EMDR protocol for urge to reduce scratching behaviour in prurigo nodularis

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Primary Objective: To investigate if treatment according to the EMDR protocol for urge reduce daily scratching behaviour in PN patientsHypothesis: Treatment according to the EMDR protocol for urge leads to a statistically significant reduction of...

Ethical review	Approved WMO
Status	Completed
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON53585

Source
ToetsingOnline

Brief title
ESPN

Condition

- Epidermal and dermal conditions

Synonym
nodular prurigo., Prurigo nodularis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dermatology, EMDR, Prurigo nodularis, Scratching behavior

Outcome measures

Primary outcome

Within a multiple baseline design across subjects, the daily measure is the frequency and duration of scratching behaviour. These daily registrations are administered via the mobile phone of participants. They will take 2 minutes daily at maximum to fill out. Scratching duration is categorized in 5 intervals: <30sec, 30sec - 1min, 1-2min, 2-4min , >4min.

Secondary outcome

Every evening, patient are administered a short questionnaire containing a Likert scale wherein patients rate the amount of itch and the severity of the scratching that day on a scale from 0 to 10.

Moreover, secondary outcomes are several common used questionnaires about disease activity; quality of life, self-control, and sleep quality. All standardized measures are administered at two time points: at baseline (T0) and after the end of the treatment phase (T1), that is the end of the study . The standardized measures used are:

Disease activity, measures to be filled out by dermatologist or dermatology resident: The Investigator Global Assessment (IGA) is a tool for the objective assessment of chronic prurigo. The IGA for stage of chronic nodular prurigo (CNPG) and signs of activity in chronic prurigo are used. Both stage and activity are scored on a scale from 0 (clear) to 4 (severe) [24].

Two Quality of Life measures, to be filled out by the patient: 1) The

SKINDEX-17 is a dermatology-specific health-related quality of life (HRQOL) instrument. It consists of 17 items to be scored on a 5-point Likert scale. The instrument has two subscales: psychosocial impact and impact of symptoms [25];

2) The EQ-5D-5L measures health-related quality of life. It is a generic instrument that can be used in a wide range of health conditions and treatments. The EQ-5D-5L consists of a descriptive system and the EQ VAS. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ VAS records the patient*s self-rated health on a vertical visual analogue scale [26].

Self-Control, measures to be filled out by the patient: The Self-Control Cognition Questionnaire, Dutch: Zelfcontrole Cognitie Vragenlijst (ZCCL). The ZCCL is an 11-item self-report questionnaire measuring perceived self-control . There are two subscales: *positive reward* (of the unwanted behaviour) and *difficulty resisting*. Each item is scored on a 5-point Likert scale [27].

Sleep quality, measures to be filled out by the patient: The Pittsburgh Sleep Quality Index (PSQI) is a self-rated questionnaire which assesses sleep quality and disturbances over the last month. It consists of 19 items that are divided into seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of the components yields one global score, ranging for 0 to 21, with a lower score indicating better sleep quality [28].

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Study description

Background summary

Prurigo nodularis (PN) is a chronic, inflammatory skin condition characterized by intensely itchy nodules. PN (lit. *itchy bumps*) is, as the name suggests, accompanied by severe itching. Compared to other dermatosis, PN shows the highest values for itch intensity and frequency [1]. Itch is associated to significant morbidities, such as suicidal ideations and sleeping problems [2]. PN is also associated with anxiety and depression, and quality of life impairment [1, 3-5].
Scratching of the skin, as a response to the itch, is rewarding in the short term, but may perpetuate the skin condition in the long run. In this way the itch-scratch cycle is maintained [6], resulting in more itch.

Besides pharmacological treatment, psychological interventions that target scratching behaviour show significant ameliorating effects on itching intensity and scratching [7]. Psychological treatments for scratching behaviour are based on *self-control procedures* and *habit reversal*. Habit reversal has been shown to be effective in treating unwanted habits, such as thumb-sucking, eyelash-picking, and scratching [8-11]. Habit reversal applies an 'incompatible response': an activity that is incompatible with performing the unwanted habit (i.e. wearing cotton gloves that make scratching impossible). Beside self-control procedures and habit reversal, self-monitoring or registration of

habitual behaviour is a common component of effective cognitive-behavioural treatments, which often leads to a decrease in the frequency of this behaviour [12, 13].

The psychological intervention to be investigated in this study is the EMDR protocol for urge (Drang EMD Protocol, DEP; Doeksen, 2018) [14], which draws on elements of Eye Movement Desensitization and Reprocessing (EMDR) therapy, cognitive behavioral therapy, and hypnotherapy. In the current treatment, not the full EMDR procedure is applied, but only the EMD-part - that is the desensitization part. Desensitization aims at the *fading out* or *losing appetite* for behavior that is longed for, in this case the scratching [15]. Patients are allowed to perform the scratching in imagination, which corresponds with the EMDR-technique of *cognitive interweaves*. Furthermore, the treatment protocol draws on elements of cognitive behavior therapy, as self-registration of behavior and homework assignments are core elements of treatment. Finally, elements of hypnotherapy are incorporated in this treatment, with respect to the interpretation to perceive the treated skin spots - that does (no longer) evokes the urge to scratch - as *calm and white*. This protocol, turned out to be successful in a number of individual treatments [14]. The results of the first study to scientifically investigated this intervention in patients with atopic dermatitis seem promising in that they show a decrease in scratching behaviour. However, the effect of DEP on scratching behaviour of patients with PN is unknown. Therefore, we aim to replicate this previous study to investigate the effects of this intervention in PN patients in a controlled study.

