EMDR treatment for scratching in atopic dermatitis

Published: 23-06-2020
Last updated: 08-04-2024

Primary Objective: 1.1 Does treatment according to the Dutch EMDR protocol for Urge reduce scratching behavior in AD patients? Hypothesis:1.1 H1: Treatment according to the Dutch EMDR protocol for Body Focused Repetitive Behavior , version...

Ethical review	Approved WMO
Status	Pending
Health condition type	Impulse control disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49676

Source
ToetsingOnline

Brief title
ESAD

Condition

- Impulse control disorders NEC
- Epidermal and dermal conditions

Synonym
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, aangevraagd;vereniging EMDR Nederland voor 5000 euro;uitslag over eventuele toekening volgt nog.

Intervention

Keyword: dermatology, eczema, EMDR, scratching behavior

Outcome measures

Primary outcome

Within a multiple baseline design across subjects, the primary endpoints are the so called target-measures. These are frequent measures that target the behavior that is to be altered by the intervention. Within this study, daily measure is:

Scratching behavior. The frequency and duration of both actual scratching and, after the start of the treatment also imaginary scratching are measured. These daily registrations are standardized and are administered automatically via the mobile phone of participants.

Secondary outcome

Within this study, secondary endpoints are the standardized measures. Standardized measures are administered to compare study participants to existing norm groups to see whether the intervention has resulted in clinical relevant changes. Standardized measures in this study are aimed at 1. Disease activity, 2. Quality of life and 3. Self-control. These measures are administered at three timepoints: at baseline (T0), directly after the end of the treatment phase (T1) and after the last follow-up measurement, that is, after 6 weeks (T2).

Standardised measures employed in this study are:

Disease activity, measures to be filled out by dermatologist, at T0 and T2 only:

- Eczema Area and Severity Index (EASI). A validated scoring system that grades the physical signs of atopic dermatitis/eczema. EASI is the core outcome for measuring the clinical signs of eczema in all trials.
- Investigator*s Global Assessment (IGA) scale. A 5-point tool to measure disease severity.

Quality of Life, measures to be filled out by the patient at T0, T1 and T2:

- Patient-Oriented Eczema Measure (POEM). The POEM is a Patient-Oriented Eczema Measure consisting of 7 items to be scored on a 4-point scale.
- SKINDEX-17. 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-pointy scale. The instrument has two subscales: psychosocial impact and impact of symptoms.
- EQ-5D-5L. The EQ-5D 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. This can be used as a quantitative measure of health outcome that reflects the patient*s own judgement.

Self-Control, measures to be filled out by the patient at T0, T1 and T2.

- Zelfcontrole Cognitie Vragenlijst (ZCCL). The ZCCL is an 11-item self-report questionnaire with two subscales: importance of positive effect and resistance difficulty. Each item is scored on a 5-point Likert scale.

Study description

Background summary

Atopic eczema, also called atopic dermatitis (AD) occurs in approximately 1 to 10 % of all adults (1, 2). AD is characterized by recurring inflammations of the skin. AD is nearly always accompanied by itch, which can result in excessive scratching of the skin, thereby worsening the skin condition. The symptom of itch has been found to drive the burden of AD. As the itch causes trouble sleeping, sleeping problems are also quite common in patients with AD (3). Next to itching and sleeping problems, patients with AD report pain, anxiety and depression. The disease and the more or less continuous itch severely impact on patients* daily and working lives, and their health-related quality of life (3, 4). The itch can drive patients to despair. Case reports are known from patients who even expressed the clear wish to end their lives because of the ongoing itch (5). Mental health scores for AD have indeed been found to be lower than those of other chronic health conditions such as diabetes and heart diseases (6). AD is typically treated with topical corticosteroids and emollients. In more severe cases several systemic treatments are used. Psychological interventions to target the scratching behavior are described in a meta-analysis by Chida (7). The authors found that although various psychological interventions had a significant ameliorating effect on itching intensity and scratching, further study is warranted to strengthen the evidence. The psychological intervention to be investigated in this study is Eye Movement desensitization and Reprocessing (EMDR) combined with imaginary scratching. This combined intervention turned out to be successful in a small number of individual treatments (5). However, this intervention has not been subject of scientific research yet. Therefore, we aim to investigate the effects of this intervention in a controlled study.

