



SaveMySkin: An Internet-based self-help intervention for skin picking. Study protocol for a randomized pilot study



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ABSTRACT

Background: Skin picking disorder is an under-recognized and understudied mental disorder associated with severe psychological and medical consequences. Affected individuals barely receive adequate treatment, given the scarcity of expertise in healthcare professionals and the lack of evidence-based interventions.

The present study seeks to evaluate an Internet-based self-help intervention for skin picking (“SaveMySkin”) within a pilot study. The intervention is based on cognitive-behavioral therapy (CBT) and provides comprehensive information materials and exercises. A daily supportive monitoring and psychological as well as dermatological counseling via Internet-chat provide additional support. The research questions focus on user attitudes, expectations and reservations, acceptance, adherences and user satisfaction as well as the feasibility of study procedures. Intervention effects will be estimated in order to plan a subsequent efficacy trial.

Methods: The pilot study will be conducted within a 2-arm randomized controlled trial design. A sample of $N = 100$ participants will be recruited via Internet. Interested individuals will answer a short screening questionnaire and may register for the study, if they meet the inclusion criteria (age ≥ 17 , at least mild severity of skin picking). Following a baseline assessment, the intervention group may use SaveMySkin. The control group will have access to the intervention after completion of a waiting time of three months.

Discussion: The present trial will provide information on the feasibility and acceptability of an Internet-based intervention for individuals with skin picking. Furthermore, the results will be used to design a randomized controlled trial investigating the efficacy of the intervention.

Research registration number: German Register for Clinical Trials (DRKS): DRKS00015236;

1. Background

In 2013, skin picking disorder was for the first time included in the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [1]. The term skin picking includes repetitive behaviors of manipulating the skin, e.g., scratching, squeezing, which lead to tissue damage. Skin picking is accompanied by psychosocial impairment and the risk of serious medical consequences [2–4]. The disorder is more commonly reported in females [4–6] and lifetime prevalence rates are estimated at 1.2–1.4% [7,8].

Only few studies investigated specific treatments for skin picking disorder (for an overview see [9,10]). Previous studies mainly focused on pharmacological treatment options (overview in reference [11]),

habit reversal training [12], interventions based on cognitive behavior therapy (CBT) [13,14], and acceptance and commitment therapy [15]. However, the validity of these studies is often limited by small sample sizes and the lack of generally accepted diagnostic criteria.

Skin picking is still rarely known by healthcare professionals and specialized treatment options are very scarce. Affected individuals are often not aware that skin picking is a mental disorder. Additionally, they mostly face a lack of understanding and the widespread misconception of skin picking as a bad habit. This is especially a problem in dermatologists, who are a common first contact point for individuals affected by the disorder. Accordingly, finding professional help is often challenging and unsuccessful.

Easily accessible, low-threshold support services are therefore of

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special importance. An Internet-based self-help program can make an important contribution to improve the healthcare situation for individuals suffering from skin picking. Interventions based on Information and Communication Technology (ICT) have been shown to be effective and cost-effective for a variety of mental disorders [16–19]. They have the advantage of independence of time and location, which enables them to reach many people with comparatively little effort. Creating such an easily accessible first contact point for individuals with skin picking is of special importance, given the insufficient healthcare situation and the lack of awareness of this disorder.

By now, only two studies investigated specific self-help interventions for skin picking: The first one is a non-randomized study ($N = 372$, no control group) investigating an Internet- and CBT-based self-help treatment based on CBT. Significant reductions in symptom severity (at least 25%) were reported for 63% of the sample [13]. The second one is a pilot study ($N = 70$) testing the feasibility and efficacy of two bibliotherapy-based interventions (habit reversal training versus decoupling). For habit reversal, significant symptom reductions were reported for 50% of the sample [20].

The present trial seeks to evaluate the Internet-based self-help program SaveMySkin, focusing on classical aims of a pilot study, i.e. the investigation of individuals' willingness to register to the program as well as participants' attitudes, expectations and potential reservations towards the intervention, acceptance, adherence, user behavior, and user satisfaction. Additionally, the feasibility of study procedures, including assessment instruments and recruitment will be examined. Intervention effects on symptoms and impairment will be estimated. The results will be used for the optimization of the intervention and the preparation of a subsequent efficacy trial.

