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: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

* Erforderlich

Your name * First Last

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Title of your manuscript * Provide the (draft) title of your manuscript.

SaveMySkin: An Internet-based self-help intervention for skin picking. Results of a randomized controlled pilot study.

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.

SaveMySkin

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?

\bigcirc	access	is	free	and	open
\smile	400000			ana	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)"

Skin picking disorder

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

attitudes and expectations towards Save

Secondary/other outcomes

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

feasibility of study procedures (e.g., recruitment, randomization), appropriateness of applied questionnaires, effects on skin picking related impairment, general psychological impairment, and dimensions of skin picking

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:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
O unknown / not evaluated
0-10%
0 11-20%
0 21-30%
0 31-40%
O 41-50%
51-60%
0 61-70%
0 71%-80%
0 81-90%
91-100%
Sonstiges: Program utilization regularly ends after 3 months

Overall	, was the	app/inter	vention	effective? *
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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:

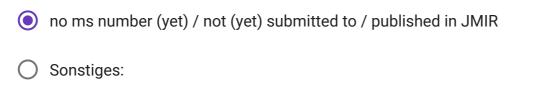
Is this a full powered effectiveness trial or a pilot/feasibility trial?



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 fourdigit number at the end of the DOI, to be found at the bottom of each published article in JMIR)





1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

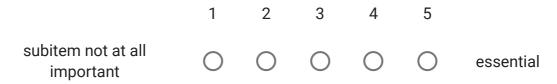
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")



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.



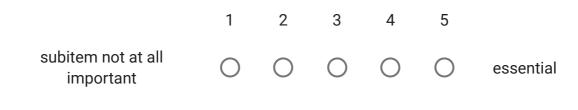
Does your paper address subitem 1a-i?*

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

"SaveMySkin: An Internet-based self-help intervention for skin picking. Results of a randomized controlled pilot study."

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").



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

Meine Antwort

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	0	0	0	0	0	essential

Does your paper address subitem 1a-iii? *

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

"SaveMySkin: An Internet-based self-help intervention for skin picking. Results of a randomized controlled pilot study."

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	0	0	0	0	0	essential

Does your paper address subitem 1b-i?*

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

"The present pilot study evaluated the Internet-based self-help program 'SaveMySkin'. The 12-week program is based on cognitive-behavioral therapy, and contains comprehensive information and exercising materials, a daily supportive monitoring system, and dermatological and psychological counseling via Internet-chat."

"Participants were randomly allocated to the intervention (N=64) or waitlist control group (N=69)."

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	0	0	0	0	0	essential

Does your paper address subitem 1b-ii?

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

Meine Antwort

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-toface 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	\bigcirc	0	0	\bigcirc	0	essential

Does your paper address subitem 1b-iii?

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

Meine Antwort

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

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)



Does your paper address subitem 1b-iv?

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

Meine Antwort

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	\bigcirc	0	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 1b-v?

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

Meine Antwort

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 standalone 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	0	0	0	0	0	essential

Does your paper address subitem 2a-i? *

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

"[...] we considered an Internet-based self-help program a promising opportunity to provide support to individuals affected by skin picking. The program is conceptualized as a stand-alone intervention in order to complement conventional health care for skin picking disorder."

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

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

	1	2	3	4	5	
subitem not at all important	\bigcirc	0	0	0	0	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

