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SOSkin: a randomized clinical trial of on-line cognitive-behavioral therapy for Skin Picking Disorder

Alice Castro Menezes Xavier^{1*}, Clarissa Prati¹, Anita Castro Menezes Xavier¹, Murilo G. Brandão², Alice Barbieri Ebert³, Malu Joyce de A. Macedo¹, Maria João Baptista Fernandes⁴, Gisele Gus Manfro^{1,5}, Carolina Blaya Dreher^{1,5,6}

¹Programa de Pós-Graduação em Psiquiatria e Ciências do Comportamento, Universidade Federal do Rio Grande do Sul (UFRGS), Porto Alegre, RS, Brasil.

²Faculdade de Medicina, UFRGS, Porto Alegre, RS, Brasil.

³Faculdade de Medicina, Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA), Porto Alegre, RS, Brasil.

⁴Programa de Pós-Graduação em Ciências da Saúde, UFCSPA, Porto Alegre, RS, Brasil. ⁵Hospital de Clínicas de Porto Alegre (HCPA), Departamento de Psiquiatria e Medicina Legal, Faculdade de Medicina, UFRGS, Porto Alegre, RS, Brasil.

⁶Departamento de Clínica Médica, Psiquiatria, Faculdade de Medicina, UFCSPA, Porto Alegre, RS, Brasil.

*Corresponding author:

Alice Castro Menezes Xavier
Rua Ramiro Barcelos, 2.400
Porto Alegre, RS, Brasil.

Email: alicexavier@gmail.com

Abstract:

Background: Cognitive Behavioral Therapy (CBT) is an effective treatment for Skin Picking Disorder (SPD). However, since individuals have limited access to CBT, telepsychotherapy can overcome this barrier.

Objective: Evaluate the efficacy of a self-guided digital CBT intervention for SPD.

Methods: This controlled clinical trial randomized 163 patients with SPD to receive 4 weeks of online CBT (SOSkin) or a control intervention (videos about quality of life).

Primary outcome was the improvement in the Skin Picking Scale-Revised (SPS-R) and secondary outcomes were the improvement in Dermatology Life Quality Index Scale (DLQI), Generalized Anxiety Disorder Assessment Scale (GAD-7), and Patient Health Questionnaire-9 Scale (PHQ-9). Instruments were applied at baseline, middle and end of intervention and at 1 and 3 months of follow up. SOSkin usability was evaluated using the System Usability Scale (SUS). Data were analyzed using the Generalized Estimating Equations model (GEE).

Conclusion: There was no difference between groups in completion rates. SOSkin has excellent usability. Both groups improved the SPS-R and the DLQI scores after treatment and at the follow-up assessments. We found a significant time*group interaction in favor of CBT on SPS-R. Effect size of the intervention compared to control over SPS-R was small after treatment and at the follow-ups; over the DLQI was moderate after treatment and small at the follow-ups. CBT was superior to control on SPS-R when we compared the percentage of change from baseline. CBT was superior to control condition over DLQI at the end of treatment and at 1 month follow-up.

Clinical Trials Registration: NCT04731389.

Keywords: cognitive-behavioral therapy; skin picking disorder; internet-delivered treatment; online CBT; excoriation disorder.

Introduction

Skin picking disorder (SPD) diagnosis and treatment response are disappointing: among patients who seek treatment for SPD, approximately 50% receive the diagnosis and only 16.1% report improvement with treatment (1). Skin picking disorder (SPD) lifetime prevalence is around 3.1% of the population, it has a chronic course and causes severe occupational and social damage to about 75% of patients (1,2). The diagnostic criteria are recurrent skin picking resulting in skin lesions, repeated failed attempts to decrease/stop skin picking and significant distress/impairment caused by the habit, which is not attributable to the physiological effects of a substance or another

medical condition (2). SPD is highly comorbid with other psychiatric disorders, especially anxiety and depression (3,4). Regarding treatment options, studies evaluating the efficacy of pharmacological treatments resulted in conflicting findings: according to a recent meta-analysis, two small clinical trials found Fluoxetine to be effective and one clinical trial found N-Acetylcysteine to be effective (5). Systematic reviews and meta-analyses emphasize the cognitive-behavioral therapy (CBT), especially those involving habit reversal techniques, as an effective treatment option (6–10). Despite the effectiveness of CBT intervention, the low knowledge of health professionals about excoriation disorder and the limited access to specialized care - due to geographic barriers and low availability of specialized therapists - are considered barriers that contribute to the low rates of diagnosis and effective treatment of SPD (7,11,12).

The use of telemedicine in mental health care is well-received by patients, who report expanded access to treatment and reduced time and money costs (13). Telepsychotherapy is well accepted among mental health professionals, with studies showing the maintenance of diagnostic accuracy, therapeutic alliance, treatment effectiveness, and patient satisfaction (14,15). The effectiveness of internet CBT interventions is well established, with the literature finding significant improvement in patients with depression, anxiety, and OCD disorders, even when they do not have the support of a therapist (16–18). Additionally, digital interventions can overcome geographical barriers and the shortage of specialized professionals, increasing the availability of treatment (19).

