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 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
A Smartphone App to Promote Patient Activation and Support Shared Decision-making in People With a Diagnosis of Schizophrenia in Outpatient Treatment Settings (Momentum Trial): Randomized Controlled Assessor-Blinded 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.

Name of app: Monsenso

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

Special version developed for the Momentum

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

Danish

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://apps.apple.com/dk/app/monsenso/id1373639965

URL of an image/screenshot (optional)

Dit svar
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
- Andet:

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)"

schizophrenia, schizotypal or delusional disorc

Primary Outcomes measured in trial *

coma-separated list of primary outcomes reported in the trial

self-reported level of activation

Secondary/other outcomes

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

self-efficacy, hope, working -alliance, satisfaction, preparedness for treatment consultation, symptom severity, of symptoms and level of functioning
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"
- [ ] Andet:

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%
- [ ] Andet:
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
- Andet:

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
- Andet:
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
- Andet:

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
- Andet: #40292
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
- [ ] Andet:

1a-i) Identify the mode of delivery in the title
Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

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

Ryd markering

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

Yes - “A Smartphone App” is in the title
1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).

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subitem not at all important  0 0 1 0 0

essential

Ryd markering

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.

Yes - "Outpatient Treatment" is in the title

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”) Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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subitem not at all important  0 0 0 0 1

essential

Ryd markering

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.

Yes - "People With a Diagnosis of Schizophrenia " is in the title
1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-i? *

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

Yes - to some degree. "advantages in terms of accessibility, structure, and reminders" and "a digital tool to support patient activation and SDM"
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

Does your paper address subitem 1b-ii?

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

No - we write: "use of a digital SDM intervention for 6 months compared with treatment as usual" and elaborate on the human involvement in the main text. Reason is due to the length of the abstract
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)

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

Yes - “The trial was designed as a randomized, assessor-blinded, 2-armed, parallel-group, multi-center trial " and "The primary outcome was the self-reported level of activation "

Ryd markering

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 1b-iii?
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)

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

Yes - "In total, of 194 participants were included". We then elaborate in the main text.

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)
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

N/A our trial is not a negative trial.

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)

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

Yes - "This study aimed to provide new evidence on the effectiveness of a digital SDM intervention in mental health care and strengthen the evidence on how digital tools may promote patient activation. We evaluated the effectiveness of a digital solution to support SDM in an outpatient setting for people diagnosed with schizophrenia."
2a-ii) Scientific background, rationale: What is known about the (type of) system
Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

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Ryd markering

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

Yes - "Digital mental health interventions, such as interventions including a smartphone app, have been found to significantly outperform control groups [10]. However, the evidence on digital mental health interventions to support SDM is sparse, but a recent meta-analysis found that digital SDM interventions may have an effect on patient activation, decisional conflict, working alliance, and severity of general symptoms [11]. The meta-analysis also concluded that while digital interventions to support SDM are promising, the limited evidence is in need for quality research."

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

Yes - "We hypothesized that the intervention would support SDM, resulting in higher levels of self-perceived patient activation. With higher levels of patient activation, we also expected to see improvements in working alliance, hope, self-efficacy, satisfaction, feeling prepared for decision-making, confidence in communicating with one's provider, severity of symptoms, level of functioning, number of hospitalizations, and adherence."

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

Yes - "This study was a 2-arm, assessor-blinded, randomized parallel-group trial conducted in 9 outpatient treatment sites called OPUS in the Capital Region of Denmark" and

"Participants were randomized with an even allocation of 1:1 to either the intervention group (TAU plus app) or the control group (TAU minus app). "

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

Yes - "As stated in our study protocol, we were interested in evaluating the mean duration per session for which the participants used the smartphone app. However, due to technical limitations, we were unable to assess the duration for which the participants used the app. Owing to the COVID-19 pandemic, several assessments were conducted web-based; however, no statistically significant differences in scores for participants being assessed physically or virtually were detected."

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

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

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Does your paper address subitem 3b-i?

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

Yes - "Owing to a fire accident at OVHcloud (a global cloud service provider that stores Monsenso's data), the digital system became unavailable for approximately 1 month during which participants were unable to access the app and web portal. This downtime affected approximately 36 participants in the intervention group. Owing to blinding, the research group did not directly reach out to participants. Instead, all providers were contacted regarding this issue and instructed to inform participants of the system being unavailable in the intervention group. After the system became available again, providers were instructed to inform participants to use the app again. In addition to the accident, a failure in the Monsenso back-up system resulted in a loss of data for the last month leading up to the fire accident. To assess whether the interruption had an impact on the usage of the system, objective data on the usage of the system before the accident were compared with data on the usage after the system became available again."

