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.

Therapist-assisted online intervention for prolonged grief disorder after cancer bereavement: Randomized-Controlled Trial.

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

"Online-Trauertherapie" (engl.: "Online Grief Th

Evaluated Version (if any)

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

Meine Antwort

Language(s) *

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

German

URL of your Intervention Website or App

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

Meine Antwort

URL of an image/screenshot (optional)

Meine Antwort

Accessibility *

Can an enduser access the intervention presently?

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

Primary Medical Indication/Disease/Condition *

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

Prolonged grief after a loss due to cancer

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Prolonged grief

Secondary/other outcomes

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

Depression, anxiety, posttraumatic stress, posttraumatic growth, somatization, sleep quality, mental and psysical health.

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ☐ Approximately Daily
- ☐ Approximately Weekly
- ☐ Approximately Monthly
- ☐ Approximately Yearly
- ☐ "as needed"
- ☒ Sonstiges: Approximately twice a week

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- ☐ unknown / not evaluated
- ☐ 0-10%
- ☐ 11-20%
- ☐ 21-30%
- ☐ 31-40%
- ☐ 41-50%
- ☐ 51-60%
- ☐ 61-70%
- ☐ 71%-80%
- ☐ 81-90%
- ☐ 91-100%
- ☒ Sonstiges: The intervention has a duration of only five weeks.

Overall, was the app/intervention effective? *

- ☒ yes: all primary outcomes were significantly better in intervention group vs control
- ☐ partly: SOME primary outcomes were significantly better in intervention group vs control
- ☐ no statistically significant difference between control and intervention
- ☐ potentially harmful: control was significantly better than intervention in one or more outcomes
- ☐ inconclusive: more research is needed
- ☐ Sonstiges:

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)
- ☐ JMIR mHealth and UHealth
- ☐ JMIR Serious Games
- ☐ JMIR Mental Health
- ☐ JMIR Public Health
- ☐ JMIR Formative Research
- ☐ Other JMIR sister journal
- ☐ Sonstiges:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ☐ Pilot/feasibility
- ☒ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ☒ no ms number (yet) / not (yet) submitted to / published in JMIR
- ☐ 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

Auswahl löschen

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

"[...] 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

Auswahl löschen

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

Not applicable, no non-web-based components or co-interventions.

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

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

	1	2	3	4	5	
subitem not at all important	☐	☐	☐	☐	☒	essential

Auswahl löschen

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

"[...] for prolonged grief disorder after cancer bereavement [...]"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

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

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

	1	2	3	4	5	
subitem not at all important	☐	☐	☐	☐	☒	essential

Auswahl löschen

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 cognitive-behavioral intervention with asynchronous therapist support, consisting of structured writing tasks adapted specifically for prolonged grief after cancer bereavement"

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
Auswahl löschen						

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

"with asynchronous therapist support"

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
Auswahl löschen

Does your paper address subitem 1b-iii?

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

"The intervention was evaluated in a purely web-based randomized waitlist-controlled trial. Open access recruitment of N = 87 participants was conducted online. Prolonged grief (Inventory of Complicated Grief), depression, anxiety, posttraumatic stress, posttraumatic growth, somatization, sleep quality, mental and physical health were assessed online via self-report measures."

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

Auswahl löschen

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

"N = 87 participants were randomized into the intervention group (IG, n = 44) or waitlist control (WCG, n = 43). Six participants dropped out of the study (n = 5 in IG). Of the 39 completers in the IG, 37 completed all intervention tasks."

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

Auswahl löschen

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

Not applicable. Intervention was effective.

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)

1 2 3 4 5

subitem not at all important ☐ ☐ ☒ ☐ ☐ essential

Auswahl löschen

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

"The current intervention was designed to address the interlinking between grief and traumatic experiences, preloss grief and preparedness for the loss, as well as role conflicts and interpersonal conflicts. As a stand-alone, fully web-based intervention it is suitable to overcome treatment barriers such as geographic and schedule restrictions and stigma."

