

# CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red \*.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF \_AND\_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126

URL: <http://www.jmir.org/2011/4/e126/>

doi: 10.2196/jmir.1923

PMID: 22209829

\* Erforderlich

**Your name \***

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**Title of your manuscript \***

Provide the (draft) title of your manuscript.

Preventing depression in adults with subthreshold depression: health-economic evaluation alongside a pragmatic randomised controlled trial of a web-based intervention

**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
- Sonstiges:

**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)
- Sonstiges:

**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

Sonstiges:

**TITLE AND ABSTRACT****1a) TITLE: Identification as a randomized trial in the title****1a) Does your paper address CONSORT item 1a? \***

I.e. does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

yes

Sonstiges:

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

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

1   2   3   4   5

subitem not at all important      essential

**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

"a web-based intervention"

**1a-ii) Non-web-based components or important co-interventions in title**

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

support”).

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 1a-ii?

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

NA.

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

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

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 1a-iii? \*

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

"adults with subthreshold depression"

## 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/functionality/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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subitem not at all important      essential

**Does your paper address subitem 1b-i? \***

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

"a web-based guided self-help intervention (i.e. cognitive-behavioural therapy and problem-solving therapy assisted by supervised graduate students or health care professionals) in addition to usual care or to usual care supplemented with web-based psycho-education (enhanced usual care)"

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

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

1 2 3 4 5

subitem not at all important      essential

**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

"assisted by supervised graduate students or health care professionals"

**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)

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 1b-iii?

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

"Participants were recruited from the general population via a large statutory health insurance company and an open access website"  
 "Depression-free years (DFYs) were assessed by blinded diagnostic raters using the telephone-administered Structured Clinical Interview for DSM-IV Axis Disorders at 6- and 12-month follow-up, covering the period to the previous assessment. Costs were self-assessed through a questionnaire."

### 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)

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 1b-iv?

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

"In total, 406 participants were enrolled in the trial. The mean treatment duration was 5.84 (SD 4.37) weeks. On average, participants completed 4.93 of 6 sessions."

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

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 1b-v?

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

NA.

## INTRODUCTION

### 2a) In INTRODUCTION: Scientific background and explanation of rationale

#### 2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

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subitem not at all important      essential

#### Does your paper address subitem 2a-i? \*

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

"Currently, major depressive disorder (MDD) is the single most important cause of years lived with disability (YLD) [1] and is further associated with substantial economic costs for society [2]. In high-income countries, the 12-month prevalence of MDD is estimated at 5.1% [3] with an annual incidence rate of 3% [4]."

"Meta-analyses provide evidence for the effectiveness of psychological interventions to prevent first onsets and recurrences in depression [7-9]."

"Using the Internet to provide community members with effective preventive interventions is currently viewed as a potentially cost-effective way of scaling up preventive interventions [12, 13]."

"Here we will evaluate the cost-effectiveness and cost-utility of such an indicated preventive intervention among self-selected members

### 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.

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 2a-ii? \*

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

"Especially indicated prevention, targeting subthreshold symptoms of an emerging depression, appears to be particularly effective [8]."  
 "Elsewhere we reported the primary outcomes with respect to progression to MDD at 12 months [14]."  
 "To the best of our knowledge, no randomised controlled trial has investigated the cost-effectiveness of a web-based guided self-help intervention to prevent the onset of diagnosed MDD."

## 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



"Here we will evaluate the cost-effectiveness and cost-utility of such an indicated preventive intervention among self-selected members from the community suffering from subthreshold depression."

## METHODS

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

#### Does your paper address CONSORT subitem 3a? \*

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

"We conducted a health-economic evaluation with a 12-month time horizon from a societal and public health care perspective alongside a 2-armed pragmatic randomised controlled trial in Germany (allocation ratio 1:1) to establish the cost-effectiveness and cost-utility of an indicated web-based guided self-help intervention in conjunction to usual care for people with subthreshold depression as compared to enhanced usual care (i.e., web-based psycho-education in addition to treatment as usual)."

### 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

NA since no changes have been made.

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

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator

during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other “unexpected events” that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

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subitem not at all important      essential

#### Does your paper address subitem 3b-i?

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

NA, no bug fixes, no changes in functionality or content.

