The effect of the EMD protocol for urge compared to care as usual on dermatology-specific quality of life

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Primary Objective: To assess the add-on effect of the EMD-U treatment compared to CAU, in improving dermatology-specific quality of life in patients with atopic dermatitis or prurigo nodularis who suffer from severe scratching behaviour. Hypothesis...

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

Summary

ID

NL-OMON56030

Source ToetsingOnline

Brief title EMD-U vs CAU

Condition

• Epidermal and dermal conditions

Synonym Prurigo nodularis (nodular prurigo); Atopic dermatitis (eczema)

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, EMD protocol for urge, Quality of life, Scratching behavior

Outcome measures

Primary outcome

The main study outcome is the dermatology-specific health-related quality of life (HRQOL), measured at the start of the study (T0), in week 4 (T1), in week 8 (T2), and during follow-up, in week 12 (T3) and six months after T0 (T4). The SKINDEX-29 is used to measure this outcome. It consists of 30 items to be scored on a 5-point response scale. The instrument has three subscales: symptoms, emotions, and functioning [17].

17. Chren, M.-M., et al., Improved discriminative and evaluative capability of a refined version of Skindex, a quality-of-life instrument for patients with skin diseases. Archives of dermatology, 1997. 133(11): p. 1433-1440.

Secondary outcome

Secondary outcomes are several commonly used measures for disease activity, health-related quality of life, self-control, depression and anxiety, and skin picking. All standardized measures are administered at four time points: at the start of the study (T0), in week 4 (T1), in week 8 (T2), and during follow-up, in week 12 (T3) and six months after T0 (T4). The standardized measures used are:

Disease activity, measures to be filled out by dermatologist or dermatology

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resident:

The disease activity of patients with atopic dermatitis is scored using the Eczema Area and Severity Index (EASI) [18]. This is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.

For patients with prurigo nodularis and excoriation disorder, the Investigator Global Assessment (IGA) is used. The IGA is a 5-point 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 [19].

Health-related Quality of Life measure, to be filled out by the patient: 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 [20].

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 [21].

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Depression and anxiety, measures to be filled out by the patient: The four item Patient Health Questionnaire for anxiety and depression (PHQ-4). The PHQ-4 is a brief self-report screening tool for depression and anxiety, consisting of four items. Two items on depression, and two items on anxiety are scored with a 4-point Likert scale, ranging from 0 (not at all) to 3 (nearly every day) [22].

Skin picking, measures to be filled out by the patient: The Skin Picking Scale (SPS) is a six-item self-report measure for the assessment of skin picking behaviour. The scale has a total score range of 0-24 [23].

 Chopra, R., et al., Severity strata for Eczema Area and Severity Index (EASI), modified EASI, Scoring Atopic Dermatitis (SCORAD), objective SCORAD, Atopic Dermatitis Severity Index and body surface area in adolescents and adults with atopic dermatitis. Br J Dermatol, 2017. 177(5): p. 1316-1321.
Zeidler, C., et al., Investigator*s Global Assessment of chronic prurigo: a new instrument for use in clinical trials. Acta Derm Venereol, 2021. 101(2): p. adv00401-adv00401.

20. Janssen, M.F., et al., Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. Qual Life Res, 2013. 22(7): p. 1717-1727.

21. Maas, J., et al., The Self-Control Cognition Questionnaire. Eur J Psychol Assess, 2015.

22. Kroenke, K., et al., An ultra-brief screening scale for anxiety and4 - The effect of the EMD protocol for urge compared to care as usual on dermatology ... 6-05-2025

depression: the PHQ-4. Psychosomatics, 2009. 50(6): p. 613-621.

23. Keuthen, N.J., et al., The Skin Picking Scale: scale construction and

psychometric analyses. Journal of psychosomatic research, 2001. 50(6): p.

337-341.

Study description

Background summary

Scratching is a common behaviour in people with dermatological conditions such as eczema, prurigo nodularis, and other itchy skin conditions. While scratching can provide temporary relief from itching, it can also lead to further damage to the skin. As a result, reducing scratching behaviour may have an impact on dermatology-specific quality of life in multiple ways. First, reducing scratching can help to reduce the severity and frequency of symptoms associated with dermatological conditions. This may lead to an improvement of the skin condition, which can improve a person's overall physical health and well-being. Moreover, the impaired skin resulting from scratching, can be a significant source of emotional distress for individuals with dermatological conditions, leading to feelings of embarrassment and shame, and diminished social interactions, as individuals may avoid certain activities or situations due to concerns about their appearance. By reducing scratching behaviour and improving skin health, individuals may feel more confident and comfortable in their own skin, leading to improved emotional well-being and a better quality of life.