Three randomized controlled trials tested digital CBT interventions for SPD in comparison to waiting list: two reported small to moderate effect sizes of intervention compared to the inactive control condition (20,21) and one that tested a therapist

guided intervention found a large effect size of intervention compared to the inactive control condition (22). Only one study used an active control comparator and found a moderate effect size of intervention over the active control condition in a sample of patients who self-reported excoriation disorder (21).

In this context, this randomized controlled clinical trial aims to test the effectiveness of a self-administered online CBT intervention for treating SPD patients compared to an active control condition. This intervention is denominated SOSkin and includes: habit reversal techniques, emotional regulation strategies and cognitive restructuring techniques. This study hypothesized that the intervention would improve the severity and impact of SPD, the quality of life of patients, as well as the depressive and anxiety comorbid symptoms, more than the active control condition.

Material and Methods

Sampling and design

This controlled randomized clinical trial included 163 individuals with a diagnosis of SPD. The sample was recruited by media advertising on Brazilian Facebook® and Instagram® profiles related to SPD in 2021. Inclusion criteria were SPD diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM 5), 18 years or older, proficiency in Brazilian Portuguese, and access to the internet. Exclusion criteria were acute mania, current psychotic episode, severe major depressive episode or suicide risk, substance abuse disorders (except tobacco) and being in cognitive behavioral therapy during the study. Participants could be taking psychotropic drugs as long as the medication was not adjusted during this trial. We referred subjects meeting the exclusion criteria to community medical support. Eligible patients were randomly allocated to receive the treatment intervention with cognitive-behavioral therapy (CBT) delivered by a remote platform (SOSkin) or an active control

intervention consisting of remote videos with psychoeducation about healthy habits during 4 weeks.

Procedure and instruments

All individuals who expressed interest in the study were initially evaluated by one of the two trained dermatologists to identify possible dermatoses in a videoconference appointment. The assessment included current and previous dermatological symptoms and treatments and a summary analysis of the lesions observed on the patient. Then, one of the four trained psychiatrists evaluated the individual via videoconference to conduct a psychiatric interview based on DSM-5 criteria to confirm the SPD diagnosis, followed by the Mini International Neuropsychiatric Interview (MINI) (23) to identify any psychiatric comorbidities. Those psychiatrists were part of the University research group and upskilled in the diagnosis of SPD according to DSM criteria and in the application of the MINI questionnaire.

Patients who met the inclusion criteria completed the baseline assessment procedure on the RedCap® digital platform (<https://www.redcapbrasil.com.br/>), which consisted of a questionnaire to collect sociodemographic characteristics and self-reported scales to assess baseline symptoms. Participants responded the Skin Picking Scale-Revised (SPS-R) (4), the Dermatology Life Quality Index Scale (DLQI) (24), the Generalized Anxiety Disorder Assessment Scale (GAD-7) (25), and the Patient Health Questionnaire-9 Scale (PHQ-9) (26). After completing the data, randomization was performed in a 1:1 ratio automatically through the RedCap® platform, using the simple randomization method due to the large sample size. Allocation was concealed, ensuring that the researchers were blinded to the group to which each participant was assigned. The primary outcome was the change in the

SPS-R scale and the effect size of CBT compared to control condition over the SPS-R. The secondary outcomes were the change in the DLQI, GAD-7, and PHQ-9 scales, the effect size of CBT over the control condition on DLQI, GAD-7 and PHQ-9. The researchers were masked to the group to which the patient was randomized. All scales were self-administered. The statistical analyses were conducted by a statistician who was blinded about the intervention received by each participant. The SPS-R is a self-administered instrument validated to the Brazilian population that assesses the severity and impact of SPD through 8 items. The total score ranges from 0 to 32 and higher scores means more severe disease and/or more significant impact. It has two factors: items 1-4 related to severity, and items 5-8 related to the impact of SPD in the individual's life (4). The DLQI is a self-report questionnaire validated to the Brazilian population that assesses the impact of dermatoses on the quality of life. It consists of 10 questions about symptoms and sensations in the last week in different domains such as daily activities, work, and personal relationships. The total score ranges from 0 to 30 and higher scores mean lower quality of life (24). The GAD-7 is a self-administered questionnaire validated for the Brazilian population with seven items that inquire about the intensity of anxiety experienced by the patient (25). The PHQ-9 is a self-report questionnaire validated to Brazilian Portuguese that consists of nine questions to assess the presence of each of the symptoms of a major depression episode described in the DSM-5 (26). The instruments SPS-R, GAD-7 and PHQ-9 were self-answered at five moments: baseline, in the middle of intervention (after week 2), post-intervention, and after one and three months of follow-up. The instrument DLQI was applied at the same moments except in the middle of the intervention.