## 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

"Inclusion criteria were: (a) age 18 and above, (b) subthreshold depression (Centre for Epidemiological Studies Depression Scale (CES-D)  $\geq 16$ ) as having some depressive symptoms not meeting the diagnostic criteria for a full-blown DSM-IV major depressive disorder as assessed by the telephone-administered Structured Clinical Interview for DSM-IV (SCID), (c) Internet access, and (d) informed consent. Exclusion criteria included (a) meeting DSM-IV criteria for bipolar disorder or psychotic disorder, (b) having a history of a major depressive disorder in the past six months based on Kupfer's model [16], (c) currently receiving psychotherapy for any kind of mental health problem, (d) being on a waiting list for psychotherapy, (e) having received psychotherapeutic treatment in the past six months, and (g) showing a significant suicidal risk (item 9 of the Beck Depression Inventory-4)".

#### 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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subitem not at all important      essential

**Does your paper address subitem 4a-i?**

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

Computer / Internet literacy was not an inclusion criterion in this study.

**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.

1 2 3 4 5

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

"Participants were recruited from March 2013 to March 2014 from the general population via a large German health insurance company and through newspaper articles, on-air media, and related websites."

"Inclusion criteria were: (a) age 18 and above, (b) subthreshold depression (Centre for Epidemiological Studies Depression Scale (CES-D)  $\geq 16$ ) as having some depressive symptoms not meeting the diagnostic criteria for a full-blown DSM-IV major depressive disorder as assessed by the telephone-administered Structured Clinical Interview for DSM-IV (SCID)"

"MDD was assessed according to DSM-IV criteria as assessed by the telephone-administered SCID [19, 20] at 6- and 12-month follow-up covering the period to the previous assessment."

"The research staff conducting SCID interviews were not trained"

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

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

1 2 3 4 5

subitem not at all important      essential

#### Does your paper address subitem 4a-iii?

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

Detailed information are presented in previous publications on this trial: Psychother Psychosom 84(6): 348-358; JAMA 315(17): 1854-1863.

## 4b) Settings and locations where the data were collected

#### Does your paper address CONSORT subitem 4b? \*

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

"Self-report measures were collected at baseline, post-treatment, 6- and 12-month follow-up using a secured online-based assessment system (AES, 256-bit encrypted). The SCID interviews at baseline, 6- and 12-month follow-up were conducted by telephone."

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

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

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subitem not at all important      essential

#### 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

"Self-report measures were collected at baseline, post-treatment, 6- and 12-month follow-up using a secured online-based assessment system (AES, 256-bit encrypted). The SCID interviews at baseline, 6- and 12-month follow-up were conducted by telephone."

#### 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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subitem not at all important      essential

#### Does your paper address subitem 4b-ii?

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

Relevant logos of universities involved in the study and the EU logo (study was financed by EU regional development fund) were presented on the information leaflet for participants.

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

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

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

1 2 3 4 5

subitem not at all important      essential

#### Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information

not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The web-based intervention, called GET.ON Mood Enhancer, is an online multimedia interactive intervention consisting of six sessions. Each session takes about 30 minutes to complete, but the amount of time spent on a session varies among users."

". The intervention is based on behavioural activation and problem-solving therapy. An emphasis was placed on homework assignments to integrate newly acquired skills into daily life. Therefore, participants had the option to receive a set of about 42 standardised text-messages supporting them to integrate the learned techniques into their lives. Participants were also supported by an online-trainer, who provided written feedback after each session. The total time a trainer spent per participant was approximately three hours."

"The intervention was developed by trained psychologists and therapists at the Leuphana University "

### 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.

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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

"The intervention was developed by trained psychologists and therapists at the Leuphana University."  
Prior to conducting the RCT (n=406) we performed a pilot feasibility study (n=10) (not published).

### 5-iii) Revisions and updating

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

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subitem not at all important      essential

### Does your paper address subitem 5-iii?

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

"The content of the intervention was frozen during the trial."

#### 5-iv) Quality assurance methods

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

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subitem not at all important      essential

#### Does your paper address subitem 5-iv?

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

Trained psychologists, therapists and researchers designed and administered the study. A research coordinator supervised the study and was responsible for quality assurance and ensured accuracy and quality of the data.

#### 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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subitem not at all important      essential

#### Does your paper address subitem 5-v?

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

Screenshots of the intervention have been published elsewhere:  
Psychother Psychosom 84(6): 348-358.

### 5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, [webcitation.org](http://www.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.

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 5-vi?