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.

Yes - "Patients were eligible for inclusion if they were receiving treatment in OPUS (see the section Treatment as Usual for information on OPUS), had at least 6 months left of their OPUS program, access to a smartphone, and understood Danish."
4a-i) Computer / Internet literacy

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

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Does your paper address subitem 4a-i?

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

No - given the target group being 18-35 years of age and the criteria of having access to a smartphone app we expected participants to be able to use the app. We firmly believe that our participants are on an average level of computer literacy within this age-group.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

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

Yes - "Eligible patients were referred to the study by their primary providers."

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4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

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

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

Yes - "Patients were enrolled after meeting a staff member from the research team who provided detailed verbal and written information about the study, and written consent was obtained"
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.

Yes - "conducted in 9 outpatient treatment sites called OPUS in the Capital Region of Denmark. OPUS is a 2-year treatment program providing specialized early intervention treatment to patients with a debutting diagnosis of schizophrenia or related psychotic disorders in the age group of 18 to 35 years in Denmark."

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

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

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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.

Yes however this is mentioned in the study protocol. "Detailed information on the trial design and methodology of the study is available in the study protocol [12]."
4b-ii) Report how institutional affiliations are displayed

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

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Ryd markering

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.

All participants received written information about the study and which institutions were affiliated with the study.

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

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

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

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subitem not at all important ○ ○ ○ ○ ○ essential

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

"The intervention group continued with TAU and was invited to use the digital system provided by the IT company Monsenso"
No members from Monsenso was part of designing, conducting or analysing the trial
Information is also described in the study protocol

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  ○  ○  ○  ○  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

"Before the trial, we developed a digital SDM tool for the process of cocreation among patients, providers, and researchers, with preparation for treatment consultation as the main function. A pilot study revealed that the tool was perceived to be useful with relevant content by patients and providers [14]. On the basis of feedback from the pilot study, the app was adjusted accordingly and included a new functionality, an option to perform a daily self-assessment."
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).

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

No major updates were done.

Quality assurance methods
Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.
Does your paper address subitem 5-iv?

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

The development of the digital system can be found in the study protocol.

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

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

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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.

The source code is property of the IT-company Monsenso.
5-vi) Digital preservation

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

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subitem not at all important ○ ○ ● ○ ○ essential

Ryd markering

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

https://apps.apple.com/dk/app/monsenso/id1373639965

5-vii) Access

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

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subitem not at all important ○ ○ ○ ● ○ essential

Ryd markering
Does your paper address subitem 5-vii? *

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

"The intention was that the patient could use the app outside of the consultation and that the provider before an upcoming consultation could become aware of what the patient would like to address at the consultation while also seeing how the patient had scored themselves on the self-assessments."

"No economic compensation was provided for participation"

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

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

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subitem not at all important ☐ ☐ ☐ ☐ ☑ essential

Ryd markering
The digital SDM tool tested in this trial consisted of a smartphone app for the patient with functions, such as preparation for consultation, daily self-assessments, action plans, and educational material. The app was synchronized to a web portal that the patient's provider could access before the consultation.

Additional information can be found in the study protocol.
5-x) Clarify the level of human involvement

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

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subitem not at all important  ○ ○ ○ ○ ○ essential

Ryd markering

5-xi) Report any prompts/reminders used

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

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subitem not at all important  ○ ○ ○ ○ ○ essential

Ryd markering

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

"patients and providers were encouraged to discuss how best to utilize the system and how to incorporate it to support the consultations."

Additional information can be found in the study protocol
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

"Patients were shown how to set up reminders within the app to enable push messages. Enabling these push messages was voluntary."