"A limited number of studies investigated pharmacological and behavioral interventions (Lochner, Roos, & Stein, 2017), including habit reversal training (HRT) (Moritz, Fricke, Treszl, & Wittekind, 2012; Teng, Woods, & Twohig, 2006), acceptance and commitment therapy (Twohig, Hayes, & Masuda, 2006), cognitive-behavior therapy (CBT) (Flessner, Mouton-Odum, Stocker, & Keuthen, 2007; Schuck, Keijsers, & Rinck, 2011), and combined approaches (e.g., acceptance-enhanced CBT) (Capriotti, Ely, Snorrason, & Woods, 2015; Flessner, Busch, Heidemann, & Woods, 2008). But it needs to be noted that most of these studies included severe methodological shortcomings (e.g., small sample sizes, lack of control conditions), and were commonly conducted before the official DSM 5 criteria for skin picking were available. One of these studies also investigated an Internet- and CBT-based self-help intervention for skin picking, and reported substantial improvements in symptom severity for 63 % of the sample (Flessner et al., 2007). However, the study was uncontrolled, and only 4 % of the initial sample (N = 372) completed the entire intervention, so that the results should be interpreted cautiously. So far, two meta-analyses suggest an overall beneficial effect of behavioral treatments on skin picking severity, but these studies must also be seen as preliminary due to the small number of included original studies and their limited validity (Schumer, Bartley, & Bloch, 2016; Selles, McGuire, Small, & Storch, 2016). Despite the poor quality and overall scarcity of previous studies, CBT seems to be a promising approach for the treatment of skin picking disorder. Behavioral interventions have for example also demonstrated efficacy (Bloch et al., 2007; McGuire et al., 2014), and are currently considered as the method of choice in the treatment of trichotillomania (Flessner, Penzel, & Keuthen, 2010), which shows substantial overlap in clinical characteristics and a high co-occurrence with skin picking disorder (Snorrason, Belleau, & Woods, 2012)."

A waitlist control group seems justified, because there is no gold-standard treatment available for skin picking disorder yet.

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

"Within the present trial, the authors developed an Internet-based self-help program for skin picking, and conducted a randomized controlled pilot trial to investigate the adequacy of the intervention SaveMySkin, and the feasibility of the study procedures. Primary objectives of the present study were the investigation of attitudes and expectations towards SaveMySkin before randomization, as well as intervention effects on skin picking severity, user satisfaction. Further outcomes were program adherence (intervention utilization), and the willingness to participate.

The feasibility of study procedures (e.g., recruitment, randomization), the appropriateness of applied questionnaires, as well as effects on skin picking related impairment, dimensions of skin picking (focused vs. automatic skin picking), and general psychological impairment were investigated as secondary outcomes."

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 current pilot study followed a 2-arm randomized controlled design with a 1:1 allocation to either intervention or waiting list control group."

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

"No essential changes have been made to the study protocol after study commencement. The actual sample size exceeded the initial aim due to a very fast recruitment via Internet, so that the original plan to expand recruitment to dermatological clinics was not pursued."

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	0	0	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 3b-i?

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

Meine Antwort

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

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

"Inclusion required at least mild self-reported skin picking severity (Skin Picking Scale-Revised (SPS-R) score \geq 7 [31, 32]) and a minimum age of 17 years. Sufficient German language skills, home access to the Internet, a smartphone, as well as literacy on Internet and computer use were applied as implicit eligibility criteria."

4a-i) Computer / Internet literacy

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



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

Meine Antwort

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	0	0	0	\bigcirc	0	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

"Potential participants were recruited via online advertisement (e.g., specific forums, support groups, university mailing lists), and at a conference for skin picking and trichotillomania. In case of interest, individuals could directly access an openly available online screening questionnaire checking for eligibility. Eligible individuals were invited to register for the study and give the required informed consent for participation."

"All assessments (scheduled at t0 + t1: baseline; t2: after six weeks; t3: after 12 weeks) were performed as self-report online questionnaires."

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.



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

Meine Antwort

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

"Potential participants were recruited via online advertisement (e.g., specific forums, support groups, university mailing lists), and at a conference for skin picking and trichotillomania. In case of interest, individuals could directly access an openly available online screening questionnaire checking for eligibility. Eligible individuals were invited to register for the study and give the required informed consent for participation."

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

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



Does your paper address subitem 4b-i? *

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

"All assessments [...] were performed as self-report online questionnaires."

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	0	0	0	0	0	essential

Does your paper address subitem 4b-ii?

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

Meine Antwort

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	\bigcirc	0	0	0	0	essential

Does your paper address subitem 5-i?

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

The center for psychotherapy research is developer, owner, and sponsor.