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

Screenshots of the intervention have been published elsewhere:  
Psychother Psychosom 84(6): 348-358.  
GET.ON Mood Enhancer available at: <http://www.webcitation.org/6k9JG7oi4>

### 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).

1 2 3 4 5

subitem not at all important      essential

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

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



"Participants created their own password to access the intervention."  
"Trial participants used the intervention free of charge."

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

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

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 5-viii? \***

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

**"Web-based guided self-help intervention**

The web-based intervention, called GET.ON Mood Enhancer, is an online multimedia interactive intervention consisting of six sessions. Each session takes about 30 minutes to complete, but the amount of time spent on a session varies among users. Participants were advised to carry out at least one, preferably two lessons per week. The mean treatment duration was 5.84 (SD 4.37) weeks. On average, participants completed 4.93 of 6 sessions [14]. The intervention was developed by trained psychologists and therapists at the Leuphana University. Participants created their own password to access the intervention. Trial participants used the intervention free of charge. The intervention is based on behavioural activation and problem-solving therapy. The content of the intervention was frozen during the trial. An emphasis was placed on homework assignments to integrate newly acquired skills into daily life. Therefore, participants had the option to receive a set of about 42 standardised text-messages supporting them to integrate the learned techniques into their lives. Participants were also supported by an online-trainer, who provided written feedback after each session. The total time a trainer spent per participant was approximately three hours. Trained and supervised graduate students and health care professionals provided guidance. Further details about the intervention can be found in the study protocol [15].

**Enhanced usual care**

Participants in the control condition got access to an online psychoeducational intervention, which was based on the German S3-Guideline/National Disease Management Guideline Unipolar Depression [17]. It informed participants about evidence-based treatments of depression should symptoms deteriorate. We thus mimicked and enhanced usual care because we provided patients with information that they may not always be offered thoroughly by their GP. Similar psycho-educational interventions have been shown to be effective in reducing depressive symptoms and is therefore suggested as a first-line intervention for early manifestations of depression in the primary care setting [18]. Participants could go

**5-ix) Describe use parameters**

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 5-ix?**

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

"Participants were advised to carry out at least one, preferably two lessons per week."

### 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).

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 5-x?

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

"Participants were also supported by an online-trainer, who provided written feedback after each session. The total time a trainer spent per participant was approximately three hours. Trained and supervised graduate students and health care professionals provided guidance."

### 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).

1 2 3 4 5

subitem not at all important      essential

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

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

"Participants were also supported by an online-trainer, who provided written feedback after each session and monitored adherence to the intervention. In case of non-adherence, online-trainers sent up to three reminders."

### 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).

1 2 3 4 5

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

"All study participants had unrestricted access to care-as-usual (CAU). CAU for subthreshold depression entails visits to the GP, but no treatment provided by mental health specialists. If depressive symptoms deteriorate, the German S3-Guideline/National Disease Management Guideline Unipolar Depression recommends psychotherapy and the prescription of antidepressant medication [17]. In our pragmatic study we did not interfere in CAU. Instead, we maintained a naturalistic CAU condition to represent current clinical practice as far as possible. It should also be noted that health care use was measured in detail (see Measures), implying that we now can describe CAU in great detail (see Table 1)."

## 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

"The main outcome in the cost-effectiveness analysis was depression-free years (DFYs). DFYs were based on the number of depression-free weeks up to the onset of a major depressive episode within the 12-month follow-up period. MDD was assessed according to DSM-IV criteria as assessed by the telephone-administered SCID [19, 20] at 6- and 12-month follow-up covering the period to the previous assessment. Time to onset of MDD was assessed as accurately as possible using the Life Chart method as developed by Lyketsos [21]."

"Quality-adjusted life years (QALYs) were used as the outcome in the cost-utility analysis. QALYs were based on the EQ-5D-3L (EuroQol [22]) and SF-6D (a subset of items of the SF-12v1 [23]). The EuroQoL and the SF-12 were assessed at baseline, post-treatment (6 weeks), and 6- and 12-month follow-up."

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

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

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 6a-i?**

Copy and paste relevant sections from manuscript text

The online questionnaires TiC-P is being used extensively in research and has been validated for online use elsewhere (ie, BMC health services research 13: 217).

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

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 6a-ii?**

Copy and paste relevant sections from manuscript text

"Intervention usage was monitored by logfile analysis."

### 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).

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

At the end of each intervention session, participants had the opportunity to evaluate the session concerned.

## 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

NA.