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

"Internet-based treatments offer an effective, flexible and more anonymous approach for addressing mental health issues [31–33], that may help overcome treatment barriers for those suffering from PGD. Internet-based treatment in general was shown to be as effective as conventional face-to-face treatment [34]. Internet-based interventions for grief reached medium to large effect sizes [35]. Specific web-based support for relatives of persons with cancer revealed promising results, but to date mainly focused on caregiving during the time of illness [e.g., 36]. There is a lack of evidence on web-based interventions specifically addressing cancer bereavement and therefore providing support beyond the time of illness. Web-based bereavement care targeted specifically at those suffering from PGD after a cancer experience should therefore be further examined. Asynchronous web-based interventions that employ cognitive-behavioral (CBT) techniques and rely on structured writing tasks and therapist feedback have proven effective in reducing syndromes such as prolonged grief, posttraumatic stress or anxiety in the past [e.g., 37,38]. They are often short and therefore highly economic and offer high flexibility for patients. An asynchronous web-based intervention designed for treatment of posttraumatic stress and PGD [39,40] has been successfully adapted by the research group to several specific bereavement situations such as pregnancy loss [38] or suicide bereavement [41]. To address the research gap concerning bereavement care after cancer, the intervention was adapted to suit the specific situation of those affected: Difficult loss experiences are often preceded by a burdensome and possibly traumatic time of illness."

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

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

"The effectiveness of the resulting therapist-assisted web-based intervention was evaluated in a randomized-controlled trial (RCT) to extent previous findings on bereavement care to the specific situation of cancer bereavement."

METHODS

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

Does your paper address CONSORT subitem 3a? *

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

"The evaluation of the web-based CBT intervention for prolonged grief after bereavement due to cancer took place in a randomized waitlist-controlled trial."

"Randomization was conducted via permuted block randomization with a block size of four and equal probabilities to be sampled into either group (pseudo-seeds, MersenneTwister)."

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

"The study was conducted in two waves with recruitment from 11/2017 to 04/2018 and from 05/2018 to 06/2019 respectively. The first wave was funded by "Deutsche José Carreras Leukämie-Stiftung" (German José Carreras Leukemia Foundation, DJCLS R15/22) and is thoroughly described in a study protocol [42]. The second wave follows the same methodology except for more liberal inclusion criteria concerning the cause of bereavement, as specified below. The recruitment duration of the first wave was determined by the duration of funding. The second wave was set to one year in advance."

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

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

	1	2	3	4	5	
subitem not at all important	☐	☐	☒	☐	☐	essential
Auswahl löschen						

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

Not applicable. There were no major changes or events.

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

"Persons were eligible as participants if they

- were bereaved to hematological cancer (first wave) / any type of cancer (second wave),
- reached a score of > 25 on the Inventory of Complicated Grief (ICG)[43,44],
- were 18 years or older, and
- were fluent in the German language and had sufficiently stable web access.

Exclusion criteria were

- current psychotherapy or change in psychopharmacological therapy within the last 6 weeks,
- cognitive or physical impairment that would impede treatment participation,
- severe depression (Patient Health Questionnaire 9 – PHQ-9 [45,46]), suicidal ideation (Beck Suicide Ideation Scale – BSIS, 47; clinical assessment in telephone interview), dissociative tendency (Somatoform Dissociation Questionnaire – SDQ-5 [48]; clinical assessment in telephone interview), psychosis (Dutch Screening Device for Psychotic Disorder – SDPD [49]; clinical assessment in telephone interview), PTSD due to an event other than the loss (Impact of Event Scale-Revised – IES-R [50,51]), or substance use disorder [52]."

4a-i) Computer / Internet literacy

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

	1	2	3	4	5	
subitem not at all important	☐	☐	☒	☐	☐	essential

Auswahl löschen

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

"sufficiently stable web access" was explicitly asked in the screening. No internet literacy was required since the intervention was designed to be very simple.

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

"Open-access recruitment was carried out from 11/2017 to 06/2019 [...]",
 "The entire study process was web-based except one mandatory phone call per participant. Measures to prevent multiple identities were the informed consent form, e-mail confirmation and a phone call."

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

Auswahl löschen

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

"Study information forms were presented on the website and again upon inclusion."

Note: All forms are in german.