References:
1. Silverberg JI. Health Care Utilization, Patient Costs, and Access to Care in US Adults With Eczema: A Population-Based Study. JAMA Dermatol. 2015;151(7):743-752.
2. Drucker AM, Wang AR, Li WQ, Sevetson E, Block JK, Qureshi AA. The burden of atopic dematitis: Summary of a Report for the National Eczema Association. J

Invest Dermatol. 2017;137(1): 26-30.
3. Simpson EL, Guttman-Yassky E, Margolis DJ, Feldman SR, Qureshi A, Hata T, Mastey V, Wei W, Eckert L, Chao J, Arnold RJG, Yu T, Vekeman F, Suárez-Fariñas M, Gadkari A. Association of inadequately controlled disease and disease severity with patient *reported disease burden in adults with atopic dermatitis. JAMA Dermatol. 2018; 154(8):903-912.
4.Misery L, Seneschal J, Reguiai Z, Merhand S, Héas S, Huet F, Taïeb C, Ezzedine K. Patient Burden is Associated with Alterations in Quality of Life in Adult Patients with Atopic Dermatitis: Results from the ECLA Study. Acta Derm Venereol. 2018; 98(7): 713-714.
5. Doeksen D, ten Broeke E. Te mooi om waar te zijn? Behandeling van drie patiënten met excessief krabben en tricotrillomanie. EMDR Magazine 19, 2009 , 5-9.
6. Silverberg JI, Gelfand Jm, Margolis DJ,Boguniewicz M, Fonacier L, Grayson MH, Simpson EL, Ong PY, Chiesa Fuxench ZC. Patient-burden and quality of life in atopic dermatitis in US adults: A population-based cross-sectional study. Ann Allergy Asthma Immunol. 2018;121(3): 340-347.
7. Chida Y, Steptoe A, Hirakawa N, Sudo N, Kubo C.The effects of psychological intervention on atopic dermatitis. A systematic review and meta-analysis. Int Arch Allergy Immunol. 2007;144(1):1-9.

Study objective

Primary Objective:
1.1 Does treatment according to the Dutch EMDR protocol for Urge reduce scratching behavior in AD patients?

Hypothesis:
1.1 H1: Treatment according to the Dutch EMDR protocol for Body Focused Repetitive Behavior , version scratching leads to a statistically significant reduction of scratching behavior in AD patients.

Secondary Objective(s):
2.1 Does treatment according to the Dutch EMDR protocol for Urge improve quality of life in AD patients?
2.2 Does treatment according to the Dutch EMDR protocol for Urge improve perceived self-control in AD patients?

Hypotheses:
2.1 H1: Treatment according to the Dutch EMDR protocol for Urge leads to a clinically relevant improvement in quality of life in AD patients.
2.2 H1: Treatment according to the Dutch EMDR protocol for Urge leads to a clinically relevant improvement in perceived self-control in AD 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 that, each participant, chosen randomly, will start their treatments on a randomly chosen working day of one of the three following weeks. The treatment phase is 10 days for all patients, and includes in total two EMDR sessions that take place in the setting of the of the psychiatry outpatient clinic of the Erasmus MC. The treatment phase is followed by a follow-up phase. The total study duration, consisting of the baseline, treatment and follow-up phase is 6 weeks and is equal for all participants.

*

Intervention

Eye Movement and Desensitization Reprocessing (EMDR) therapy an evidence-based psychological treatment that is recommended by national guidelines for the treatment of PTSD (8). Since then, it has been shown to be effective for a variety of anxiety and somatic complaints (9-11). In the current study, The Dutch EMDR protocol for Urge is tested. This protocol has recently been developed and applied and clinical results so far have been positive. However, scientific research on it*s effectivity so far is lacking. For this reason, we aim to conduct the current study.

