**CONSORT-EHEALTH Checklist V1.6.2 Report**

**Date completed**
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by Matilda Cederberg

**Effects of a person-centred eHealth intervention for patients on sick leave due to common mental disorders (PROMISE): An open randomised controlled trial**

**1a-ii) Identify the mode of delivery in the title**
*eHealth*

**1a-iii) Primary condition or target group in the title**
"on sick leave due to common mental disorders"

**ABSTRACT**

"The intervention group received usual care with addition of a person-centred eHealth intervention. The intervention was built on PCC principles and consisted of phone support and an interactive digital platform".

**1b-ii) Level of human involvement in the METHODS section of the ABSTRACT**

"The intervention group received usual care with addition of a person-centred eHealth intervention. The intervention was built on PCC principles and consisted of phone support and an interactive digital platform".

**1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT**

**1b-iv) RESULTS section in abstract must contain use data**

**INTRODUCTION**

**2a) Problem and the type of system/solution**

"Because previous studies based on PCC have shown positive effects on self-efficacy and because of the potential influence of self-efficacy in affecting sick leave, it is warranted to construct and evaluate PCC interventions targeting patients on sick leave due to CMDs."*

**2a-ii) Scientific background, rationale: What is known about the (type of) system**

"Internet interventions have proven to be a viable option to face-to-face treatments in patients with CMDs [13-16]. Due to the high accessibility and direct involvement of the patient, internet interventions may also enhance self-management [17]. To date, very few studies have evaluated interventions using eHealth alternatives for CMDs that specifically target return to work (RTW) [18].”*

**2b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons**

"There were no changes in, for example, eligibility criteria after trial commencement."

**METHODS**

**3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio**

"The study was an open randomised controlled trial (RCT) with 1:1 allocation to either a control group receiving usual care only or an intervention group receiving usual care in conjunction with a person-centred eHealth intervention embracing phone support and access to an interactive digital platform."

**3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons**

"There were no changes in, for example, eligibility criteria after trial commencement."

**3b-ii) Bug fixes, Downtimes, Content Changes**

**4a) CONSORT: Eligibility criteria for participants**

"Patients aged 18-65 years were eligible if they were currently on sick leave due to one of the following conditions in ICD-10 and diagnosed by a physician: mild to moderate depression (F32 and F33), mild to moderate anxiety disorder (F41), reaction to severe stress and adjustment disorders (F43), except post-traumatic stress disorder), which includes the Swedish diagnosis Exhaustion disorder (F43.8A). In order to reach patients early in their sick leave process, their current sick leave episode should not have exceeded 30 days. Patients were eligible only if they were employed or studying at least part-time during the past 9 months."

**4a-i) Computer / Internet literacy**

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

"Designated health care professionals (HCPs) consecutively screened the medical records of nine primary health care centres for eligible participants. Eligible participants were sent an information letter about the study, notifying them that further contact would be made. Next, patients were contacted by phone or they contacted the HCPs using instructions in the information letter. More information about the study was given over the phone. Patients interested in participating were sent a consent form and information about their rights as participants by regular mail. After written consent had been returned by mail to the HCPs, patients were randomised to the control or intervention group. Randomisation was based on a computer-generated random list created by a third party and stratified by age (<50 or ≥50 years) and diagnostic group (1: Depression, 2: Anxiety, 3: Stress-reactions and disorders). After randomisation, participants were informed of their study arm".

**4a-iii) Information giving during recruitment**

**4b) CONSORT: Settings and locations where the data were collected**

"The study took place in a large, socioeconomically diverse city area in Western Sweden. Nine public primary health care centres participated. The intervention and each study procedure were managed remotely."

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

"Data included responses to questionnaires sent by letter at baseline and after 3 and 6 months, during the intervention".

**4b-ii) Report how institutional affiliations are displayed**

**5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered**

"The intervention model involved the time course of the intervention in detail. The intervention aimed to operationalise person-centred ethics into action by safeguarding the relational aspects of personhood and care according to PCC [39, 45].”* By offering an infrastructure in the form of phone support and an interactive digital platform it was designed to facilitate the co-creation of care and work in partnership between HCPs and patients (and their extended social network) if needed without face-to-face meetings. The intervention design allowed for individual tailoring in terms of content (i.e., the personal health plans) and structure (i.e., the number, intensity and form for communication). The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences."*

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

**5-ii) Describe the history/development process**

**5-iii) Revisions and updating**

"The intervention model involved the time course of the intervention in detail. The intervention aimed to operationalise person-centred ethics into action by safeguarding the relational aspects of personhood and care according to PCC [39, 45].”* By offering an infrastructure in the form of phone support and an interactive digital platform it was designed to facilitate the co-creation of care and work in partnership between HCPs and patients (and their extended social network) if needed without face-to-face meetings. The intervention design allowed for individual tailoring in terms of content (i.e., the personal health plans) and structure (i.e., the number, intensity and form for communication). The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences."*

**5-iv) Quality assurance methods**

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

**5-vi) Digital preservation**

**5-vii) Access**

"Shortly after inclusion, the HCPs called the patients to help them access the digital platform, described its features and scheduled a phone conversation."

