your answer

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

As per recent guidelines, we included one post-intervention question assessing perceived bad effects for each intervention arm. The number of participants self-reporting bad effects for each intervention arm are reported in Table 3.
In the Results section of the manuscript, we also report the proportion of participants in each intervention arm with increases in PHQ-8 scores meeting the definition of meaningful deterioration (an increase >5 from baseline).

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

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

There were no privacy breaches or technical problems affecting the study groups during or after the study.

However, "Due to a technical error, planned per protocol analyses of secondary outcomes could not be conducted".

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.

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 19-ii?

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

Your answer

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

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 first paragraph of the Discussion restates the study questions and summarizes the answers:

"This study evaluated the feasibility, acceptability and preliminary efficacy of three brief digital interventions for low mood and depressive symptoms in working adults. Mean baseline scores indicated that participants were a mildly symptomatic, largely untreated group with below average wellbeing. Scores on the WPAI showed considerably impaired workplace functioning, but low absenteeism when compared to a large pre-existing sample of individuals experiencing depressive symptoms [45]. All three digital interventions were found to be feasible and acceptable to this group. This was a pilot study and therefore not powered for formal hypothesis testing, but significant improvements in mental health and wellbeing were observed for all intervention groups compared to waitlist control. Between group effect sizes ranged from small to large and all predefined progression criteria for a definitive trial were met".

Other important points covered in paragraphs two and three that meet this requirement include, for example:

"Engagement with the study interventions was high (overall completion rate = 67%; Table 3), far exceeding the minimum of 30% specified in the study progression criteria, and numerically higher than the 53% completion rate reported in a recent meta-analysis of digital interventions for depression".

"Very few bad effects were reported (Table 4) and the proportion of participants in the intervention groups that experienced a clinically important increase in scores was lower than the expected level of deterioration following in-person psychotherapy [47], further demonstrating that these are acceptable digital interventions for low mood and depressive symptoms".

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

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

Your answer

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

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

The Discussion includes a "Strengths and limitations" section. For example:

"However, this study recruited participants exclusively from Prolific, and therefore participants are a self-selected group likely to be highly motivated to engage with research, and open to using a digital, app-based intervention. In addition, completion of study assessments was incentivised. Therefore, it remains unknown whether the findings reported here would generalize to the wider UK working population experiencing symptoms of depression. It also remains unknown to what extent the wider population would be open to using an app-based intervention. Additionally, it was not possible to blind participants to group allocation, as is usually the case with online trials. To capture feasibility and acceptability outcomes, we adapted questions from the original expert-rater version of the MARS, rather than the newer user-specific version, which would have been more a more appropriate means of gathering intervention feedback in this study. To reduce participant burden, we also only included a subset of questions from the MARS deemed to be most relevant, and not the full scale. This included feasibility outcomes identified as being important for evaluating complex interventions, but excluded factors such as intervention aesthetics.

We also note that absenteeism rates in our study sample were low at baseline, and regression model diagnosis using QQ plots indicated that the residuals were not normally distributed. Therefore, any efficacy findings pertaining to absenteeism should be interpreted with caution. We were also not able to conduct planned exploratory analyses to evaluate the impact of intervention engagement due to a technical error. This study employed a wait list, passive control group design meaning that inferences cannot be made about intervention mechanisms of action at this stage, though we note that such an evaluation was not an aim of the present study".

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

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

Your answer

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.

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem 21-ii?

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

Your answer

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

"The study protocol was pre-registered on ISRCTN (registration number ISRCTN13067492) and the Open Science Framework (https://osf.io/)".

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

A full study protocol was preregistered at Open Science Framework (OSF), which can be accessed at https://osf.io/4gruv/ upon publication of the current study paper.

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

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

"This study was fully funded by Unmind Ltd., the creator of the interventions evaluated".

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.

subitem not at all important

- 1 ○
- 2 ○
- 3 ○
- 4 ○
- 5 ○

essential

Does your paper address subitem X27-i?

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

Your answer

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

- ○ yes, major changes
- ◉ yes, minor changes
- ○ no

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

Your answer

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

14 hours were spent going through the checklist and making changes in the manuscript

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- (●) yes
- ( ) no
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- ( ) yes
- ( ) no
- ( ) Other:

Any other comments or questions on CONSORT EHEALTH

Your answer

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