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

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subitem not at all important ○ ○ ○ ○ ○ 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

"The intervention group continued with TAU "
"TAU in this trial was provided by OPUS, a treatment facility offering specialized early intervention by combining three key elements: (1) assertive community treatment aimed at maintaining/developing the patient’s coping skills and integration in society; (2) family involvement through multifamily groups and single-family sessions; and (3) social skills training to support patients with impaired social skills [13]. Patients starting OPUS are assigned to a primary provider with weekly sessions (excluding group sessions) lasting for approximately 40 to 60 minutes. "
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

*Primary Outcome
Our primary outcome was the difference in self-perceived patient activation between the groups after the intervention, as measured by the 10-item Consumer Health Activation Index for mental health (CHAI-MH) [16].

Secondary Outcomes
Our secondary outcomes consisted of questionnaires completed by participating patients and providers, a clinical interview, and data from the Danish National Patient Register. Patients completed the following questionnaires: self-perceived feeling of hope and optimism measured by the 6-item Adult State Hope Scale [17], self-efficacy measured by the 10-item General Self-Efficacy Scale (GSE) [18], confidence in communicating with one’s provider measured by the 5-item Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI) [19], therapeutic alliance between the patient and provider measured by the 12-item Working Alliance Inventory—short (WAI-S) [20], feeling prepared to make a treatment decision by the 10-item Preparation for Decision-Making (PrepDM) [21], and satisfaction with treatment measured by the 8-item Client Satisfaction Questionnaire (CSQ) [22]. In addition, a clinical interview was conducted to assess the participants’ positive and negative symptoms, together with their level of functioning. We used the Scale for the Assessment of Positive Symptoms (SAPS) [23], Scale for the Assessment of Negative Symptoms (SANS) [23], Global Assessment of Functioning (GAF) [24] and Personal and Social Performance Scale (PSP) [25]. A blinded researcher conducted the interviews. Providers completed two questionnaires for each of their patients participating in the trial: the therapeutic alliance between the provider and patient measured by the 12-item WAI-S [20] and the patient’s engagement measured by the Service Engagement Scale—collaboration subscale (SES) [26]. Finally, we collected data for all participating patients from the Danish National Patient Register-Psychiatry on the following: number of hospital admissions, length of admissions in days, and adherence to OPUS appointments. Reasoning for choosing the outcomes can be found in the study protocol.

Additional information can be found in the study protocol
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed.

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

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subitem not at all important ○ ○ ○ ○ ○ essential

Ryd markering

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

information can be found in the study protocol

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/adoptions metrics are important process outcomes that should be reported in any ehealth trial.

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subitem not at all important ○ ○ ○ ○ ○ essential

Ryd markering

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

"objective data on the usage of the system (user sessions per day, screen views per day, screens per session, session duration and session instances, and user retention) were provided by Monsenso."
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

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subitem not at all important ○ ○ ○ ○ ○ essential

Ryd markering

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

Owing to the blinding of the trial, feedback from participants was given to a staff member not directly involved in the study to avoid bias.

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

*

In our study protocol, we calculated Cohen Kappa for the CDMS questionnaire to assess the level of agreement between patients and providers. However, due to the data structure of the CDMS, this was not possible, and we instead performed a t test to assess if there was a statistically significant difference between the responses of patients and providers. While we planned to assess the effect of the intervention based on duration in OPUS (e.g., patients at the beginning of their treatment versus those at the end of their treatment), we were unable to do so because of safety procedures regarding merging patient-reported outcome data with data from the Danish National Health Registers.

*
7a) How sample size was determined
NPT: When applicable, details of whether and how the clustering by care providers 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.

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

"Before recruitment, we estimated that 30% would be lost to follow-up (ie, not responding to contact after the intervention). To adjust for this, a sample size of 260 participants is needed. However, during the recruitment of the first 100 participants, only 7 out of 100 (7%) were lost to follow-up. As the rate was significantly lower than anticipated, we changed our estimated percentage of lost-to-follow-up from 30% to 7%, resulting in a required sample size of 194 participants."

7b) When applicable, explanation of any interim analyses and stopping guidelines
Does your paper address CONSORT subitem 7b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable since we did not stop ahead of time.

8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

8b) Type of randomisation; details of any restriction (such as blocking and block size)
Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*Participants were randomized with an even allocation of 1:1 to either the intervention group (TAU plus app) or the control group (TAU minus app). Randomization was performed after completion of the baseline assessment. Block randomization was used to achieve balance in the allocation of participants to both treatment arms. The block sizes were randomly altered among 2, 4, and 6. The block sizes were concealed from the researchers during recruitment. *

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

"The nonstratified randomization sequence was computerized and facilitated by the Odense Patient Data Explorative Network (OPEN) to ensure allocation concealment. The concealment was kept digital at OPEN until data collection ended and data analysis began. "

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.