2. Methods

2.1. Study design

The study will be conducted within a 2-arm randomized controlled trial. We follow the definition of the National Institute for Health Research UK [21]. According to this reference, a pilot study is a miniature study focusing on study procedures and the feasibility of recruitment, randomization, treatment and the appropriateness of assessment instruments.

One hundred eligible individuals will be randomized to either the SaveMySkin intervention or a waiting list control group. Assessments will be conducted online via self-report at three assessment points, i.e. at baseline (t1), after six weeks (t2) and after 12 weeks (t3).

Study procedures and design have been approved by the ethical committee of the Medical Faculty of Heidelberg University.

2.2. Participants

2.2.1. Eligibility criteria

Participants must be affected by at least mild skin picking severity, i.e. defined as a score of at least 7 on the Skin Picking Scale-Revised (SPS-R). Participants need to be at least 17 years old. This restriction is made due to aggravated dermatological conditions in puberty and stricter ethical requirements regarding informed consent in younger study populations.

Furthermore, sufficient German language skills, a smartphone and home access to the Internet are required.

2.2.2. Sample size

Due to the nature of the present pilot study, one hundred participants will be recruited. We follow the recommendations of Leon, Davis and Kraemer regarding sample size determination in pilot studies [22]. Accordingly, sample size in the present study is not determined by power calculations, but based on practical considerations of financial and time-based feasibility. Yet, the sample size of 100 participants will

allow to answer the research questions with sufficient certainty.

2.2.3. Recruitment

Participants will be recruited via support groups, social media networks and dermatological clinics. Interested individuals can directly access the study portal and answer a short online screening questionnaire. Those, who meet the inclusion criteria will be invited to register for participation in the study. They will be informed about aims and procedures of the intervention, data collection, data privacy, and the voluntariness of participation. Informed consent is required to complete the registration.

2.2.4. Randomization

After completing the screening questionnaire followed by registration and baseline assessment, participants will be randomized to one of the two study groups. Randomization will be stratified by gender and follows a permuted block design.

2.3. Study arms

Participants will be randomized to either the intervention or the waiting list control group.

All participants can utilize additional treatment as usual without reservations throughout the course of the study. SaveMySkin is only a supplementary service. Usual treatment providers keep their function as primary contacts in all medical and therapeutic concerns. The utilization of other accompanying treatments will be assessed as a part of the final questionnaire.

2.3.1. Intervention

After randomization, the intervention group will have immediate access to all modules of the SaveMySkin intervention for the duration of three months. To ensure an adaptive and demand-oriented support, participants are encouraged to use the intervention depending on their own needs and preferences. They are only expected to answer the daily monitoring on a regular basis (max. 5 min a day).

Support within the SaveMySkin program will be provided by psychologists as well as dermatologists. This interdisciplinary collaboration enables SaveMySkin to provide comprehensive support by bridging the gap between the dermatological and psychological perspective on skin picking, which is an important barrier to treatment in regular healthcare, since dermatologists often mistake skin picking for a bad habit.

The intervention is accessible via smartphone, tablet, PC and can be used for a duration of three months supplementary to primary healthcare. The program is based on methods of CBT and contains the following modules:

2.3.1.1. Information. Comprehensive information materials about skin picking in general, etiology and treatment options are provided. A second information section focuses on dermatological topics, e.g. infections and hygiene, consequences of skin picking, and skin care.

2.3.1.2. Self-management. Participants will have access to a variety of information, materials, and exercises that aim at strengthening their self-management skills. This module contains downloadable materials for offline trainings (e.g., self-observation protocols), and online exercises that can be accessed on the platform (e.g., therapeutic writing). An additional module focuses on emotional regulation, since skin picking is often used as a maladaptive strategy for emotional regulation.

The focus of this module is on techniques for stimulus control, stress resilience, motivation and an elaborated understanding of the individual skin picking behavior.

2.3.1.3. Supportive monitoring. Participants receive two e-mails from SaveMySkin every day. In the morning, they receive a motivating

message expressing understanding and social support. The second e-mail is sent in the evening and contains a link to a short questionnaire assessing the severity of skin picking behavior, related circumstances, strategy use, and emotional states on that particular day.