## 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.

1 2 3 4 5

subitem not at all important      essential

#### Does your paper address subitem 7a-i?

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

"The study was powered to demonstrate a risk reduction of 10% between study conditions as statistically significant in a survival analyses with  $\alpha < 0.05$  (2-tailed), a power of  $(1-\beta) = 0.80$  using survival analysis and accounting for a 20% dropout (calculated using PASS 12). However, the study was not powered to statistically test differences in health economic outcomes. Therefore, we took a probabilistic decision-making approach for our health economic interferences [36]."

### 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

NA.

### 8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

#### Does your paper address CONSORT subitem 8a? \*

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information

not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Randomisation took place at individual level and was conducted centrally by an independent statistician not otherwise involved in the study using an automated computer-generated random numbers table."

## 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

"Block randomisation, of size two, was used to ensure equal sample sizes across both conditions. Details about the randomisation procedure can be found elsewhere [14]."

## 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

"Randomisation took place at individual level and was conducted centrally by an independent statistician not otherwise involved in the study using an automated computer-generated random numbers table. Block randomisation, of size two, was used to ensure equal sample sizes across both conditions. Details about the randomisation procedure can be found elsewhere [14]."

## 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

"Randomisation took place at individual level and was conducted centrally by an independent statistician not otherwise involved in the study using an automated computer-generated random numbers table. Block randomisation, of size two, was used to ensure equal sample sizes across both conditions. Details about the randomisation procedure can be found elsewhere [14]."

## 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).

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 11a-i? \*

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

"Study participants were not masked to their treatment allocation because of the nature of the intervention. SCID interviewers were, however, unaware of participants' randomisation status. Steps taken to maintain blinding are described in detail elsewhere [14]. In case of evidence for blinding breakdown, the interviewer was changed to the second outcome interview. The research staff conducting SCID interviews were not otherwise involved in the study."

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

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 11a-ii?**

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

"Study participants were not masked to their treatment allocation because of the nature of the intervention."

**11b) If relevant, description of the similarity of interventions**

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

**Does your paper address CONSORT subitem 11b? \***

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

NA.

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

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

**Does your paper address CONSORT subitem 12a? \***

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

"Evaluation of clinical outcomes

We reported all analyses in accordance to the CONSORT statement [37]. Data were analysed on an intention-to-treat basis meaning that all participants were included in the analyses as randomised. To this end, we used Cox proportional hazard regression analyses to test differences in time to onset of MDD (in weeks) between intervention and control group.

Costs

Missing costs data were imputed using the regression imputation procedure in Stata version 13 [38], but we did not impute hospitalisation costs because only three participants (0.7%) were hospitalised during the 12-month follow-up period leading to instable imputations. Therefore, we re-assessed the impact of hospitalisation costs on outcomes in a sensitivity analysis. Mean total costs were estimated by multiplying the units of resource use with corresponding unit cost prices. Cumulative costs for each participant over the full 12-month follow-up period were estimated by calculating the area under the curve (AUC) of linearly interpolated costs. Differences in mean total costs between intervention and control groups were estimated using 2,500 bootstrap replications."

**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]).

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 12a-i? \***

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

"Missing costs data were imputed using the regression imputation procedure in Stata version 13 [38], but we did not impute hospitalisation costs because only three participants (0.7%) were hospitalised during the 12-month follow-up period leading to instable imputations."

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

### Does your paper address CONSORT subitem 12b? \*

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

"Sensitivity analyses

We tested the robustness of the outcomes of the main analysis in sensitivity analyses. Firstly, the EQ-5D-3L might suffer from ceiling effects when measuring QALY changes in people with mild conditions. Therefore, we did plan to also measure SF-6D QALYs, which have been reported to be more sensitive to QALY changes in milder conditions such as subthreshold depression [27]. Secondly, we assessed the impact of in-patient care on the ICER because in-patient care is one of the main cost drivers and was surrounded by much uncertainty since only three hospital admissions occurred in the whole sample ( $3/406 = 0.7\%$ ). Such outliers (driving costs in the control condition) could lead to misleading results and these costs

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

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

1 2 3 4 5

subitem not at all important      essential

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

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

"The study was approved by the medical ethics committee of the University of Marburg (reference number AZ 2012-35K)."

### x26-ii) Outline informed consent procedures

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

documents.

1 2 3 4 5

subitem not at all important      essential

### 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

Participants could send the signed informed consent form via post or e-mail.