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	0	0	0	0	0	essential

Does your paper address subitem 5-ii?

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

Meine Antwort

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	0	0	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 5-iii?

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

Meine Antwort

5-iv) Quality assurance methods

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



Does your paper address subitem 5-iv?

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

Meine Antwort

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	0	0	0	0	0	essential

Does your paper address subitem 5-v?

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

Meine Antwort

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, <u>webcitation.org</u>, 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	0	0	0	0	0	essential

Does your paper address subitem 5-vi?

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

Meine Antwort

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	0	0	0	0	0	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

"In case of interest, individuals could directly access an openly available online screening questionnaire checking for eligibility. Eligible individuals were invited to register for the study and give the required informed consent for participation."

Backdoor access cannot be provided at the moment as the software as currently adapted for the planned efficacy trial.

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

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



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

"Participants randomized to the intervention group received immediate access to the Internet-based intervention 'SaveMySkin' for 12 weeks. The program is based on CBT techniques and consists of several modules: (1) Psychoeducation: Information about skin picking disorder, treatment options and dermatological topics; (2) Self-management: A module with three sub-modules aiming at the reduction of skin picking behavior, and the enhancement of self-management skills ('Skills': information materials, and online exercises; 'Tools': downloadable offline trainings; 'Emotions': online exercises on emotion regulation); (3) Supportive monitoring: Daily support via E-Mail including a motivational message in the morning, and a short monitoring questionnaire in the evening, which is combined with an automatically generated, tailored feedback; (4) Counseling via Internet-chat: Optional personal support in individual chat sessions with psychologists, or psychological and dermatological group chats. Overall, the intervention follows a flexible and demand-oriented design. Participants were therefore expected to use the program depending on their individual needs. Recommendations on the use of certain program modules or exercises were given within chat sessions or in the monitoring feedback."

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	0	0	0	0	0	essential

Does your paper address subitem 5-ix?

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

Meine Antwort

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	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 5-x?

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

Meine Antwort

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	0	\bigcirc	0	0	0	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

In case that participants did not activate their account or did not respond to the study assessments at t2 and t3, the program automatically sent two reminder emails.

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	0	0	0	0	0	essential

Does your paper address subitem 5-xii? *

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

"The program is conceptualized as a stand-alone intervention in order to complement conventional health care for skin picking disorder."

"Study participation did not include any restrictions concerning additional treatment utilization."

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

"Attitudes and expectations

Attitudes and expectations towards SaveMySkin were investigated by 10 statements, which are rated on a 4-point Likert scale from 'does not apply' to 'totally applies' (see Table 3). In addition, participants could report further reasons for participation.

Skin picking severity

Skin picking severity was assessed with the German version of the Skin Picking Scale-Revised (SPS R) [31, 32]. The first four items of the scale refer to the subscale 'symptom severity' and assess the frequency and intensity of the urge to pick the skin, time spent on skin picking and control over skin picking behavior. The other four items form the subscale 'impairment' and assess impairing consequences caused by skin picking (avoidance, interference in social and occupational life, emotional distress, skin damage). All items are rated on a 5-point Likert scale from 0 to 4 in reference to the last seven days. In the present study, a very good internal consistency with a coefficient of α = .81 was observed for the total scale (symptom severity: α = .72; impairment: α = .83).

User satisfaction

User satisfaction was measured with self-designed items assessing overall satisfaction criteria (e.g., recommendation to others, fulfillment of expectations). Satisfaction with single modules was assessed with statements rated on a 4 point Likert scale from 'does not apply' to 'totally applies' (e.g., 'I like the idea that individual chat sessions with psychologists are offered'). Participants could also indicate 'not able to evaluate'.

Adherence and utilization

Adherence and program utilization were automatically documented within the program. Monitoring compliance was assessed by the number of completed monitoring questionnaires. Chat utilization was evaluated by the number of booked individual chat appointments and logins into group chats. The utilization of other modules and of the overall program was investigated by the number of page views per module and user, as well as logins per user.