"The nonstratified randomization sequence was computerized and facilitated by the Odense Patient Data Explorative Network (OPEN) to ensure allocation concealment."

"Researchers collecting and analyzing data were blinded, but given the nature of the intervention, patients and health care providers were not blinded. All patients were at each visit, with the researcher thoroughly instructed not to mention anything about their randomization allocation. Therefore, all questionnaire outcomes (answered by the patient or provider) were not blinded, whereas the interview outcomes (assessor-rated) were blinded."

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn’t

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

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

Ryd markering
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.

"Researchers collecting and analyzing data were blinded, but given the nature of the intervention, patients and health care providers were not blinded. All patients were at each visit, with the researcher thoroughly instructed not to mention anything about their randomization allocation. Therefore, all questionnaire outcomes (answered by the patient or provider) were not blinded, whereas the interview outcomes (assessor-rated) were blinded."

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”.

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.

"given the nature of the intervention, patients and health care providers were not blinded."

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)
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

12a-i) Imputation techniques to deal with attrition / missing values
Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

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subitem not at all important ○ ○ ○ ○ ☐ essential

*Generalized linear mixed effects regression analyses were performed to assess the 6-month intervention. A binary logistic regression was performed to evaluate the impact of the intervention on participants’ use of antipsychotic medication. Negative binomial regression was performed for count outcomes to estimate the incidence rate ratios (IRRs) on the number of hospitalizations and the length of hospitalization after the intervention based on the group allocation. *
12a) Methods for additional analyses, such as subgroup analyses and adjusted analyses

To handle missing data, we created and analyzed 100 imputed data sets using multiple imputations by chained equations using the group variable ("intervention" and "control"); the use of antipsychotic medicine variable; completed interview after the intervention; and the participants’ baseline, midintervention, and postintervention scores. The use of antipsychotic medication at baseline (score=yes/no) was used as a variable for the imputed data sets due to a significant difference between groups in the use of antipsychotic medication at baseline.

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

We also performed a complete case analysis for comparative purposes. The midintervention assessment was included for explorative purposes to assess whether a potential effect occurred before or after 3 months of intervention.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)
X26-i) Comment on ethics committee approval

Does your paper address subitem X26-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The trial was approved by the Regional Ethics Committee in the Capital Region of Denmark under file number H-17025550 and the Knowledge Centre on Data Protection Compliance (Videnscenter for Dataanmeldelser) under approval number P-2019-502."

x26-ii) Outline informed consent procedures

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

Does your paper address subitem X26-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

information can be found in study protocol
X26-iii) Safety and security procedures
Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

Does your paper address subitem X26-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

information can be found in study protocol

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

"In total, 194 participants were included and randomized, with 98 to the control group and 96 to the intervention group. "

subitem not at all important

Ryd markering

essential
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

Yes - see the consort table

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.

Yes - see the consort table

Does your paper address subitem 13b-i?

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

no diagram but "Objective data on usage of the app revealed that the intervention group had a mean use of 0.55 log-ins per day during their active usage period (corresponding to roughly one session every second day). The active usage period ranged from 1 day to 180 days, with a mean of 39 days (SD=37.70), whereas the mean number of unique sessions was 23 ranging from 1 session to 148 sessions. When using the app, participants saw an average of 20 different screens, ranging from 5 to 28 screen views. Finally, 47 out of 96 (54.7%) participants in the intervention group logged in after the first month. "
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 began in January 2019, and the last patient was enrolled in September 2021."

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

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

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subitem not at all important 〇 〇 〇 〇 〇 essential

Ryd markering
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.

Yes - "Owing to a fire accident at OVHcloud (a global cloud service provider that stores Monsenso’s data), the digital system became unavailable for approximately 1 month during which participants were unable to access the app and web portal. This downtime affected approximately 36 participants in the intervention group. Owing to blinding, the research group did not directly reach out to participants. Instead, all providers were contacted regarding this issue and instructed to inform participants of the system being unavailable in the intervention group. After the system became available again, providers were instructed to inform participants to use the app again. In addition to the accident, a failure in the Monsenso back-up system resulted in a loss of data for the last month leading up to the fire accident. To assess whether the interruption had an impact on the usage of the system, objective data on the usage of the system before the accident were compared with data on the usage after the system became available again."