The treatment intervention developed and tested in this study is the SOSkin platform (can be accessed at www.soskin.com.br), which consists of a website with

information about psychodermatosis, like trichotillomania and SPD, using short texts, videos and illustrations. The platform has a restricted area where individuals can log in using a username and password and access the self-applied CBT techniques for SPD (consult the supplementary material with the password for access). This CBT intervention consists of four self-applied 30 minute modules in an online format. The intervention includes all the techniques used in the Rothbaum protocol adapted for the treatment of excoriation disorder, such as: psychoeducation, habit self-monitoring, habit reversal techniques, muscle relaxation, diaphragmatic breathing, cognitive restructuring techniques, and relapse prevention (11). The platform emailed weekly notices to patients to remind them to do the week module and its homework. The control group received 4 videos with guidance on quality of life, 2 minutes long each, that were emailed weekly to the participants. The videos used were developed for the “TelePSI project”, a randomized clinical trial involving one thousand Brazilians that assessed the effectiveness of telepsychotherapies for symptoms of depression, anxiety, and irritability, and found symptomatic improvement in participants who received those videos (27). The complete content of each intervention module and active control videos are described in Table 1.

Table 1: Description of the content of each module of the CBT intervention group and videos of the active control group.

CBT=cognitive-behavioral therapy. SPD=skin picking disorder.

CBT modules	videos
1. Psychoeducation about SPD, symptom self-monitoring and habit reversal techniques;	1. Guidelines on sleep hygiene;
2. Techniques to cope with anxiety (diaphragmatic breathing and muscular relaxation);	2. Guidelines on healthy eating;
3. Management of cognitive dysfunctions with techniques such as: stopping the thinking, evidence analysis, reassignment of severity and of responsibilities;	3. Guidelines on the practice of physical activity;
4. Review of the techniques learned and creation of the SPD relapse prevention guide.	4. Guidelines on excessive use of social networks.

The platform is a non-profit website created using a grant from the Research Incentive Fund of Brazil (FIPE) received by the Federal University of Rio Grande do Sul (a public university) where the research was conducted. The university is public and is part of the Brazilian Unified Health System - SUS, therefore offering free care to the population, with no cost to participants. The \$100 annual cost of the platform is currently funded using the grant received for this research.

Adherence to treatment was assessed electronically according to patients' access to the modules. Access to the next module was only granted after the patient

completed the previous module (including the homework). Adherence to the control group was assessed by actively asking patients whether they watched the videos. Those who did not complete the 4 sessions or did not watch the 4 control videos were considered losses. The SOSkin platform usability was assessed using the System Usability Scale (SUS) validated to Brazilians, which assesses the degree of user's satisfaction with the tool through 10 interspersed positive or negative phrases, with the individual being able to agree or disagree with each one on a Likert scale of 0-5. The total score varies from 0 to 100, with higher values meaning better system usability (28).

Statistical analysis

We calculated the sample size based on a previous study using remote CBT for treating 133 German individuals with SPD (20), aiming for a statistical power of 95% and an alpha error of 5%, estimating losses of 20%. The sociodemographic variables were analyzed in terms of their distribution using the Kolmogorov-Smirnov test and, depending on the result, comparisons between the groups used the Student's t-test or the Mann-Whitney test. Comparisons between categorical variables were performed using the chi-square test. Data about the intervention's efficacy at different moments were analyzed using the Generalized Estimating Equations (GEE) model with the Bonferroni correction, as this method accounts for the correlation between repeated measures within the same individual. Missing data were not imputed; instead, all available data points were included in the analysis, regardless of whether participants had complete information at all-time points (29). The effect size of CBT over the control condition was calculated by the d of Cohen. The percentage of change

in primary outcome (SPS-R) was calculated using the independent samples t-test. All statistical analysis was performed using SPSS® software version 16.0.

Ethics statement

This study follows the Guidelines and Norms Regulating Research Involving Human Beings according to the Declaration of Helsinki. The local Ethics and Research Committee (CEP) approved the study under protocol number 2020-0453 and registered it in the Clinical Trials database under the number NCT04731389. The Free and Informed Consent Form was explained to participants in the first online assessment, with all their doubts being explained by the researchers. All patients signed the Free and Informed Consent Form in a digital format, also signed by the principal investigator, giving written informed consent to publication of their case details.