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

"Participants could apply for the study by taking the open-access online screening questionnaire (T-1) [see 42]). A subsequent telephone screening was carried out by the participant's prospective therapist to clear any ambiguities concerning eligibility criteria", "All constructs examined in this article were assessed in online self-report questionnaires, except for the PG-13 (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.

	1	2	3	4	5	
subitem not at all important	☐	☐	☐	☒	☐	essential

Auswahl löschen

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

"Participants could apply for the study by taking the open-access online screening questionnaire (T-1) [see 42]). A subsequent telephone screening was carried out by the participant's prospective therapist to clear any ambiguities concerning eligibility criteria", "All constructs examined in this article were assessed in online self-report questionnaires, except for the PG-13 (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)

	1	2	3	4	5	
subitem not at all important	☐	☒	☐	☐	☐	essential

Auswahl löschen

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

Not Applicable.

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

"An asynchronous web-based intervention designed for treatment of posttraumatic stress and PGD [39,40] has been successfully adapted by the research group to several specific bereavement situations such as pregnancy loss [38] or suicide bereavement [41]. To address the research gap concerning bereavement care after cancer, the intervention was adapted to suit the specific situation of those affected:" (Introduction)

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

	1	2	3	4	5	
subitem not at all important	☐	☐	☒	☐	☐	essential

Auswahl löschen

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

"To address the research gap concerning bereavement care after cancer, the intervention was adapted to suit the specific situation of those affected

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).

	1	2	3	4	5	
subitem not at all important	☐	☒	☐	☐	☐	essential

Auswahl löschen

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

"Instructions for all modules as well as psychoeducational material are standardized and therapist feedback is highly structured, but can be adapted to a specific patient's situation."

5-iv) Quality assurance methods

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

	1	2	3	4	5	
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

Not applicable.

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.

	1	2	3	4	5	
subitem not at all important	☐	☒	☐	☐	☐	essential
Auswahl löschen						

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

Not applicable.

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](https://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
Auswahl löschen

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

Webcite does not work at the moment. We have made screenshots.

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 did not pay for the intervention, neither were they paid.", Editor access not applicable, since the intervention does not contain self-help or automated content.

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

Auswahl löschen

Does your paper address subitem 5-viii? *

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

"The intervention "Online-Trauertherapie" ("Online Grief Therapy") was conducted remotely via a secure website and consisted of 10 structured writing tasks which participants worked on independently in two self-scheduled 45-minute writing sessions per week. Participants received individualized therapist feedback from trained psychologists on all writing assignments within 24 hours, alternating between short and thorough feedback. If participants missed a scheduled session, they were reminded up to two times and called once if they did not respond. The structured writing tasks are organized in 3 modules (Table 1) that aim at working through the grief and coping with the new situation: (1) self-confrontation, (2) cognitive reappraisal, and (3) social sharing.

In the first module, self-confrontation, participants receive information on prolonged grief, the treatment rationale and the treatment platform. They are then asked to describe their loss experience repeatedly in multiple sessions in order to reprocess traumatic memories and reduce avoidance behavior. An emphasis on emotional, cognitive and bodily processes enables multimodal reprocessing. Addressed specifics of cancer bereavement include traumatic aspects of the illness experience, burdensome caregiving experiences and ambiguity between hope for survival and preparation for the loss.

In the second module, cognitive reappraisal, participants are asked to write a letter to a hypothetical friend, who shares the same loss experience. Participants are encouraged to focus on validating their counterpart's suffering as well as on building and reinforcing resources and coping strategies. Specific to cancer bereavement are validation of one's own suffering, especially if the deceased's suffering was so far perceived as more important, addressing of guilt and anger and reflection of one's role during the time of illness.

In the third module, social sharing, participants are asked to write (but not necessarily send) a letter to a real person involved in the loss experience (e.g., themselves, the deceased, or a family member), in order to summarize and communicate their experience as well as new strategies and perspectives.

Instructions for all modules as well as psychoeducational material are standardized and therapist feedback is highly structured, but can be adapted to a specific patient's situation."