Working-memory theory offers an explanation for how EMDR might work (12, 13). 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 EMDR for scratching behavior, 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 it*s urgency so to say.

In this study the EMDR intervention consists of two sessions of 90 minutes divided over two weeks (so one session in week 1, and one in week 2). As the after-effects of EMDR may last up to 3 days, this makes that the *treatment phase* as described in the design (chapter 3) lasts 10 days in total (that is: EMDR session 1 on day 1 of the treatment phase, EMDR session 2 on day 8 of the treatment phase and day 8-10 as extra days to clear off the possible after-effects of the last session). An important part of the Dutch EMDR

protocol for Urge 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.

During the EMDR session with the therapist, the patient is asked to focus on those spots on his/her skin where the urge to scratch is highest. The patients is then asked to rate the level of urge on a 10-point scale and to imagine that they scratch this sport as they would like. At the same time the distracting stimulus is offered for 30 seconds. Then, the level or urge is rated again and the procedure is repeated until the level of urge to scratch that particular spot has become nihil. Then the patient is asked to imagine that this spot has become *white*, that is calm and quite. Next, this procedure is repeated for all skin parts where the patient may experience an urge to scratch, until there are no skin parts left that the patients wished 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 should imagine that he/she is actually scratching in the way he/she 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 by playing tetris on one*s mobile phone. In case those distracting stimuli for whatever reason do not work for the patient or in a particular situation, then the patient is asked to use cognitive distraction, for instance by making calculations like distracting from 200 with 7 per time. Experiences so far with these methods learns that this is feasible for patients. Three working days after each of the face-to-face sessions, the patient is called by the therapist to ask how the practicing at home is going. In case the patient experiences difficulties in practicing at home, these difficulties will be discussed and patient and therapist together will aim to find a solution to enable practicing at home.

8. Balkom ALJM van, Vliet IM van, Emmelkamp PMG, Bockting CLH, Spijker J, Hermens MLM, & JAC, M. (2013). MULTIDISCIPLINAIRE RICHTLIJN ANGSTSTOORNISSEN Utrecht: Trimbos-instituut.

9. Logie RD, & de Jongh A. The Flashforward Procedure: Confronting the Catastrophe. Journal of EMDR practice and research 2014; 8(1): 25-32.

10. Dautovic E, de Roos C, van Rood Y, Dommerholt A & Rodenburg R. Pediatric seizure-related posttraumatic stress and anxiety symptoms treated with EMDR: a case series. Eur J Psychotraumatol. 2016; 7: 10.3402/ejpt.v7.30123.

11. van Rood YR & de Roos C. EMDR in the treatment of medically unexplained symptoms: a systematic review. Journal of EMDR practice and research 2009; 4(3): 248-263.

12. Engelhard IM, van den Hout MA, Dek EC, Giele CL, van der Wielen JW, Reijnen MJ & van Roij B.Reducing vividness and emotional intensity of recurrent "flashforwards" by taxing working memory: an analogue study. J Anxiety Disord. 2011; 25(4):599-603.

13. de Jongh A, Ernst R, Marques L, & Hornsveld H. The impact of eye movements and tones on disturbing memories involving PTSD and other mental disorders. J Behav Ther Exp Psychiatry 2013; 44(4): 477-483.

Study burden and risks

We expect that the intervention will reduce unwanted behavior, that is the scratching worsening the skin condition in patients with AD. 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

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 40
Rotterdam 3015 GD
NL

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 AD
- Systemic treatment for AD with stable disease activity
- Suffering from persistent scratching behavior, no successful response to care as usual
- Sufficiently motivated to take part in a new intervention aimed at behavior change

Exclusion criteria

- Insufficient understanding of Dutch language
- Severe psychiatric disorders that require treatment first
- 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:	Pending
Start date (anticipated):	01-10-2020

Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO Date:	23-06-2020
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	NL72842.078.20