Skin picking related impairment

Skin picking related impairment was assessed with a German translation of the Skin Picking Impact Scale (SPIS) [33, 34]. The ten items of the scale are rated on a 5-point Likert scale form 'not at all' (0) to 'severe' (4) and refer to the past seven days. The SPIS demonstrated an excellent internal consistency in the present

study ($\alpha = .94$).

Focused vs. automatic skin picking

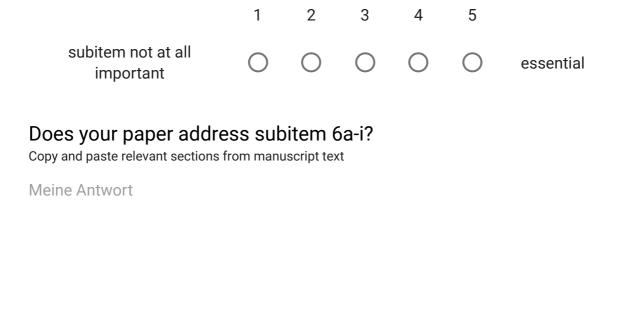
Modes of skin picking relating to the awareness of performing the behavior were assessed with a German translation of the Milwaukee Inventory for the Dimensions of Adult Skin Picking (MIDAS) [35]. Twelve items are rated on a 5-point Likert scale from 'not true for any of my skin picking' (1) to 'true for all of my skin picking' (5) and form the two subscales 'focused' and 'automatic' with six items each. The current study revealed acceptable internal consistencies for both subscales (focused: $\alpha = .73$; automatic: $\alpha = .69$)

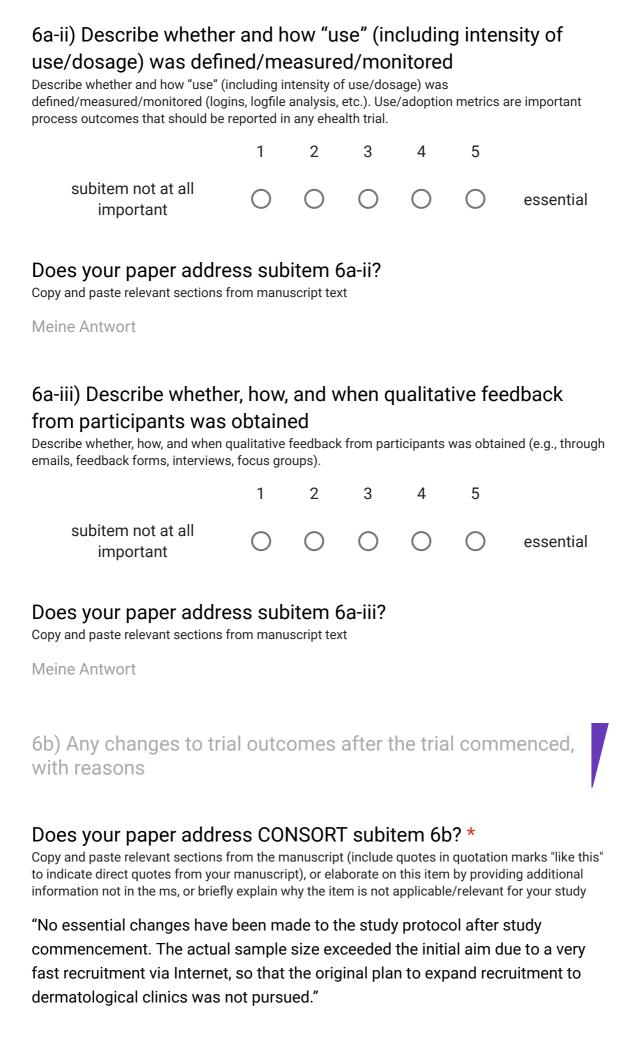
General psychological impairment

General psychological impairment was assessed with the Clinical Psychological Diagnosis System 38 (KPD-38) [36, 37]. The scale consists of 38 items assessing psychological impairment, social problems, general physical condition, general life satisfaction, competence skills, and social support. The items are rated on a 4-point Likert scale from 'does not apply' (1) to 'totally applies' (4). In the present sample, the internal consistency of the KPD 38 total score was excellent, with a Cronbach's alpha coefficient of α = .94."