### 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)

1 2 3 4 5

subitem not at all important      essential

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

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

"Exclusion criteria included: (...) (g) showing a significant suicidal risk (item 9 of the Beck Depression Inventory > 1)."

Besides, trained psychologist were available via telephone and email to increase safety and security.

## 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, 406 participants were enrolled in the study (NINT = 202; NCTR = 204). At post treatment, 366 participants (90.1%) were still participating. At 6- and 12-month follow-up, 325 (80.1%) and 286 (70.4%) participants completed the questionnaires, respectively. The CONSORT flowchart (of the participants through the trial) can be found elsewhere [14]."

"Data were analysed on an intention-to-treat basis meaning that all participants were included in the analyses as randomised."

## 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

"In total, 406 participants were enrolled in the study (NINT = 202; NCTR = 204). At post treatment, 366 participants (90.1%) were still participating. At 6- and 12-month follow-up, 325 (80.1%) and 286 (70.4%) participants completed the questionnaires, respectively. The CONSORT flowchart (of the participants through the trial) can be found elsewhere [14]."

### 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.

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 13b-i?**

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

See Multimedia Appendix.

## 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

"In total, 406 participants were included in the study. Participants were recruited from March 2013 to March 2014 from the general population via a large German health insurance company and through newspaper articles, on-air media, and related websites."

### 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"

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 14a-i?

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

NA.

## 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

NA.

## 15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

**Does your paper address CONSORT subitem 15? \***

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

Table showing baseline characteristics has been previously published: JAMA 315(17): 1854-1863.

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

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

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 15-i? \***

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



Table showing baseline characteristics has been previously published: JAMA 315(17): 1854-1863. We did not assess computer/Internet literacy.

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

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

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

1 2 3 4 5

subitem not at all important      essential

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

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

All analyses were based on intention-to-treat meaning that all randomised participants were included in the analyses.

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

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

1 2 3 4 5

subitem not at all important      essential

### 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

"Data were analysed on an intention-to-treat basis meaning that all participants were included in the analyses as randomised."

## 17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

### Does your paper address CONSORT subitem 17a? \*

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

Since this is an economic evaluation:  
 "From a societal perspective, the intervention resulted in a greater mean health benefit (0.12 DFY gained) achieved at higher mean total costs (€134; £114) as compared to enhanced CAU."  
 "The ICER based on the QALY gains showed a small health benefit (0.01 QALYs gained) for higher mean costs (€134 from a societal perspective and €135 from a health care perspective)."

### 17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 17a-i?

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

NA since we report on an economic evaluation.

## 17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

### Does your paper address CONSORT subitem 17b? \*

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

NA since we report an economic evaluation.

## 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

#### "Sensitivity analyses

Using the SF-6D resulted in a greater incremental QALY gain in favour of the intervention group (0.70 QALY, SD= 0.08) as compared to the control group (0.67 QALY, SD = 0.07), which was statistically significant ( $t(404) = -4.40$ ,  $P < 0.001$ ). This agrees with available evidence that the EQ-5D suffers from a ceiling effect in less severe diseases [40]. At a WTP of €20,000 for gaining one QALY the probability of being cost-effective was 84% (societal perspective) and 99% (health care perspective). Hospital costs were higher in the control group so excluding these costs resulted in higher ICERs (Table 2). From a societal perspective and at a WTP of €20,000, the

### 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).

1 2 3 4 5

subitem not at all important      essential

#### Does your paper address subitem 18-i?

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

NA since we report on an economic evaluation.

## 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

NA.

#### 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].

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem 19-i?**

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

NA.

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

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

1 2 3 4 5

subitem not at all important      essential

**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

NA since we report on an economic evaluation.

## 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

"Our study was set out to evaluate the cost-effectiveness and cost-utility of a web-based guided self-help intervention to prevent the onset of major depressive disorder (MDD) in adults suffering from subthreshold depression in comparison to usual care enhanced with web-based psycho-education. Main outcomes were depression-free life years (DFYs) and quality adjusted life years (QALYs).

Significantly more depression-free years (DFYs) were gained in the intervention group as compared to the control group. The probability that the intervention is deemed to be cost-effective depends on the willingness-to-pay (WTP) for a depression-free year. At a WTP of €1,500, €5,000 and €20,000 the likelihood was 52%, 76% and 99%, respectively, suggesting that a WTP of €1,500 and above for gaining a DFY would make the intervention cost-effective. While these DFY health gains were not mirrored in EQ-5D QALY gains, they were observed in SF-6D QALY gains with the latter being more sensitive to change in milder conditions such as subthreshold depression and therefore not suffering as much from a ceiling effect as the EQ-5D does.[27] If society would be willing to pay €20,000 (£17000) for gaining a QALY, the probability of being cost-effective will be 64% for EQ-5D QALY and 64% for SF-6D QALY."