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

Auswahl löschen

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

"The intervention "Online-Trauertherapie" ("Online Grief Therapy") was conducted remotely via a secure website and consisted of 10 structured writing tasks which participants worked on independently in two self-scheduled 45-minute writing sessions per week. Participants received individualized therapist feedback from trained psychologists on all writing assignments within 24 hours, alternating between short and thorough feedback. If participants missed a scheduled session, they were reminded up to two times and called once if they did not respond."

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

Auswahl löschen

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 received individualized therapist feedback from trained psychologists on all writing assignments within 24 hours, alternating between short and thorough feedback."

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

"If participants missed a scheduled session they were reminded up to two times and called once if they did not respond."

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

Auswahl löschen

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

Not applicable. There were no co-interventions.

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

Does your paper address CONSORT subitem 6a? *

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

"A detailed account of all measurement tools can be found in Hoffmann et al. [42].",

"Primary Outcome

The current article examines the primary outcome prolonged grief as measured with the German version of the ICG [43,44]. At T0, the ICG had an internal consistency of Cronbach's $\alpha = .82$.

Secondary outcomes

The 19 original items of the ICG were augmented by three additional items adapted from Xiu et al. [57] to fully capture the ICD-11 criteria of PGD. They address feelings of guilt, difficulty accessing positive memories and anhedonia. The augmented version of the ICG with 22 items is considered as a secondary outcome in all analyses (ICGa; Cronbach's $\alpha = .85$).

Further secondary outcomes were depression (PHQ-9 [45,46], Cronbach's $\alpha = .86$), anxiety (Generalized Anxiety Disorder Screener – GAD-7 [58,59], Cronbach's $\alpha = .84$), posttraumatic stress due to the loss (IES-R [50,51], Cronbach's $\alpha = .85$), posttraumatic growth (Posttraumatic Growth Inventory – PGI [60,61], Cronbach's $\alpha = .90$), somatization (Patient Health Questionnaire 15 – PHQ-15 [45,46], Cronbach's $\alpha = .65$), sleep quality (Pittsburgh Sleep Quality Index – PSQI [62,63], Cronbach's $\alpha = .75$) and physical and mental health (Short-Form Health Survey – SF-12 [64,65])."

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

"Primary Outcome

The current article examines the primary outcome prolonged grief as measured with the German version of the ICG [43,44]. At T0, the ICG had an internal consistency of Cronbach's $\alpha = .82$.

Secondary outcomes

The 19 original items of the ICG were augmented by three additional items adapted from Xiu et al. [57] to fully capture the ICD-11 criteria of PGD. They address feelings of guilt, difficulty accessing positive memories and anhedonia. The augmented version of the ICG with 22 items is considered as a secondary outcome in all analyses (ICGa; Cronbach's $\alpha = .85$).

Further secondary outcomes were depression (PHQ-9 [45,46], Cronbach's $\alpha = .86$), anxiety (Generalized Anxiety Disorder Screener – GAD-7 [58,59], Cronbach's $\alpha = .84$), posttraumatic stress due to the loss (IES-R [50,51], Cronbach's $\alpha = .85$), posttraumatic growth (Posttraumatic Growth Inventory – PGI [60,61], Cronbach's $\alpha = .90$), somatization (Patient Health Questionnaire 15 – PHQ-15 [45,46], Cronbach's $\alpha = .65$), sleep quality (Pittsburgh Sleep Quality Index – PSQI [62,63], Cronbach's $\alpha = .75$) and physical and mental health (Short-Form Health Survey – SF-12 [64,65])." The CHERRIES criteria have been applied.

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

Auswahl löschen

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

"Of the 39 completers in the IG, 37 completed all writing tasks, while two completed seven and nine of the tasks, respectively." - Use was measured via the number of writing assignments completed.

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

Auswahl löschen

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Not applicable. Qualitative feedback was not explicitly elicited.

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

Not applicable. No changes.

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

Auswahl löschen

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

There is a published study protocol delienating the power analysis. Referenced in the current article e.g. here: "As stated in the study protocol [42], a sample size of N = 128 was intended,"

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

"The recruitment duration of the first wave was determined by the duration of funding. The second wave was set to one year in advance."