An evidence-based psychological treatment to reduce scratching behaviour is cognitive behavioural therapy, 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 [1-4]. 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 [5, 6]. More recent, novel types of treatment to reduce scratching behaviour in AD patients appear to be effective, such as internet-delivered and exposure-based cognitive behavioural therapy [7, 8].

The EMD protocol for urge (EMD-U) is a recently developed treatment which draws on elements of Eye Movement Desensitization and Reprocessing (EMDR) therapy, cognitive behavioural 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 reducing the urge to perform certain behaviour, in this case the scratching [9]. Patients are allowed to perform the scratching in imagination, which shows similarities with the EMDR-technique of *cognitive interweaves*. Furthermore, the treatment protocol draws on elements of cognitive behaviour therapy, as self-registration of behaviour 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 [10]. 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 [11]. In addition, this intervention is currently being investigated in patients with prurigo nodularis.

 Azrin, N.H. and R.G. Nunn, Habit-reversal: a method of eliminating nervous habits and tics. Behaviour research and therapy, 1973. 11(4): p. 619-628.
Daunton, A., C. Bridgett, and J.M.R. Goulding, Habit reversal for refractory atopic dermatitis: a review. The British journal of dermatology, 2016. 174(3): p. 657-9.

3. Tsakok, T., et al., The effectiveness of habit reversal on treatment outcome and quality of life in patients with chronic eczema: a prospective observational study in the UK. Br J Dermatol, 2017. 177(2): p. 554-556.

4. Teng, E.J., D.W. Woods, and M.P. Twohig, Habit reversal as a treatment for chronic skin picking: a pilot investigation. Behavior modification, 2006. 30(4): p. 411-422.

 Korotitsch, W.J. and R.O. Nelson-Gray, An overview of self-monitoring research in assessment and treatment. Psychol Assess, 1999. 11(4): p. 415.
Maas, J., et al., Changing automatic behavior through self-monitoring: does overt change also imply implicit change? J BEHAV THER EXP PSYCHIATRY, 2013. 44(3): p. 279-284.

7. Hedman-Lagerlöf, E., et al., Internet-Delivered Cognitive Behavior Therapy for Atopic Dermatitis: A Randomized Clinical Trial. JAMA dermatology, 2021. 157(7): p. 796-804.

8. Hedman-Lagerlöf, E., et al., Exposure-based cognitive behavior therapy for atopic dermatitis: an open trial. Cognitive behaviour therapy, 2019. 48(4): p. 300-310.

9. Markus, W., et al., Addiction*focused Eye Movement Desensitization and Reprocessing Therapy as an Adjunct to Regular Outpatient Treatment for Alcohol Use Disorder: Results from a Randomized Clinical Trial. Alcohol Clin Exp Res, 2020. 44(1): p. 272-283.

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10. Doeksen, D. and E. ten Broeke, Te mooi om waar te zijn? Behandeling van drie patiënten met excessief krabben en tricotrillomanie, in EMDR Magazine. 2009. p. 5-9.

11. de Veer, M.R., et al., Reducing scratching behavior in atopic dermatitis patients using the EMDR treatment protocol for urge: a pilot study. Frontiers in Medicine, 2023. 10: p. 660.

Study objective

Primary Objective:

To assess the add-on effect of the EMD-U treatment compared to CAU, in improving dermatology-specific quality of life in patients with atopic dermatitis or prurigo nodularis who suffer from severe scratching behaviour.

Hypothesis: EMD-U treatment leads to significant improvement of dermatology-specific quality of life, compared to CAU.

Secondary Objective(s):

2.1 To investigate if EMD-U treatment leads to significant improvement of the skin condition, compared to CAU.

2.2 To investigate if EMD-U treatment leads to significant improvement of health-related quality of life, compared to CAU.

2.3 To investigate if EMD-U treatment leads to significant improvement of perceived self-control, compared to CAU.

2.4 To investigate if EMD-U treatment leads to significant improvement of perceived severity of depression and anxiety, compared to CAU.