Results

A total of 163 individuals were included in the study (the flow chart is depicted in Figure 1). There were no differences in sociodemographic or clinical characteristics, neither in the treatment with psychotropic drugs and/or psychotherapy, between patients randomized to treatment or control groups at baseline (see Table 2 and Table 3). Regarding previous diagnosis and treatment of SPD, 62.7% (n=42) of individuals consulted a dermatologist (receiving the diagnosis of SPD in 50% of the cases), and 76.1% (n=51) previously consulted a psychiatrist (being diagnosed with SPD in 33% of the cases). Fifty-eight patients (47.5% of the sample) had never received treatment for SPD. Regarding SPD history, the median age of incidence was 13 years old, 36.1% (n=44) of individuals also have another skin disease, and 30.3% (n=37) of the sample

reported having a family member diagnosed with SPD. These data did not differ between the groups (see Table 2). Concerning adherence rates to treatment, there was no statistical difference between the groups according to the Yates chi-square test ($p=0.055$), with 66.3% ($n=53$) of the sample randomized to the CBT intervention completing the treatment and 80.7% ($n=66$) of subjects from the control intervention completing the trial. We also found no difference in adherence rates between the groups during the follow-up assessments: after 1 month, 47.5% ($n=42$) from the CBT group and 63.9% ($n=51$) from the control group ($p=0.052$) answered the questionnaires and at 3-month 33.7% ($n=25$) and 38.6% ($n=31$) from the CBT and the control group respectively answered the self-report assessment ($p=0.635$). No significant difference was found in baseline sociodemographic or clinical characteristics comparing patients who adhered to treatment with those who did not (see table 4 in the supplementary files). Regarding satisfaction with the SOSkin platform, the System Usability Scale had a median score of 82.5 (minimum 45 – maximum 100).

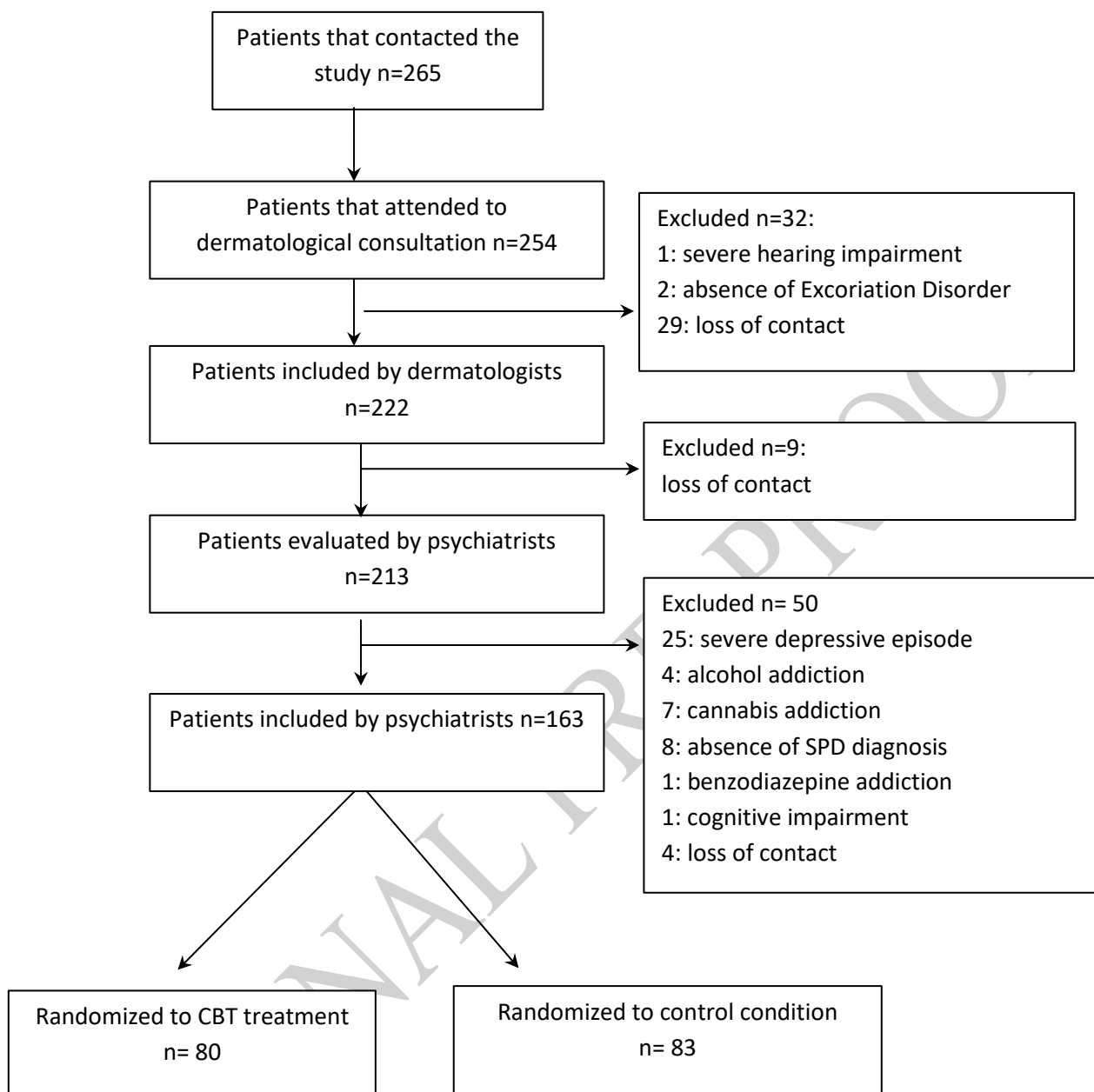


Figure 1: flow chart of the progress through the phases of the study, showing the number of individuals excluded at each stage and for what reason. CBT= Cognitive behavioral therapy.