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

"Randomization was conducted via permuted block randomization with a block size of four and equal probabilities to be sampled into either group (pseudo-seeds, MersenneTwister)."

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

"Randomization was conducted via permuted block randomization with a block size of four and equal probabilities to be sampled into either group (pseudo-seeds, MersenneTwister)."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

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

"The allocation sequence was generated by a research assistant with the software "Randomization in Treatment Arms (RITA)" and stored separately from other study materials. Participants were automatically assigned to a treatment condition after completing the baseline measurement."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions**Does your paper address CONSORT subitem 10? ***

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

"The allocation sequence was generated by a research assistant with the software "Randomization in Treatment Arms (RITA)" and stored separately from other study materials. Participants were automatically assigned to a treatment condition after completing the baseline measurement."

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

Auswahl löschen

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

"Informed consent was acquired as a signed form (mailed or scanned) from those who were included, and a baseline questionnaire (T0) was administered.

Subsequently, randomization into either the intervention group (IG) or waitlist control group (WCG) was conducted as described below. Therefore, participants, as well as study personnel were blind to group allocation up to this point." After that, blinding was not feasible.

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

Auswahl löschen

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

Not directly applicable. There is only one intervention, while the comparator was the waitlist control.

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

Not applicable.

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

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

Does your paper address CONSORT subitem 12a? *

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

"The efficacy of the intervention was examined with linear mixed models for the primary and secondary outcomes. This method allows for an intention-to-treat analysis under the assumption of data being missing at random. A restricted maximum-likelihood-algorithm was applied. Analyses were carried out in two steps. (1) The appropriate base model was chosen by comparing the fit (AIC and BIC) of three base models via ANOVA: the unconditional means model (no random effects), random intercept model (unconditional growth model) and random intercept and random slope model. (2) Fixed effects were added to the base model with the best fit to examine the effect of time, group, and time*group. Significance was assessed with p values approximated via Kenward-Roger approximations [67]. Because there is one primary and nine secondary outcomes, Bonferroni correction was applied, so that $p = .05/10 = .005$ was deemed the threshold for significance in all linear mixed models. Effect sizes were calculated as Cohen's d (between) and η^2 , with the latter representing the percentage of variance explained by the model. Effect sizes were considered small if $d < .5$ ($\eta^2 < .06$), moderate, if $.5 \leq d < .8$ ($.06 \leq \eta^2 < .14$) and large if $d \geq .8$ ($\eta^2 \geq .14$) [68]. Additionally Hedge's g was computed to aid comparability across studies. To determine within-group effects, separate multilevel analyses were performed for each of the two treatment groups for all outcomes with time as a fixed effect."

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

Auswahl löschen

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

"The efficacy of the intervention was examined with linear mixed models for the primary and secondary outcomes. This method allows for an intention-to-treat analysis under the assumption of data being missing at random."

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

"Additional analyses were carried out for the primary outcome (ICG) as follows:

- (1) In addition to the intention-to-treat analysis a completer analysis was conducted with a linear mixed model.
- (2) To test for differences in symptom trajectories across waves, a separate linear mixed model was run with wave*time as an additional fixed effect.
- (3) Clinical significance of the change in ICG-scores was evaluated by three metrics: (1) The reliable change index (RCI) [26] weighs pretest-posttest differences by standard error (in this case derived from Cronbach's α at baseline). By comparing the score with z-scores, a dichotomous assessment (95% CI) of whether or not a participant exhibits clinically significant improvement between two measurement points is derived. (2) The cut-off criterion of the ICG (25 points [43]) was used to provide an additional approximation of clinical significance and (3) as a more conservative measure, the intersection of both was chosen, indicating clinically significant improvement only if both, the RCI- and cut-off-criterion were satisfied. χ^2 -tests were carried out for all three dichotomous measures (RCI, cut-off and their intersection) to examine differences between treatment groups at posttreatment."

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
Auswahl löschen						

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 registered with the German Clinical Trial Register (UTN: U1111–1186-6255) and approved by the University of Leipzig Ethics Committee (No. 450–15-21,122,015 (20.01.17))."