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Study objective

Primary Objective:
To investigate if treatment according to the EMDR protocol for urge reduce daily scratching behaviour in PN patients

Hypothesis: Treatment according to the EMDR protocol for urge leads to a statistically significant reduction of daily scratching behaviour in PN patients.

Secondary Objective(s):
2.1 To investigate if treatment according to the EMDR protocol for urge improve the skin condition in PN patient.
2.2 To investigate if treatment according to the EMDR protocol for urge improve quality of life in PN patients.
2.3 To investigate if treatment according to the EMDR protocol for urge improve perceived self-control in PN patients.
2.4 To investigate if treatment according to the EMDR protocol for urge improve sleep quality in PN patients.

Hypotheses:
2.1 H1: Treatment according to the EMDR protocol for urge leads to a clinically relevant improvement in skin condition in PN patients.
2.2 H1: Treatment according to the EMDR protocol for urge leads to a clinically

relevant improvement in quality of life in PN patients.
2.3 H1: Treatment according to the EMDR protocol for urge leads to a clinically relevant improvement in perceived self-control in PN patients.
2.4 H1: Treatment according to the EMDR protocol for urge leads to a clinically relevant improvement in sleep quality in PN patients.

Study design

The current study applies a multiple baseline across subjects design, in which participants will be randomly allocated to different baseline lengths. All patients will start their daily registration at the same time, at day 1 (Monday) of week 1. After a minimum of three weeks baseline registration, pairs of two patients were randomly selected and were assigned to one of three possible starting weeks, with a randomly selected weekday for each patient to start treatment. The intervention phase starts when the first DEP treatment is applied and ends on the last day of week eight. During the intervention phase a total of two DEP sessions take place in the setting of the of the psychiatry outpatient clinic of the Erasmus MC. The total study duration, consisting of the baseline and intervention phase is 8 weeks and is equal for all participants.

Intervention

Eye Movement and Desensitization Reprocessing (EMDR) therapy is an evidence-based psychological treatment that is recommended by national guidelines for the treatment of PTSD [18]. Since then, it has been shown to be effective for a variety of anxiety and somatic complaints [19-21]. In the current study, the EMDR protocol for urge (DEP) is tested. This protocol has recently been developed and applied and clinical results so far have been positive [14]. However, scientific research on its effectivity so far is scarce. For this reason, we aim to conduct the current study.
Working-memory theory offers an explanation for how EMDR might work [22, 23]. The theory states that the short-term or working memory can perform various tasks at the same time. However, the working memory has a limited attention capacity. As a result, by performing one task, performance on another task comes under pressure. In DEP, the patient is asked to focus on the distracting stimulus, but at the same time also to focus on the urge to scratch his/her skin. So, the attention, which is focused on the urge to scratch, is distracted by the eye movements. The hypothesis is that as a result, 'decay' (desensitization) of the urge to scratch takes place and the urge loses more and more of its urgency.
In this study the DEP consists of two sessions of 90 minutes divided over two weeks (so one session in week 1, and one in week 2 of the intervention phase). An important part of DEP consists of homework exercises. These homework exercises comprise to practice/apply the intervention as learned during the sessions with the therapist, in those situations wherein the urge to scratch

their skin is present. In the text below, we will explain in more detail what the treatment protocol entails.

In the DEP sessions, the patient is asked to focus on the spot on his/her skin where the urge to scratch is highest. The patient then is asked to rate the level of urge to scratch this spot on a 10-point scale and to imagine that they scratch this spot as they would like. At the same time eye movements are offered for 30 seconds. Then, the level of urge is rated again and the procedure is repeated until the level of urge to scratch that particular spot has become nihil. After that the patient is asked to imagine that this spot had become *white*, that is calm and quiet. Next, this procedure is repeated for all other skin parts where the patient experiences an urge to scratch, until there are no skin parts left that the patient wishes to scratch during the session. As a homework assignment straight after the first session, the patient is instructed and encouraged to practice the same intervention at home. That is, each time that the patient experiences the urge to scratch his skin, he has to imagine that he is actually scratching in the way he would like to do and at the same time focus on a distracting stimulus that taxes working memory. This distracting stimulus is either the following of one*s own finger moving from left to right, or playing Tetris on one*s mobile phone. Within three days after each of the face-to-face sessions, the patient is called by the therapist to ask for their experiences with the practicing at home. In case the patient experiences difficulties in practicing at home, these difficulties are discussed and patient and therapist together try to find a solution to enable practicing at home.

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Study burden and risks

We expect that the intervention will reduce unwanted behaviour, that is the scratching worsening the skin condition in patients with PN. Apart from the time investment (to attend two therapy sessions and to fill out the questionnaires), no disadvantages are expected to participate in the study. However, participants may be disappointment in case the experimental treatment may not bring what the patients had hoped for. However, this is no other than the risk any patient faces in undergoing experimental treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18 >=
- A confirmed diagnosis of PN
- Stable disease activity
- Suffering from persistent and frequent scratching behaviour, no successful

response to care as usual
- Sufficiently motivated to take part in a new intervention aimed at behaviour change

Exclusion criteria

- Insufficient understanding of Dutch language
- Severe psychiatric disorders that require treatment first, such as delusional disorder or major depression
- If medication is changed during the course of the study, the participant will be considered a drop-out from the moment the medication has changed.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-08-2023
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83202.078.22