2.5 To investigate if EMD-U treatment leads to significant improvement of perceived severity of skin picking, compared to CAU.

Hypotheses:

2.1 H1: EMD-U treatment leads to a clinically relevant improvement in skin condition, compared to CAU.

2.2 H1: EMD-U treatment leads to a clinically relevant improvement in health-related quality of life, compared to CAU.

2.3 H1: EMD-U treatment leads to a clinically relevant improvement in perceived self-control, compared to CAU.

2.4 H1: EMD-U treatment leads to a clinically relevant improvement in perceived severity of depression and anxiety, compared to CAU.

2.5 H1: EMD-U treatment leads to a clinically relevant improvement in perceived severity of skin picking, compared to CAU.

Study design

The current study applies open randomized controlled trial, in which participants will be randomly allocated to one of two treatment conditions: EMD-U or CAU. After a patient is found eligible to participate in this study, the patient is randomly assigned to one of the conditions. Prior to the start of the intervention, patients should have a stable treatment course for 2 weeks. Patients in the EMD-U condition receive the EMD-U treatment in addition to the care as usual. The EMD-U treatment lasts eight weeks, in which two EMD-U sessions take place and patients are called twice in the first three weeks. After the first EMD-U session, the patients apply the learned technique at home until the end of the study. During the following five weeks, patients are called twice to ask for their experiences with the practicing at home. A follow-up meeting takes place twelve weeks and 6 months after the start of the study. Physical appointments for the EMD-U treatments take place in the setting of the dermatology outpatient clinic of the Erasmus MC. Patients in the CAU condition receive only care as usual during the study period.

Intervention

EMD-U:

The EMD protocol for urge has recently been developed and applied and clinical results so far have been positive [11, 14]. Working-memory theory offers an explanation for how EMDR might work [15, 16]. 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 EMD-U, 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.

EMD-U consists of two sessions of 60 minutes in the first three weeks. An important part of EMD-U 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. Patients in this condition receive the EMD-U treatment in addition to the care as usual.

In the EMD-U 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 both 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. The two EMD-U sessions and two phone calls, take place in the first three weeks of the study. After the first EMD-U session, the patients apply the learned technique at home until the end of the study. During the following five weeks, patients are called twice to ask for their experiences with the practicing at home.

CAU:

Patients in the control group receive care as usual (CAU), which is the standard care of the dermatologist. In addition to completing the questionnaires at T0, 1, 2, 3, and 4 these patients are not offered any additional treatment or support aimed at their scratching behaviour.

11. de Veer, M.R., et al., Reducing scratching behavior in atopic dermatitis patients using the EMDR treatment protocol for urge: a pilot study. Frontiers in Medicine, 2023. 10: p. 660.

14. Doeksen, D. and E. ten Broeke, Te mooi om waar te zijn? Behandeling van drie patiënten met excessief krabben en tricotrillomanie, in EMDR Magazine. 2009. p. 5-9.

5. Engelhard, I.M., et al., Reducing vividness and emotional intensity of recurrent *flashforwards* by taxing working memory: An analogue study. Journal of anxiety disorders, 2011. 25(4): p. 599-603.

16. de Jongh, A., et al., The impact of eye movements and tones on disturbing memories involving PTSD and other mental disorders. Journal of behavior therapy and experimental psychiatry, 2013. 44(4): p. 477-483.

Study burden and risks

We expect that the intervention will improve dermatology-specific quality of

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life and reduce unwanted behaviour, that is the scratching worsening the skin condition of the patients. Apart from the time investment (to attend two therapy sessions and to fill out the questionnaires), no disadvantages are expected toparticipate 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) Elderly (65 years and older)

Inclusion criteria

- Age 18 >=
- A confirmed diagnosis of atopic dermatitis or prurigo nodularis
- Suffering from persistent and frequent scratching behaviour

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- IGA-CPG activity score >= 3 OR Skindex-29 symptoms subscale score >= 42

- Stable course of treatment in the two weeks prior to the study (no medication change, etc.)

- 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

Primary purpose: Treatment	
Masking:	Open (masking not used)
Allocation:	Randomized controlled trial
Intervention model:	Parallel
Study type:	Interventional

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	11-03-2024
Enrollment:	120
Туре:	Actual

Ethics review

Approved WMO	
Date:	06-11-2023
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	02-02-2024
Application type:	Amendment
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 CCMO **ID** NL84417.078.23