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.

not relevant since the trial did not end 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

Yes table 1 and table 2..

---

15-i) Report demographics associated with digital divide issues

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

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subitem not at all important | | | | | essential

Ryd markering

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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

Yes table 1 and table 2.. no info on ehealth literacy

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16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
**16-i) Report multiple “denominators” and provide definitions**

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

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

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**Does your paper address subitem 16-i?** *

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

See table 3 and table 4

"The Momentum Trial resulted in a statistically significant difference between the intervention and control groups in our primary outcome, CHAI-MH (mean difference 4.39, 95% CI 0.99-7.79, Cohen d=0.33, P=.01), favoring the intervention group. For the secondary outcomes, there were 2 scales with a minor statistically significant difference: PEPPI (mean difference 1.85, 95% CI 0.01-3.69, Cohen d=0.24, P=.05) and PrepDM (mean difference 5.12, 95% CI 0.16-10.08, Cohen d=0.27, P=.04), both favoring the intervention group. For the remaining outcome we found no statistically significant differences between the groups: Hope (mean difference 1.66, 95% CI −0.44 to 3.75, Cohen d=0.20, P=.12), GSE (mean difference 1.66, 95% CI −0.32 to 2.57, Cohen d=0.19, P=.13), WAI-Patient (mean difference 2.43, 95% CI −0.25 to 5.12, Cohen d=0.22, P=.08), CSQ (mean difference 0.89, 95% CI −0.13 to 1.91, Cohen d=0.22, P=.09), SAPS-Psychotic (mean difference −0.2, 95% CI −0.43 to 0.04, Cohen d=−0.20, P=.10), SANS (mean difference −0.14, 95% CI −0.33 to 0.04, Cohen d=−0.18, P=.13), SANS-Disorganized (mean difference −0.02, 95% CI −0.16 to 0.11, Cohen d=−0.06, P=.71), GAF (mean difference 1.35, 95% CI −1.01 to 3.72, Cohen d=0.13, P=.26), PSP (mean difference 1.38, 95% CI −0.68 to 3.44, Cohen d=0.13, P=.19). There were no statistically significant differences between provider scores WAI-Provider (mean difference −0.81, 95% CI −2.5, 0.87, Cohen d=−0.09, P=.34) or SES (MD=−0.10, 95% CI −0.48 to 0.28, Cohen d=−0.06, P=.60). Finally, we found no statistically significant difference between the intervention and control groups in the use of antipsychotic medication after the intervention (odds ratio 0.46, 95% CI 0.13-1.61, P=.23)."
16-ii) Primary analysis should be intent-to-treat

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

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| subitem not at all important | essential |
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Ryd markering

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

"Table 3 shows the results of the mid- and post-intervention ITT analyses, while Figure 3 illustrates the effect of the intervention. "

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
The Momentum Trial resulted in a statistically significant difference between the intervention and control groups in our primary outcome, CHAI-MH (mean difference 4.39, 95% CI 0.99-7.79, Cohen d=0.33, P=.01), favoring the intervention group. For the secondary outcomes, there were 2 scales with a minor statistically significant difference: PEPPI (mean difference 1.85, 95% CI 0.01-3.69, Cohen d=0.24, P=.05) and PrepDM (mean difference 5.12, 95% CI 0.16-10.08, Cohen d=0.27, P=.04), both favoring the intervention group. For the remaining outcome we found no statistically significant differences between the groups: Hope (mean difference 1.66, 95% CI −0.44 to 3.75, Cohen d=0.20, P=.12), GSE (mean difference 1.12, 95% CI −0.32 to 2.57, Cohen d=0.19, P=.13), WAI-Patient (mean difference 2.43, 95% CI −0.25 to 5.12, Cohen d=0.22, P=.08), CSQ (mean difference 0.89, 95% CI −0.13 to 1.91, Cohen d=0.22, P=.09), SAPS-Psychotic (mean difference −0.2, 95% CI −0.43 to 0.04, Cohen d=−0.20, P=.10), SANS (mean difference −0.14, 95% CI −0.33 to 0.04, Cohen d=−0.18, P=.13), SANS-Disorganized (mean difference −0.02, 95% CI −0.16 to 0.11, Cohen d=−0.06, P=.71), GAF (mean difference 1.35, 95% CI −1.01 to 3.72, Cohen d=0.13, P=.26), PSP (mean difference 1.38, 95% CI −0.68 to 3.44, Cohen d=0.13, P=.19). There were no statistically significant differences between provider scores WAI-Provider (mean difference −0.81, 95% CI −2.5, 0.87, Cohen d=−0.09, P=.34) or SES (MD=−0.10, 95% CI −0.48 to 0.28, Cohen d=−0.06, P=.60). Finally, we found no statistically significant difference between the intervention and control groups in the use of antipsychotic medication after the intervention (odds ratio 0.46, 95% CI 0.13-1.61, P=.23).
For binary outcomes, presentation of both absolute and relative effect sizes is recommended.
18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