Table 2: Sociodemographic characteristics of the sample comparing individuals randomized to intervention or control groups.

	Intervention (n=62)	Control (n=60)	Test Coefficient / p value
Age ^{mean(SD)}	33(10.1)	32(9.2)	-0.57/0.56 [#]
Female gender ^{n(%)}	61(98.4)	60(100)	1.00 [*]
Caucasian ^{n(%)}	48(74.2)	37(61.7)	2.70/0.61 [†]
Marital Status ^{n(%)}			3.72/0.29 [†]
<i>Married</i>	25(40.3)	24(40)	
<i>Single</i>	32(51.6)	34(56.7)	
<i>Divorced</i>	5(8.1)	1(1.7)	
<i>Widower</i>	0	1(1.7)	
Religion ^{n(%)}			8.81/0.18 [†]
<i>Catholic</i>	24(38.7)	21(30)	
<i>Spiritist</i>	5(8.1)	3(5)	
<i>Protestant</i>	0	2(3.3)	
<i>Evangelical</i>	9(14.5)	3(5)	

<i>Lutheran</i>	1(1.6)	0	
<i>Other</i>	4(6.5)	9(15)	
<i>No religion</i>	19(30.6)	22(36.7)	
Education^{n(%)}			10.35/0.05 [†]
<i>High School</i>	2(3.2)	10(16.7)	
<i>Incomplete University</i>	11(17.7)	14(23.3)	
<i>Education</i>			
<i>Complete University Education</i>	49 (79.1)	36(60)	
<i>or Postgraduate Studies</i>			
What is your occupation at the moment? ^{n(%)}			
<i>Working</i>	49(75.4)	41(66.1)	0.91/0.34 ^B
<i>Studying</i>	18(27.7)	21(33.9)	0.32/0.57 ^B
<i>Housewife</i>	7(10.8)	8(12.9)	0.01/0.92 ^B
<i>Unemployed</i>	4(6.2)	8(12.9)	0.99/0.32 ^B
<i>Retired</i>	3(4.6)	2(3.2)	1.00 ^B
<i>On sick leave and receiving</i>	1(1.5)	0	1.00 [*]
<i>compensation</i>			
Have you ever seen a Dermatologist due to your Skin			0.29/0.58 ^β
Picking Disorder^{n(%)}			
<i>Yes</i>	21 (58.3)	21 67.7)	

Have you ever seen a psychiatrist due to your Skin Picking 0.27/0.60^β

Disorder^{n(%)}

Yes	26(72.2)	25(80.6)
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Have you ever started a treatment for your Skin Picking 5.76/0.33[†]

Disorder? ^{n(%)}

None	29(46.8)	29(48.3)
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CBT	7(11.3)	6(10)
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Only medication	11(17.7)	12(20)
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CBT+medication	5(8.1)	10(16.7)
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Currently on antidepressants

n(%)

SSRI	23(35)	17(27)	0.6/0.43 ^β
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SNRI	7(11)	12(19)	1.22/0.26 ^β
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Do you have any skin related diseases^{n(%)} 0.10/0.74^β

Yes	21(33.0)	23(38.3)
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#Student t test; *Fisher's Exact Test; †Pearson Chi-square; ^βYates Chi-square.

SSRI: Selective Serotonin Reuptake Inhibitor. SNRI: Serotonin and Noradrenalin Reuptake Inhibitor

* The sample in this table is smaller than the total sample of the trial because some individuals did not fill out the self-administered form with sociodemographic data sent by the researchers.

Table 3: Results of the Mini-International Neuropsychiatric Interview (M.I.N.I.) applied to the sample comparing individuals randomized to intervention or control groups.

	Intervention (N-80)	Control (N-82)	Test Coefficient/ p-value
Major Depression episode (Current) ^{n(%)}	23(14.2)	24(14.8)	0.47/ 0.78 ^β
Major Depression episode (Past) ^{n(%)}	32(19.7)	32(19.7)	0.00/1.00 ^β
Dysthymia ^{n(%)}	5(3.0)	8(4.9)	0.26/0.26 ^β
Bipolar Disorder ^{n(%)}	7(4.3)	7(4.3)	0.00/1.00 ^β
Panic disorder ^{n(%)}	9(5.5)	8(4.9)	0.00/0.93 ^β
Agoraphobia ^{n(%)}	10(6.2)	7(4.3)	0.32/0.57 ^β
Social Anxiety Disorder ^{n(%)}	13(8.0)	12(7.4)	0.00/0.94 ^β
Obsessive-Compulsive Disorder	9(5.5)	9(5.5)	0.00/1.00 ^β
Posttraumatic Stress Disorder	1(0.6)	4(4.3)	0.36*
Psychotic Disorder ^{n(%)}	4(2.4)	3(1.8)	0.71*
Anorexia Nervosa ^{n(%)}	1(0.6)	0	0.49*
Bulimia Nervosa ^{n(%)}	0	5(3.0)	0.059*
Generalized Anxiety Disorder ^{n(%)}	47(29)	48(29.6)	0.00/1.0 ^β