Monitoring results are classified in 4 categories for functional behavior (“none” and “almost no skin picking”) and 12 categories for nonfunctional behavior (“moderate” to “extreme” skin picking). The subcategories are defined by different combinations of the variables “related circumstances” and “strategy use”, and the results of the previous monitoring assessment. Immediately after completion of the questionnaire, an automatically generated feedback message is displayed according to the applicable category. Feedback messages aim at reinforcing positive development, providing practical advice and suggesting the use of certain program modules (e.g., chat counseling for individuals with severe symptoms).

2.3.1.4. Counseling via internet-chat. Participants can book individual counseling sessions with a psychologist in an Internet chat. The chat sessions do not aim at providing psychological treatment, but offering support, clarifying individual questions, and supporting participants to find and utilize face-to-face treatment in case they experience severe impairment. In addition, group chats moderated by a psychologist or a dermatologist are offered. All participants can join these chat sessions without prior booking. As a supplement to the psychosocial support that the other modules provide, participants can ask general questions and share their experiences in the psychological group chat. Questions related to dermatological topics can be posed in the dermatological group chat. Although skin picking is a psychological disorder, sufferers deal with a variety of skin-related medical issues that require adequate care.

2.3.2. Control condition

Participants randomized to control group do not have access to the SaveMySkin intervention in the first three months after randomization (waiting list). After the final assessment, they can use the program for three months.

2.4. Study procedures: assessment instruments and outcomes

All assessments will be conducted online via self-report measures. [Table 1](#) provides a detailed overview of the assessments.

2.4.1. Primary outcomes

The primary outcomes of the pilot study will be attitudes and expectations towards the program SaveMySkin at baseline, user satisfaction, adherence – defined as the extent to which the intervention group uses the program –, dropout-rate and the willingness to participate.

Expectations and attitudes towards with the intervention

SaveMySkin will be assessed within a self-designed questionnaire administered before randomization. Another questionnaire will inquire user satisfaction with SaveMySkin after participation ended. Intervention utilization and compliance will be automatically documented within the program. These access logs provide information on aspects such as time and number of logins, viewed pages, download of training materials, and booked chat appointments.

For an estimation of intervention effects, skin picking severity will be assessed with the German version of the Skin Picking Scale-Revised (SPS-R) [23]. The SPS-R consists of eight items assessing the two subscales, ‘symptom severity’ (frequency and intensity of the urge to pick, time spent on skin picking, control over the behavior) and ‘impairment’ (avoidance, interference and emotional distress due to skin picking, damage to skin caused by skin picking) in reference to the last week. The German translation of the SPS-R will be used in the present study [24].

2.4.2. Secondary outcomes

The secondary outcomes will be the eligibility of applied questionnaires, evaluated by the scales’ internal consistency coefficients and their distribution parameters to explore possible basement and ceiling effects. In preparation of a larger efficacy trial, the feasibility of organizational processes including recruitment and randomization will be evaluated (e.g., number of screened individuals per month, number of registered individuals per month, proportion of registered individuals that get randomized, retention and dropout rates). Furthermore, intervention effects on general psychological impairment, skin picking related psychosocial impairment, dimensions of skin picking (focused vs. automatic), and emotion regulation strategies will be investigated.

General mental impairment will be assessed with the *Clinical Psychological Diagnosis System 38* (KPD-38) [25,26]. The KPD-38 is a commonly used 38-item questionnaire assessing psychological impairment, general physical condition, social problems, general life satisfaction, competence skills and social support.

Skin picking related psychosocial impairment will be assessed with the *Skin Picking Impact Scale* (SPIS, 10 items, Likert scale) [27,28].

Dimensions of skin picking relating to the awareness of performing the behavior (focused vs. automatic) will be analyzed with the *Milwaukee Inventory for the Dimensions of Adult Skin Picking* (MIDAS) [29]. The MIDAS consists of 12 items which assess automatic and focused skin picking with six items each. In the present study, the German version of the MIDAS will be used. Following generally accepted recommendations [30], the first author of the present study translated the MIDAS into German. Backtranslation was approved by one of the authors of the English version (D. W. Woods).

Phenomenological aspects of skin picking (e.g., number of affected body areas, frequency and duration of single skin picking episodes, current skin status, lifetime duration of skin picking, associated

Table 1
Assessment plan.