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
Auswahl löschen

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

"Informed consent was acquired as a signed form (mailed or scanned) from those who were included"

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

Auswahl löschen

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

"Participants could proactively contact their therapists via the website in case of questions or problems.", "Participants received individualized therapist feedback from trained psychologists", "The intervention "Online-Trauertherapie" ("Online Grief Therapy") was conducted remotely via a secure website", "All data was stored in encrypted servers with password protection."

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

"The baseline questionnaire was completed by 87 participants, who were randomized into IG (N = 44) or WCG (N = 43).", "After randomization, 6 participants (7%, 5 in IG, 1 in WCG) dropped out of the study (i.e., did not provide post-treatment data).", "Of the 39 completers in the IG, 37 completed all writing tasks, while two completed seven and nine of the tasks, respectively."

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

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

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

"After randomization, 6 participants (7%, 5 in IG, 1 in WCG) dropped out of the study (i.e., did not provide post-treatment data).", "Of the 39 completers in the IG, 37 completed all writing tasks, while two completed seven and nine of the tasks, respectively."

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

Auswahl löschen

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

We decided against an attrition diagram, since in our case the information could be integrated in the participant flow diagram.

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

"Open-access recruitment was carried out from 11/2017 to 06/2019", Follow-up was conducted until the last participant received their 12-Month follow-up.

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

Auswahl löschen

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

Not applicable. No events.

14b) Why the trial ended or was stopped (early)**Does your paper address CONSORT subitem 14b? ***

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

"The recruitment duration of the first wave was determined by the duration of funding. The second wave was set to one year in advance."

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 2 Demographic and clinical characteristics of the study sample at baseline"

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 2 Demographic and clinical characteristics of the study sample at baseline"; eHealth and computer literacy was considered of relatively little importance in our trial since the intervention required very little computer literacy as its mode of delivery largely resembles a simple exchange of e-mails."

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

Auswahl löschen

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

"The baseline questionnaire was completed by 87 participants, who were randomized into IG (N = 44) or WCG (N = 43).", "After randomization, 6 participants (7%, 5 in IG, 1 in WCG) dropped out of the study (i.e., did not provide post-treatment data).", "Of the 39 completers in the IG, 37 completed all writing tasks, while two completed seven and nine of the tasks, respectively."

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

Auswahl löschen

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

Primary: "The efficacy of the intervention was examined with linear mixed models for the primary and secondary outcomes. This method allows for an intention-to-treat analysis under the assumption of data being missing at random.", Secondary: "Additional analyses were carried out for the primary outcome (ICG) as follows: (1) In addition to the intention-to-treat analysis a completer analysis was conducted with a linear mixed model."

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

Reported in "Table 3 Results of mixed model analyses (intention-to-treat, N = 87)"

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

"Of the 39 completers in the IG, 37 completed all writing tasks, while two completed seven and nine of the tasks, respectively."

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

Not applicable.

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

Reported in "Table 3 Results of mixed model analyses (intention-to-treat, N = 87)"

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

Auswahl löschen

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

Not applicable, since in the current sample, all completers are also users.

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

"There was no deterioration of mean scores of any secondary outcome. No unintended effects were detected."

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

[Auswahl löschen](#)**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

Not applicable. No breaches.

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

[Auswahl löschen](#)

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

Not applicable.

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

Auswahl löschen

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

"In light of unmet mental health care needs among those bereaved by cancer, we adapted and evaluated a web-based intervention for PGD after cancer bereavement.", "A total of N = 87 participants could be included and randomized. With N = 6 participants dropping out, N = 81 completed the posttreatment measurement. The dropout rate of 7% is in line with previous studies on web-based interventions for grief [35], which indicates sufficient acceptability.", "A linear mixed model was used to examine the intervention's efficacy and revealed a significant interaction effect, indicating a greater decrease of PGD symptoms (ICG) in the intervention group compared to the waitlist control group.", "Small to moderate effects were found for depression, anxiety, posttraumatic stress, posttraumatic growth and mental health."