* Fisher's Exact Test; ^β Yates chi square

3.1 Primary outcome: both groups significantly improved considering the SPD severity and its impact after the treatment and at the two follow-up assessments. We found a significant time*group interaction in favor of CBT ($p=0.017$) however, this interaction is not significant after Bonferroni's correction (see Figure 2). The effect size of the intervention in relation to control condition over the SPS-R scale was very small at the middle of intervention ($d=0.15$) and small at the end ($d=0.35$), at the 1 month follow up ($d=0.25$) and at the 3 month follow up ($d=0.28$). When we compared the percentage of change of SPS-R from baseline assessment, participants from the CBT group significantly differed from the control group: -14.13% Vs. -5.29%, $p=0.01$ at the middle of intervention; and -19.19% Vs. -5.31%, $p=0.001$ after intervention.

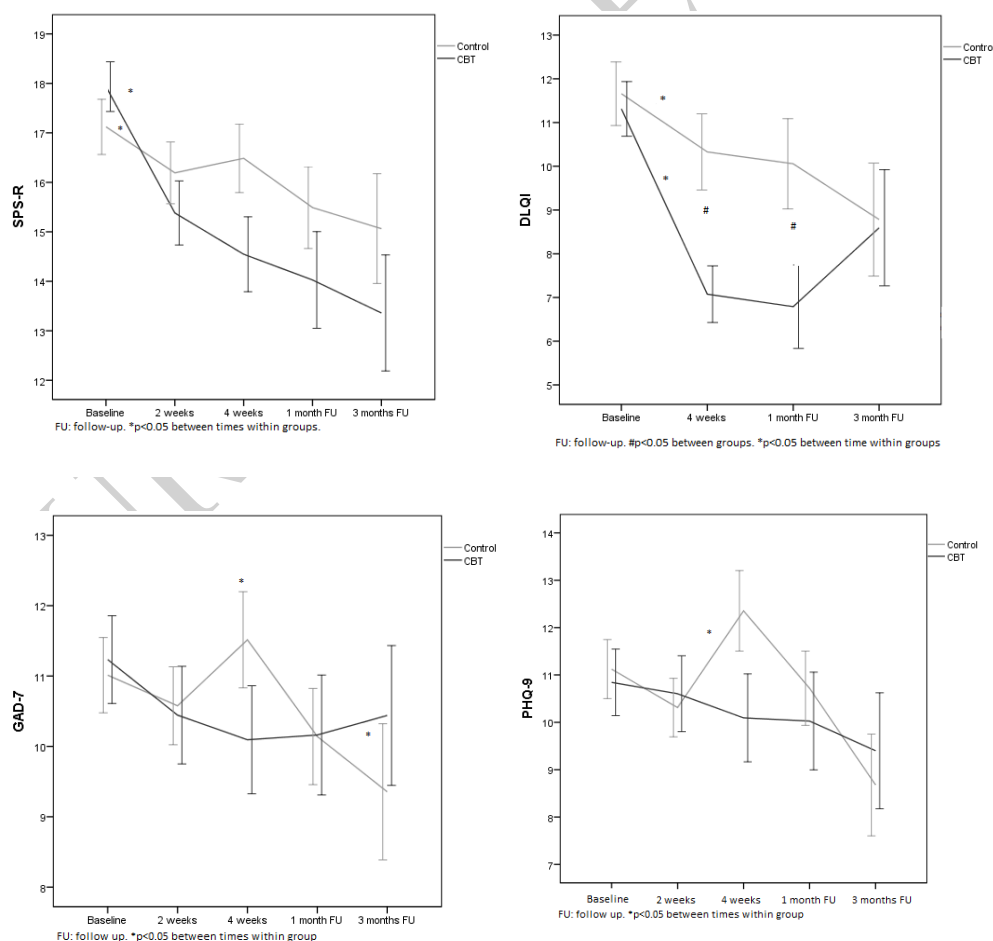


Figure 2: Values of the scales applied before, during, after and in the 1 and 3 months follow-up of the treatment in the control group and in the intervention group. DLQI: Dermatology Life Quality Index Scale; SPS-R: revised skin picking scale; GAD-7: Generalized Anxiety Disorder Assessment Scale; PHQ-9: Patient Health Questionnaire-9 Scale.