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].





7a) How sample size was determined

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

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

	1	2	3	4	5	
subitem not at all important	\bigcirc	0	0	0	0	essential

Does your paper address subitem 7a-i?

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

Meine Antwort

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

Stopping criteria: In case of adverse effects for participants trial would have been stopped. No interim analyses were conducted.

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

"The allocation sequence was produced with a computerized random number generator."

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

Does your paper address CONSORT subitem 8b? *

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

"Participants were equally (1:1) randomized to one of the study groups by the software, based on an a priori defined list (intervention vs. waiting list control), after they completed the registration and the following baseline questionnaire. Randomization was stratified by gender and followed a permuted block design."

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

Does your paper address CONSORT subitem 9?*

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

"Participants were equally (1:1) randomized to one of the study groups by the software, based on an a priori defined list (intervention vs. waiting list control), after they completed the registration and the following baseline questionnaire. Randomization was stratified by gender and followed a permuted block design."

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

"Participants were equally (1:1) randomized to one of the study groups by the software, based on an a priori defined list (intervention vs. waiting list control), after they completed the registration and the following baseline questionnaire. Randomization was stratified by gender and followed a permuted block design. The allocation sequence was produced with a computerized random number generator."

The biostatistician of the study generated the random allocation sequence with a computerized random number generator.

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	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 11a-i?*

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

Blinding was not possible in the present study.

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

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 11a-ii?

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

Meine Antwort

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 relevant for the present study.

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

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

Does your paper address CONSORT subitem 12a? *

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

"Descriptive statistics were used to analyze data on attitudes, expectations, user satisfaction, and program utilization. Continuous variables were dichotomized by splitting the Likert scale (e.g., 'Agree' contains 'applies mostly' and 'totally applies'; 'Helpful' contains 'a little helpful' and 'very helpful') to analyze data with frequencies. Efficacy was tested by mixed models. Intervention effects were analyzed as cross-level interactions (group x time). Control group was coded 0, and intervention group was coded 1. Assessment points were coded as follows: baseline (t0, t1) = 0; t2 = 1; t3 = 2. In accordance with the recommendations of Lorah [39], another run of mixed models analyses was conducted with standardized outcome variables to calculate Cohen's d based on the estimated coefficient per time span (Cohen's d = standardized coefficients of the time x group interaction * max(time)). It has to be noted that one participant in each study group did not complete the entire post assessment. The analyses regarding user satisfaction and help-seeking at t3 therefore refer to N=38 (intervention group) and N=47 (control group)."

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	0	0	\bigcirc	0	\bigcirc	essential

Does your paper address subitem 12a-i?*

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

Data analyses followed intention-to-treat principles. All randomized subjects were analyzed. Mixed-models can handle missing data.

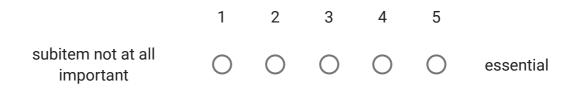
12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses Does your paper address CONSORT subitem 12b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study No additional analyses were conducted in the present study. X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item) X26-i) Comment on ethics committee approval 2 3 4 1 5 subitem not at all \bigcirc essential important 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 present trial was approved by the ethical committee of the Medical Faculty of Heidelberg University."

x26-ii) Outline informed consent procedures

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



Does your paper address subitem X26-ii?

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

Meine Antwort

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	0	0	0	0	0	essential

Does your paper address subitem X26-iii?

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

Meine Antwort



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

" A detailed overview of the participant flow including the number of analyzed cases for each objective is provided in the CONSORT Flow diagram in Figure 1."