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

Auswahl löschen

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 research may study differential effects of the treatment modules used in the current study, the role of therapist support, and long term effects of web-based interventions, especially in comparison to face-to-face approaches. Also, it might be fruitful to explore the acceptability and effectiveness of web-based grief interventions when blended into existing health care structures (e.g., primary care), and to examine economical aspects such as cost-effectiveness."

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

Auswahl löschen

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

"We argue that the current study is methodologically suitable to examine the effectiveness of a web-based intervention for PGD. There are however some methodological aspects that merit discussion:

As stated in the study protocol [42], a sample size of $N = 128$ was intended, to ensure enough power to detect a moderate effect. Although we did not meet this criterion, the achieved sample size of $N = 87$ was sufficient to detect the large effect that the intervention had on PGD.

The current study was conducted in two waves, with the second wave's (05/2018 to 06/2019) inclusion criteria concerning the cause of bereavement being more liberal than the first wave's (11/2017 to 04/2018). Yet, participants of both waves displayed similar amounts of distress, were from similar socioeconomic backgrounds and had similar characteristics of their loss. Moreover, PGD trajectories did not differ between waves. Therefore, we deemed the groups homogeneous enough to be included in a joint analysis.

Treatment groups were considered mostly equal, for they differed only in that the WCG had more favorable values for posttraumatic growth at baseline than the IG. This may to some extent weaken the interpretability of the results concerning posttraumatic growth.

Females are overrepresented in the current study, as is the case in many previous studies on web-based interventions [35] or caregiving and bereavement [e.g., 24]. To some extent this may reflect women in Germany being more often affected by bereavement than men. For example, women are more often widowed than men [70]. Also, women do more often assume caregiver roles for sick relatives [71], which makes them more vulnerable to burdensome caregiving experiences and witnessing traumatic aspects of illness and death. This may lead to increased levels of PGD among women compared to men. Yet, women may also be more likely to seek support via the Internet or to be open to therapist contact [72].

Therefore, our sample, while not representative of the German population, may well be representative of those who suffer from PGD after a loss due to illness and are willing to undergo web-based treatment.

The current study relied on online self-report measures to assess primary and secondary outcomes. While the use of interviews would have provided added validity, our questionnaires were comprised of instruments that were designed and validated for administration as self-report assessments. Therefore, we deem our assessments adequately valid."

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

Auswahl löschen

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

"Females are overrepresented in the current study, as is the case in many previous studies on web-based interventions [35] or caregiving and bereavement [e.g., 24]. To some extent this may reflect women in Germany being more often affected by bereavement than men. For example, women are more often widowed than men [70]. Also, women do more often assume caregiver roles for sick relatives [71], which makes them more vulnerable to burdensome caregiving experiences and witnessing traumatic aspects of illness and death. This may lead to increased levels of PGD among women compared to men. Yet, women may also be more likely to seek support via the Internet or to be open to therapist contact [72]. Therefore, our sample, while not representative of the German population, may well be representative of those who suffer from PGD after a loss due to illness and are willing to undergo web-based treatment."

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

Auswahl löschen

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

Not applicable. No differences, if applied in routine setting.

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 Register (UTN: U1111-1186-6255)"

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

"German Clinical Trial Register (UTN: U1111-1186-6255)", also the published study protocol is cited: Hoffmann R, Große J, Nagl M, Niederwieser D, Mehnert A, Kersting A. Internet-based grief therapy for bereaved individuals after loss due to Haematological cancer: study protocol of a randomized controlled trial. BMC Psychiatry 2018;18(1):52. PMID:29482525

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

Does your paper address CONSORT subitem 25? *

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

"This work was partially funded by "Deutsche José Carreras Leukämie-Stiftung" (German José Carreras Leukemia Foundation, grant number DJCLS R15/22), which was not involved in study design, data collection, analysis, or interpretation, or writing of the report."

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

[Auswahl löschen](#)**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

"All authors declare that they have no conflicts of interest."

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?

We included more thorough information on methodology and participant flow.

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

Unfortunately, I did not track the time.

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:

Auswahl löschen

Any other comments or questions on CONSORT EHEALTH

I would like to suggest that a version of this checklist that can be saved and returned to later would be useful, as the checklist is quite extensive.

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