3.2 Secondary outcomes: both groups improved considering the quality of life in dermatology after the intervention, maintaining improvement during 1-month follow-up (see figure 2). The CBT intervention was superior to the control condition at the end of treatment and at 1 month follow-up assessment ($p=0.007$ and $p=0.01$, respectively). The effect size of the intervention over the active control condition on the DLQI scale after treatment was moderate ($d=0.53$) and in the 1 and 3 month follow ups was small ($d=0.48$ and 0.2 respectively). There were no significant improvements in anxiety and depressive symptoms (see figure 2). Figure 2 shows the improvement according to all rating scales at baseline, during the trial, after the intervention, and in the two follow-up assessments for both groups (1 and 3 months). When we analyzed the predictors of outcomes, we found that baseline anxiety symptoms predicted worse treatment response at the middle of the intervention in the CBT group (Yates chi-square=0.04). No other associations were found. During the conduct of the study no adverse effects related to the intervention were reported to the researchers.

The data that support the results are available on the supplementary files.

Discussion

As far as we know, this is the first study to evaluate the effectiveness of online CBT for patients with a confirmed diagnosis of SPD compared to an active control condition. Most studies evaluating online interventions use a sample of self-report

habits of SPD and compare the intervention to the waiting list. Our study showed that patients treated using the SOSkin platform had a higher percentage of improvement than individuals who received active control considering our primary outcome (SPR-S): 20% of improvement on the SPS-R scale at the end of CBT, compared to only 5% of improvement after control condition. This difference is statistically significant and clinically relevant, as small changes SPS-R scores reflect significant changes in the impact and/or severity of the condition (30). Besides this, we found that the effect size of the intervention over the active control was significant. Although the effect size of SOSkin in relation to the control was small on the primary outcome, it is important to highlight that we used an active control that itself had a significant effect size. Previous literature used the waiting list as a comparator, so it is not surprising that resulted in larger effect size compared to other types of controls, such as psychological placebo or usual care (31). Even using an active control, our intervention showed a moderate relative effect size on the participants' quality of life, highlighting the positive impact of the intervention on the patient's functionality. The maintenance of improvement over time is a challenge, and our study innovated by evaluating patients after 1 and 3 months. We found sustained improvement on the SPS-R scale at both follow-up points and of the DLQI scale after one month. The sustained response also observed in the active control group could be explained by the placebo effect, since recent studies show placebo response rates in patients with SPD are around 5-10% (32,33). Moreover, all individuals received the diagnosis of SPD during the interview with the psychiatrist and were psychoeducated about this disorder, and it is known that psychoeducation itself can induce the improvement of psychiatric symptoms (34).

Internet-based interventions can overcome barriers and increase patient's access to treatment; however, adherence to online treatments is often challenging

(35). Previous studies that tested the efficacy of online platforms to treat SPD found it to be effective; however, dropout rates were between 30% and 96%, being higher in those without therapist support (20,36,37). In our study, although we tested a totally self-applied intervention, we found an adherence rate similar to the ones with therapist support (37). Indeed, SOSkin was evaluated by users as a system with very high usability, reflecting that its interface was inviting and easily accessible. Furthermore, compared to therapist-assisted treatment, self-applied interventions can reduce the treatment cost (35).

In our sample, less than 10% of diagnosed patients had received the first-line treatment before, a finding in accordance with the recent literature that shows that less than 20% of patients with SPD received the first-line treatment (8). In our study, almost half of patients had some dermatological condition, which can be a barrier to SPD improvement, since skin lesions can trigger the habit of picking. We found a peak incidence of SPD in early adolescence, a time with a higher prevalence of acne, which is in line with the literature, showing that irregularities in the skin can be triggers for the beginning of the habit (38). Therefore, the recognition and treatment of dermatoses in patients with SPD are essential to increase treatment success.

Our results should be interpreted in light of some limitations. Despite being in line with the literature, treatment dropout rates are high and should be considered when interpreting the results. In addition, dropout rates during the follow-up exceeded 50%, which may have compromised the extrapolation of the results to the entire sample. Another point is that our sample consisted of people with educational status above our country's mean and with internet access. Individuals who are active on social media may not be representative of the general population. Additionally, some participants had received CBT in the past. Thus, care is needed when assuming the