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

Complete case analyses can be found in table 4

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).

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

This was not performed as this was not planned for in the protocol

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.

"Disengagement can also be interpreted as a potentially harmful outcome of using a digital SDM tool. However, the absolute numbers of lost-to-follow-up were relatively low, and the reasons in the intervention group were mostly due to ending OPUS treatment prematurely."

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].

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.

Nothing that has not already been mentioned regarding the fire incident.
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.

[Rating: 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

Feedback was given to a non-blinded staff member not associated with recruiting or analysing data. Qualitative data will be presented in another study.

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).

1  2  3  4  5

subitem not at all important  ○  ○  ○  ○  ○ essential

Does your paper address subitem 22-i? *

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

"This study presents the results of a clinical trial investigating a digital SDM tool to promote patient activation for people diagnosed with schizophrenia. The study found a statistically significant difference in our primary outcome, patient activation, CHAI-MH (mean difference 4.39, 95% CI 0.99-7.79, Cohen d=0.33, P=.01), favoring the intervention group. "

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

Highlight unanswered new questions, suggest future research.

1  2  3  4  5

subitem not at all important  ○  ○  ○  ○  ○ essential
Does your paper address subitem 22-ii?

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

"Future trials investigating a digital system are encouraged to carefully consider how participants (patients and providers) are supported in the case of issues or barriers."

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  ○  ○  ○  ●  ○  essential

Ryd markering
21) Generalisability (external validity, applicability) of the trial findings
NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

Does your paper address subitem 20-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"However, this pragmatic approach is limited in terms of support for participants. Participants who encountered an issue with the app were instructed to ask their provider for assistance who were then able to consult with a blinded student assistant or an IT supporter. This placed a large responsibility on the provider. If the provider did not resolve the situation or contact support, the patient could be prone to stop using the app."

"During our recruitment, we randomized patients to either the control or intervention group, meaning that providers were able to have patients in both groups. This creates a risk for a contamination effect, since providers were able to use elements from the intervention with patients in the control group."

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

1 2 3 4 5

subitem not at all important 〇 〇 〇 〇 〇 essential

Ryd markering
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.

This recruitment process may challenge the generalizability of the study. The vast majority of participants were recruited by providers to inform patients about the study. While providers were strongly encouraged to ask all of their patients about the research project, providers were able to, on their own, select which patients to inform about the study. Providers may have been more prone to ask patients they assume would use a smartphone app or patients whom the provider believed were able to participate in such a trial. This recruitment process may have affected the distribution of the study participants’ characteristics, such as gender, diagnosis, or use of antipsychotic medication.

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.

Does your paper address subitem 21-ii?

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

"the study had a pragmatic nature, in which the usage of the system would be similar to how it would be used in practice outside of the trial. Therefore, the results should be generalizable to other similar services."
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

ClinicalTrials.gov under the identifier: NCT03554655.

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

https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-019-2143-2

25) Sources of funding and other support (such as supply of drugs), role of funders
**Does your paper address CONSORT subitem 25?**

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

"This study was funded by TrygFonden in Denmark under ID number 115441. TrygFonden had no role in the conduct of the study; collection; management; analysis and interpretation of data; review, approval, or submission of the manuscript."

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**X27) Conflicts of Interest (not a CONSORT item)**

**X27-i) State the relation of the study team towards the system being evaluated**

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

1  2  3  4  5

- subitem not at all important
- essential

Ryd markering

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**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.

The authors declare no conflict of interests - None declared.

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- yes, minor changes
- no

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

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

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- yes
- no
- Andet:

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Dit svar

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