Assessment instruments/variables	t0 Screening	t1 baseline	t2 6 weeks	t3 12 weeks
<ul style="list-style-type: none"> ● Sociodemographics ● Dermatological conditions ● Help-seeking behavior and health care utilization ● Health care utilization in the participation period 	X	X		X
Primary Outcomes <ul style="list-style-type: none"> ● Attitudes and expectations towards SaveMySkin ● User satisfaction with SaveMySkin ● SPS-R: Skin picking severity 	X	X	X	X
Secondary Outcomes <ul style="list-style-type: none"> ● KPD-38: General mental impairment ● SPIS: Psychosocial impact of skin picking ● MIDAS: Focused vs. automatic skin picking) ● HFERST: Emotion regulation strategies 		X	X	X

emotions and skin picking related emotional regulation (reactions to skin picking episodes)) will be assessed by single items.

Emotion regulation strategies will be assessed by the *Heidelberg Form for Emotion Regulation Strategies* (HFERST) [31]. The HFERST consists of 28 items assessing eight emotion regulation strategies: rumination, reappraisal, acceptance, problem solving, suppression of emotional expression, suppression of emotional experience, avoidance and social support.

2.5. Data analyses

Data analyses will focus on descriptive analyses exploring the willingness to participate, attitudes, expectations, and program utilization within the target group. Frequencies and 95% confidence intervals will be calculated. The appropriateness of the applied assessment instruments will be tested (SPS-R, SPIS, MIDAS) to gain information about their eligibility for interventional studies. Distribution parameters (e.g., potential floor- or ceiling effects, deviations from normal distribution) and sensitivity for change will be explored. Inferential statistical analyses will be conducted to support sample size calculation for a subsequent efficacy study. For that purpose, changes in symptomatology in control and intervention group will be compared at three assessment points using mixed models (intervention effect is tested as a cross-level interaction of the dummy coded group variable*time). In addition, effect sizes (Cohens *d*) and 95% confidence intervals will be calculated.

3. Discussion

Previous studies show that skin picking disorder is a common mental condition often accompanied by severe psychosocial and medical consequences [2,3,7,8]. Despite the high burden of illness, there is a devastating gap between the need for treatment and the availability of specialized interventions and well-informed healthcare professionals. This situation necessitates easily accessible interventions with a large reach and the potential to function as a first contact point for affected individuals. Against this background, SaveMySkin was developed as an Internet-based intervention, which is designed to provide low-threshold support for sufferers. The program is expected to strengthen self-management skills (e.g., stimulus control, emotion regulation), reduce symptoms and encourage healthcare utilization in case of severe impairment.

Comprehensive information materials and exercises combined with a supportive monitoring and chat counseling enable SaveMySkin to provide adaptive and demand-oriented support for different levels of symptom severity. The combination of automated modules (e.g., monitoring, psychoeducation) and personalized modules (i.e., optional counseling via chat) allows to match the intensity of support to the individual needs and level of impairment of participants. This flexible approach also allows to address large samples at reasonable cost and effort because only a subgroup of participants will engage in the more intense (and thus more expensive) personalized modules.

In a first step, the present pilot study examines the acceptability and feasibility of the program. This is of special importance, given the paucity of validated assessment instruments and the lack of studies about the appropriateness of Internet-based interventions in skin picking disorder. The present study will provide insights on the willingness to participate in such programs, acceptance, adherence, expectations and attitudes. Another strength of the study is the estimation of intervention effects based on a randomized-controlled design. The results of the pilot study will enable us to adapt SaveMySkin even closer to the needs of sufferers and to plan an adequately powered efficacy study.

Potential limitations result from the way of recruitment and assessment exclusively via Internet. The screening questionnaire is openly accessible and the invitation to register is based on self-reported skin

picking severity, which might challenge the internal validity of the study, but allows sufferers to seek help anonymously. Anonymity plays an important role in skin picking related interventions, but it may also lead to lower compliance and increased study or intervention dropout rates. The online administration of registration and assessments may however maximize the accessibility of study participation.

Despite these limitations, the present trial will provide novel basic information about the eligibility of Internet-based interventions in skin picking. This promising approach is of special importance due to the current lack of treatment options in primary care: Offering far-reaching and easily accessible support appears to be the best way to improve the healthcare situation for affected individuals in the short-term. Therefore, SaveMySkin will be successively evaluated with the aim to establish a freely accessible self-help program functioning as a first contact point for sufferers.

Trial status

The present pilot study was registered at the German Register for Clinical Trials (DRKS; DRKS00015236). First participants will be enrolled in Oktober 2018.

Conflicts of interest

The authors declare that they have no competing interests.

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