results to the general population, mainly those with lower educational status and not used to digital devices (39). Besides this, our sample size was calculated for a study power of 95% and took into account the possible losses. However, the small sample size could be responsible for our loss of significance after Bonferroni's correction test. Although a potential limitation is the fact that the control group received a shorter intervention, it is important to highlight that this same intervention proved effective in a previous large clinical trial (27), making the presence of this comparator a distinguishing feature of our study. The video conference diagnosis may not be as accurate as face-to-face diagnosis, but the fact that all patients were evaluated by psychiatrists and dermatologists is a strength of the study. The lack of a structured clinical interview for the diagnosis of SPD may be a limitation, however, unlike most previous studies, where the diagnosis was based on self-report, in our study all the participants were evaluated by specialized professionals with extensive experience in the field that conducted the interview based on DSM-5 criteria. Also, our robust methodology, using adequate randomization, active control, and blinded evaluation of patients, are essential strengths. Another limitation of the study is that no data were collected on possible adverse effects caused by the intervention; however, no participant reported adverse events to the researchers during the clinical trial. Despite the high prevalence of SPD worldwide, instruments for assessment and treatment of this pathology are mainly in English, so an additional importance of this study is the fact that the SOSkin platform is in Portuguese and can be applied to millions of people who live in developing countries that speak Portuguese such as Brazil and other African countries.

Conclusion

The SOSkin intervention has a slightly superior effect compared to an active control in improving the severity and impact of SPD, and a moderately superior effect in improving individuals' quality of life. Patients who received the intervention showed a higher percentage of improvement than patients who received the active control, this finding being statistically and clinically significant. The improvement in SPD severity and impact after treatment was sustained after 3 months. The SOSkin platform is easy to use by patients and can increase availability and reduce the cost of SPD treatment. Studies that replicate our findings in large sample sizes and that evaluate whether the inclusion of booster sessions or continuous access to the platform after the treatment can bring additional benefits are expected. Studies that include a longer follow-up and that assess the SOSkin effectiveness in a therapy assisted model are also awaited.

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Disclosure

The authors report no conflicts of interest.

Author contributions: CRediT Taxonomy Alice Castro Menezes

Xavier Conceptualization-Lead, Data curation-Lead, Formal analysis-Lead, Investigation-Lead, Methodology-Equal, Project administration-Lead, Visualization-Equal, Writing - original draft-Lead, Writing - review & editing-Lead Clarissa Prati Conceptualization-Lead, Investigation-Lead, Methodology-Lead, Project administration-Lead, Writing - review & editing-Lead Anita Xavier Data curation-Equal, Writing - review & editing-Lead Murilo Brandão Data curation-Lead, Software-Lead,

Writing - review & editing-SupportingAlice EbertData curation-Lead, Software-Lead, Writing - review & editing-SupportingMalu MacedoData curation-Equal, Investigation-Equal, Resources-Equal, Writing - review & editing-SupportingMaria João FernandesData curation-Equal, Investigation-Equal, Resources-Equal, Writing - review & editing-SupportingGisele Gus ManfroConceptualization-Lead, Funding acquisition-Lead, Project administration-Lead, Supervision-Lead, Writing - original draft-Equal, Writing - review & editing-EqualCarolina DreherConceptualization-Lead, Formal analysis-Supporting, Funding acquisition-Lead, Investigation-Lead, Methodology-Lead, Project administration-Lead, Resources-Lead, Software-Supporting, Supervision-Lead, Validation-Lead, Writing - original draft-Equal, Writing - review & editing-Equal

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Supplementary material:

Table 4: Baseline sociodemographic and clinical characteristics of patients who adhered and did not adhered to treatment

Total Sample	Adhered (N=118)	Not Adhered (N=41)	Test coefficient/ p-value
DLQI: Dermatology Life Quality Index Scale	11,56	11,29	-0.24/.080 ^M
SPS-R: revised skin picking scale	17,88	16,46	-1.65/1 ^t
GAD-7: Generalized Anxiety Disorder Assessment Scale	11,14	11,07	-0.06/0,91 ^M
PHQ-9: Patient Health Questionnaire-9 Scale.Female gender	11,19	10,40	-0.75/0,48 ^M
	Adhered (n=112)	Not adhered (N=42)	Test Coefficient/ p-value
Age			
Female gender	111	42	0.48 [*]
Caucasian	76	29	1.98/0.74 [†]
Marital Status			1.26/0.74 [†]
<i>Married</i>	45	14	
<i>Single</i>	60	26	
<i>Divorced</i>	6	2	

<i>Widower</i>	1	1	
Religion			2.84/0.83 [†]
<i>Catholic</i>	40	18	
<i>Spiritist</i>	8	3	
<i>Protestant</i>	2	1	
<i>Evangelical</i>	10	6	
<i>Lutheran</i>	1	0	
<i>Other</i>	12	5	
<i>No religion</i>	39	10	
Education			2.41/0.49 [†]
<i>High School</i>	12	7	
<i>Incomplete University Education</i>	23	12	
<i>Complete University Education or Postgraduate Studies</i>	77	24	
What is your occupation at the moment?			
<i>Working</i>	82	26	1.29/0.26
<i>Studying</i>	35	16	0.35/0.55
<i>Housewife</i>	11	9	2.65/0.10
<i>Unemployed</i>	12	6	0.11/0.74

<i>Retired</i>	5	0	0.78/0.38
<i>On sick leave and receiving compensation</i>	1	0	1.00

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