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

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

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

"Six participants of the intervention group neither logged into the program after the initial registration process, nor completed any of the daily monitoring assessments, so that they did not receive the allocated intervention. The response rate for the assessment at t2 (six weeks after randomization) was 59 % in the intervention group and 70 % in the control group. The final assessment (t3: twelve weeks after randomization) was completed by 61 % of the intervention group and 70 % of the control group.

A detailed overview of the participant flow including the number of analyzed cases for each objective is provided in Figure 1."

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	\bigcirc	0	\bigcirc	0	0	essential

Does your paper address subitem 13b-i?

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

Meine Antwort

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

"Participant enrolment started in October 2018. The planned sample size of 100 participants was already achieved after 18 days of recruitment. Advertisement was stopped then, but due to ethical considerations, screening and registration were not closed before December 2018."

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	0	0	0	0	0	essential

Does your paper address subitem 14a-i?

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

Meine Antwort

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

This item is not applicable. The trial was stopped, because the planned sample size was achieved.

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

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

Does your paper address CONSORT subitem 15? *

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

"Table 1 and 2 show the demographic and clinical characteristics for each study group."

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	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0	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 1 and 2 show the demographic and clinical characteristics for each study group."

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 predefined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.



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

"On average, participants filled in 25.81 daily monitoring assessments (SD=26.96; range=0-81). Three quarters of the sample (N=48) completed more than 3 monitorings, 50% (N=32) answered more than 9, and 25% (N=16) filled out more than 45 monitoring questionnaires. In sum, 47% (N=30) participated in the monitoring at least once a week (42% twice a week).

Five individual chat sessions were booked and carried out (6%; N=4 participants;). The psychological group chat was used by three participants (5%) and the dermatological group chat by six individuals (9%), who participated up to three times in one of the chat types. Participants were asked why they had not used the chat. The most common answers were 'I don't really know, why I didn't use the chat' (53% N=20), 'I had no need, because I could seek advice somewhere else (e.g., psychotherapy)' (34%; N=13) and 'I had no need, because I felt good.' (32%; N=12).

On average participants logged in M=6.42 times (SD=10.15; Md=3; range=1-67). The average number of page views per user across all modules was M=29.31 (SD=42.04) ('Information': M=8.17; SD=11.92; 'Skills': M=11.52, SD=20.84; 'Tools': M=5.59, SD=8.09, 'Emotions': M=4.03, SD=6.16). Answering the daily monitoring questionnaire was not counted as a login. "

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	\bigcirc	0	\bigcirc	\bigcirc	0	essential

Does your paper address subitem 16-ii?

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

Meine Antwort

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

Table 4 contains 95% CI for the model coefficients.

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).



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

Meine Antwort

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

This item is not applicable. The results do not contain binary outcomes.

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

This item is not applicable for the present study. No additional analyses have been conducted.

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	0	0	0	0	0	essential

Does your paper address subitem 18-i?

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

Meine Antwort

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

No harms or unintended effects were observed.

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].



Does your paper address subitem 19-i?

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

Meine Antwort

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.



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

Meine Antwort

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	0	0	0	0	0	essential

н

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

"Skin picking disorder is associated with psychological distress, impairment in social life, as well as medical risks, but currently, individuals with skin picking rarely receive the required professional support due to an insufficient healthcare supply. Therefore, the present study investigated attitudes and expectations towards an Internet-based self-help program for skin picking, as well as user-satisfaction, and effects on skin picking severity and impairment.

Full recruitment of the initially targeted sample size for the present pilot trial was rapidly archieved, indicating a high willingness to participate in an Internet-based intervention for skin picking. Randomization resulted in two comparable study groups, which only differed marginally in the SPS R subscale symptom severity. Participants reported positive expectations regarding skin picking symptoms and wellbeing. Flexibility in terms of time and location, expertise related to skin picking, and a lack of other healthcare options were further reasons for participating.