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

"In addition to usual care, the intervention group received PCC via an interactive digital platform and phone support during the 6-month intervention period... The intervention aimed to operationalise person-centred ethics into action by safeguarding the relational aspects of personhood and care according to PCC [39, 45].”* By offering an infrastructure in the form of phone support and an interactive digital platform it was designed to facilitate the co-creation of care and work in partnership between HCPs and patients (and their extended social network) if needed without face-to-face meetings. The intervention design allowed for individual tailoring in terms of content (i.e., the personal health plans) and structure (i.e., the number, intensity and form for communication). The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences."*

"The intervention group received usual care with addition of a person-centred eHealth intervention. The intervention was built on PCC principles and consisted of phone support and an interactive digital platform".

**5-ix) Describe use parameters**

**Does your paper address CONSORT subitem 2b?**

"Thus, this study aims to evaluate the effects of a person-centred eHealth intervention for patients on sick leave due to CMDs."
**5a**) Clarify the level of human involvement

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**5a-ii) Report any prompts/reminders used*

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**5a-iii) Describe whether and how “use” (including intensity of use/dosage) was defined/monitored*

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

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

* "The primary outcome of this study was a composite score of changes in GSE and sick leave at the 6-month follow-up [49]. At the 3- and 6-month follow-ups, participants in both arms were classified by the following standards:

- Participants with reduced sick leave percentage at follow-up compared to baseline and increased GSE scores by ≥5 units were classified as improved.
- Participants with an increased sick leave percentage at follow-up compared to baseline or reduced GSE scores by ≥5 units were classified as deteriorated.
- Participants with neither deteriorated nor improved were classified as unchanged.

To calculate the primary outcome both study groups were dichotomised into two subgroups: improved and unchanged/deteriorated. The designated five-point difference corresponds closely to the reported standard deviation [50, 51] and previous research suggesting five points to be a threshold for a minimal important change [42, 43]. For further details on participants’ trajectories, the composite score was also analysed without dichotomising in an ordered categorical version, including all three possible outcomes (improved/unchanged/deteriorated)."

**6a) Online questionnaires: describe for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed**

**6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/monitored**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**7a) CONSORT: How sample size was determined**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

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

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**8a) CONSORT: Method used to generate the random allocation sequence**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**9) CONSORT: 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**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

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

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

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

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”**

**12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

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

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.

**13b-i) Attrition diagram**

* The patients were encouraged to use the platform’s different functions, but all use was optional and based on the patient’s preferences.
DISCUSSION

19-i) Include privacy breaches, technical problems

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

19) CONSORT: All important harms or unintended effects in each group

Not applicable as we in this study do not address unintended effects or potential harms. However that will be part of an upcoming process evaluation.

19-i) Include privacy breaches, technical problems

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

20-i) Typical limitations in ehealth trials

*This study has several limitations. First, in this study data on sick leave and GSE were self-reported. Although self-reported sick leave data have shown to be congruent with employers' register [52], not having access to complete register data impeded more detailed information on the participants' sick leave trajectories (e.g., the total number of days on sick leave throughout the intervention). Furthermore, about 50% of the participants in both study arms reported 0% sick leave at the 3-month follow-up, indicating that the sick leave outcome reached a floor effect already at 3 months. Consequently, the primary outcome should have been set earlier than 6 months. However, because there was no difference in sick leave levels between the groups at 3 and 6-months, either the intervention was unsuccessful in affecting the level of sick leave altogether, or the effects were insignificant at these specific time points."

21) CONSORT: Generalisability (external validity, applicability) of the trial findings

21-i) Generalisability to other populations

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

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

"No statistically significant differences between the control and intervention group on the composite score of self-efficacy and level of sick leave at the 6-month follow-up. However, there was a significant difference at the 3-month follow-up. The intervention did not affect the level of sick leave and the differences observed in the composite score were largely due to increased self-efficacy”

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

Other information

23) CONSORT: Registration number and name of trial registry

* The trial was registered in the ClinicalTrials.gov (Identifier NCT03404583)*

24) CONSORT: Where the full trial protocol can be accessed, if available

*A detailed description of the intervention has been published elsewhere [44].*

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

*This work was supported by The Swedish Research Council for Health, Working Life and Welfare (reference number 2016-07418, 2017-00557 and 2019-01726). The funder has no role in the design of the study, data collection, analysis, or interpretation. The study was financed by grants from the Swedish state under the agreement between the Swedish government and the country councils, the ALF agreement (ALFGBG-772191 and ALFGBG-932659). *

26-i) Comment on ethics committee approval

26-ii) Outline informed consent procedures

26-iii) Safety and security procedures

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