### 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 studies should thus clarify whether web-based guided self-help interventions are cost-effective both for the prevention of first depression onset and the prevention of recurrence."

## 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.

1 2 3 4 5

subitem not at all important      essential

### Does your paper address subitem 20-i? \*

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

Limitations to the trial have been described in detail elsewhere: JAMA 315(17): 1854-1863.  
 Here we report limitations specific to the economic evaluation:  
 "This study has some limitations. Firstly, the time horizon of this study was limited to 12 months. Secondly, we did not assess lifetime history of MDD at baseline and therefore we cannot be sure if we prevented first-ever onsets of MDD or MDD recurrences. Future studies should thus clarify whether web-based guided self-help interventions are cost-effective both for the prevention of first depression onset and the prevention of recurrence. Thirdly, costs were assessed with the help of self-reports and may suffer from under-reporting. However, the structured questionnaire used in the current study can be considered as valid instrument for recall periods up to 3 months [46]. Finally, participants in this trial differed from the general population as they were better educated and predominately female. Conclusions might therefore not be safely generalised to other population segments. That said, the present trial is likely to have good ecological validity because we used the same open recruitment strategy that is routinely used for recruiting people from the general population for web-based interventions as applied in real practice. Therefore we expect that the sample on which our

## 21) Generalisability (external validity, applicability) of the

## trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

### 21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

1 2 3 4 5

subitem not at all important      essential

#### Does your paper address subitem 21-i?

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

"Conclusions might therefore not be safely generalised to other population segments. That said, the present trial is likely to have good ecological validity because we used the same open recruitment strategy that is routinely used for recruiting people from the general population for web-based interventions as applied in real practice. Therefore we expect that the sample on which our study was based is representative for the population of future users of this preventive intervention."

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

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

1 2 3 4 5

subitem not at all important      essential

#### 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



We conducted a pragmatic randomised controlled trial thus mimicking routine care in our trial.

## OTHER INFORMATION

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

**Does your paper address CONSORT subitem 23? \***

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

German Clinical Trial Registry Identifier: DRKS00004709

### 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

The study protocol has been previously published: Buntrock, C., et al. (2014). "Evaluating the efficacy and cost-effectiveness of web-based indicated prevention of major depression: design of a randomised controlled trial." BMC psychiatry 14: 25.

### 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

"Funding was received from the European Union (project number: EFRE: CCI 2007DE161PR001) and the BARMER GEK (German statutory health insurance company). The funders did not have a role in study design; data collection, analysis the interpretation of results or the decision to publicise the study results."

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

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

1 2 3 4 5

subitem not at all important      essential

**Does your paper address subitem X27-i?**

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

"The Leuphana University, Lueneburg, has the exploitation rights of the intervention. The authors will not have a share in any possible license revenues from the Leuphana University Lueneburg. DE, MB, SN, and DL are stakeholders of the "Institute for Online Health Trainings", a company aiming to transfer scientific knowledge related to the present research into routine health care. This institute licenses the intervention under study from the Leuphana University, Lueneburg, to provide the intervention within routine preventive services of health insurance companies in Germany. The foundation of such an institute to disseminate findings and products from the research project was the primary aim of the European Union for funding the presented research. At the time of planning, conducting, and evaluating the study, the institute did not yet exist."

**About the CONSORT EHEALTH checklist****As a result of using this checklist, did you make changes in your manuscript? \***

- yes, major changes  
 yes, minor changes

no

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

Description of the web-based intervention.

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

4hrs

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

yes

no

Sonstiges:

**Would you like to become involved in the CONSORT EHEALTH group?**

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

yes

no

Sonstiges:

**Any other comments or questions on CONSORT EHEALTH**

- 1) It would be really helpful to have the opportunity to save entries and come back later to complete the form.
- 2) You asked to generate a PDF of this form but you only explain to Mac users how to do it. It would be much appreciated to extend the explanation to non-Mac users!
- 3) For economic evaluations: Ask authors to complete the CHEERS checklist as this is more appropriate even if a web-based intervention is evaluated.

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