At post assessment, the majority of the intervention group reported a high satisfaction with the modules included in SaveMySkin, and the program in general (e.g., appropriateness, length, recommendation to others). About half of the sample participated in the monitoring at least once a week, and a quarter used the monitoring more than four times a week. The monitoring frequency highly varied between users, the adherence in this module was overall satisfying. The intervention group yielded substantial reductions in skin picking severity (SPS-R total score), and specifically in symptom severity (SPS-R subscale) compared to the control group. The size of these effects (d = 0.67; 0.79) is comparable to the overall effect of behavioral treatments reported in a meta-analysis (SMD = 0.68) [20].

The analyses did not confirm meaningful differences between groups regarding improvements in skin picking related impairment measured via the SPS R and the SPIS. Given the rather short time period covered in the present trial, this result is not surprising, since skin picking related impairment (e.g., impaired self-esteem, avoidance, skin damage) may only improve slowly, even if skin picking frequency and intensity are improved. Furthermore, some medical consequences, especially scars, often need to be considered as permanent. The short study period may also be responsible for the lack of effects on general psychological impairment, and different dimensions of skin picking (focused vs. automatic) in the present study. Dimensions of skin picking were assessed with regard to habitual, but not necessarily current patterns (e.g., 'I am usually not aware of picking my skin during the picking episode.') so that potential changes might not be reflected properly. Also, sensitivity to change has yet to be explored for this assessment instrument (MIDAS). Apart from the MIDAS, the applied instruments turned out to

be appropriate for interventional studies. As the primary outcome measure, the SPS R furthermore proved to be sensitive to change. This is of special importance for subsequent studies, given the lack of interventional studies on skin picking disorder and the associated uncertainty about the adequate measurement of intervention effects.

Concerning utilization of the self-help program, it turned out that the chat module was utilized only rarely, even though most participants (more than 76 %) liked the idea that different chat modules were included in the program. However, the low chat utilization is not concerning, but in accordance with previous research suggesting that a considerable number of users in online communities does not actively produce content, but rather read and browse through the platform [40]. More than half of the participants in the present study indicated that they were not sure, why they had not used the chat. A reluctance to commit to chat participation at a certain date and time might be also a reason for the rather infrequent utilization of this module."

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	0	0	0	0	0	essential

Does your paper address subitem 22-ii?

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

Meine Antwort

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.



Does your paper address subitem 20-i? *

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

"The present study included several limitations, which should be considered in the interpretation of results. First, all assessments were conducted online and inclusion relied exclusively on self-reported data so that the internal validity and generalizability to a larger clinical population might be compromised. Another shortcoming results from the rather low response rate at post assessment. The lack of data from approximately one third of the sample limits the validity of the present findings, since it remains unclear, how satisfied the non-responders were and how they changed in symptomatology. Additionally, the present study did not investigate the stability of effects, as it focused on the classical aims of a pilot study and therefore did not include extended follow-up assessments. However, the results of this study clearly demonstrated the feasibility of an Internet-based intervention in the target group. Furthermore, the study provided preliminary evidence for the efficacy of the intervention. Subsequent research should thus investigate the efficacy and cost-effectiveness of SaveMySkin in a fully powered RCT. This trial should apply a sequential enrolment procedure including a clinician-rated assessment of psychiatric conditions as well as a dermatological assessment, and documentation of the skin status. Moreover, the study period should be expanded to assess the stability of intervention effects, and to explore potential long-term effects on impairment."

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	0	0	0	0	0	essential

Does your paper address subitem 21-i?

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

Meine Antwort

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	0	0	0	0	0	essential

Does your paper address subitem 21-ii?

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

Meine Antwort



23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

"The present trial was registered at the German Register for Clinical Trials (DRKS; DRKS00015236), and approved by the ethical committee of the Medical Faculty of Heidelberg University."

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

Does your paper address CONSORT subitem 24? *

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

"The study protocol was published before recruitment was completed (Gallinat et al., 2019)."

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

The present study did not receive funding.

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.



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

Meine Antwort

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?

Meine Antwort

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

5 hours

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



🔵 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



) Sonstiges:

Any other comments or questions on CONSORT EHEALTH

Meine Antwort

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