Prevalence of fear of injections in patients with atopic dermatitis and the feasibility and acceptability of EMDR Flashforward in treating fear of injections in the dermatology outpatient clinic

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Primary Objective: 1.1 To assess the prevalence of fear of injections in patients with atopic dermatitis1.2 To assess the prevalence of fear of injections in the partners of patients with atopic dermatitis, as a proxy for the age-matched general...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON57015

Source
ToetsingOnline

Brief title
IFFR

Condition

- Anxiety disorders and symptoms
- Epidermal and dermal conditions

Synonym
eczema; fear of injections

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: Atopic dermatitis, Dermatology, EMDR Flashforward, Fear of injections

Outcome measures

Primary outcome

The main study outcome is the feasibility and acceptability of the EMDR-FF treatment, measured four weeks after the check-up session. Feasibility will be assessed by evaluating patient accessibility (evaluating any logistical or practical barriers they encounter, such as travel, scheduling, or availability of the treatment), time investment (both staff and patient), resource allocation (EMDR kit), staff training, personnel capacity, and associated costs. The treatment will be considered feasible if at least 80% of patients can access the treatment without significant barriers, the required time and resources are acceptable, and the personnel can be adequately trained within the allocated timeframe. Percentages above 75% are often considered acceptable [11].

Acceptability of the treatment will be determined through a comprehensive analysis of individual structured interviews conducted four weeks post-treatment. A topic list include a series of questions designed to gather detailed feedback on various aspects of the patient's experience. To begin,

patients will be asked to describe their overall experience with the treatment, providing an opportunity to express their general feelings and impressions. They will then be encouraged to reflect on specific aspects of the treatment they found positive, as well as any elements they found less pleasant.

The interviews will also explore practical aspects of the treatment by asking patients whether they found it easy to follow and, if so, why. If they experienced difficulties, they will be asked to elaborate on the challenges they encountered, such as issues with scheduling sessions or following instructions.

To assess the perceived effectiveness of the treatment, patients will be asked if they believe it was successful in addressing their condition. Additionally, the interview will address the topic of side effects by inquiring whether the patient experienced any adverse effects during or after the treatment, and how they managed these side effects.

Further, the interviews will identify any barriers or challenges the patients faced while following the treatment. Finally, patients will be asked whether they would recommend the treatment to others and why or why not, along with any suggestions they may have for improving the treatment.

The treatment will be deemed acceptable if at least 75% of patients report a positive experience or express satisfaction with the treatment during these interviews [11].

11. Lambert, S.D., et al., A study protocol for a multicenter randomized pilot trial of a dyadic, tailored, web-based, psychosocial, and physical

activity self-management program (TEMPO) for men with prostate cancer and their caregivers. Pilot and Feasibility Studies, 2021. 7: p. 1-16.

Secondary outcome

Three secondary outcome measures are used:

- The Dutch translation of the Injection Phobia Scale - Anxiety (IPS-Anx) [12], the Injectiefobie Schaal (IFS), The IFS is an 18-item self-report measure. For the purpose of this study, two additional items are included, namely: *Having an injection in your thigh* and *Having an injection in your belly*. Items are scored on a 5-point Likert scale. It measures the anxiety level with different injection and/or venepuncture procedures. Individuals rate their anxiety on a scale ranging from 0 (No anxiety) to 4 (Maximum anxiety). The IFS is measured at baseline (T0), post treatment 1 week after the check-up session (T1) and at follow-up 4 weeks after the check-up session (T2).
- The SKINDEX-17, which is a dermatology-specific health-related quality of life (HRQOL) instrument [13]. 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. The SKINDEX-17 is measured at baseline (T0), post treatment 1 week after the check-up session (T1) and at follow-up 4 weeks after the check-up session (T2).
- The Generalised Anxiety Disorder - 7 (GAD-7) is a 7-item instrument which assesses the severity of generalised anxiety disorder [14]. Patients are asked to rate the severity of his or her symptoms over the past two weeks. Items are scored on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day).

Other study parameters:

Patients are asked if they have experienced a traumatic event in the past that may have caused the fear of injections at T0. Moreover, patients are asked at T0 whether they have refused treatment in the past because of their fear of injections. Further, the number of treatment sessions per patient (1-3) will be registered.

12. Öst, L.-G., K. Hellström, and A. Kåver, One versus five sessions of exposure in the treatment of injection phobia. Behavior therapy, 1992. 23(2): p. 263-281.

13. Nijsten, T.E.C., et al., Testing and reducing skindex-29 using Rasch analysis: Skindex-17. J Invest Dermatol, 2006. 126(6): p. 1244-1250.

14. Spitzer, R.L., et al., A brief measure for assessing generalized anxiety disorder: the GAD-7. Archives of internal medicine, 2006. 166(10): p. 1092-1097.

Study description

Background summary

The prevalence of injection phobia in the adult population remains hard to determine, but its consequences should not be underestimated. Prevalence rates of fear of injections and needle phobia are estimated at 16.1% and 1.1% respectively in the Netherlands [1]. The prevalence of needle fear varies across different diseases, with rates ranging from 17-52% in cancer, 25-47% in kidney failure, and 0.2-80% in diabetes patients [2]. However, the nature of needle fear hampers incidence determination as those affected actively avoid healthcare settings, potentially leading to an underestimation of the true number [3].

Fear of injections can lead to intense anxiety and active avoidance. While other specific phobias are generally not directly harmful and may have limited impact on daily life, fear of injections can have serious implications for therapy compliance and patient health. For example, during the COVID-19 pandemic, it was found that approximately 10% of vaccine hesitancy cases across adults in the UK can be attributed to blood-injection-injury fears [4]. Chronically diseased patients may require injections as part of their treatment. Avoiding these necessary injections due to fear of injections can result in severe, even life-threatening, consequences. Ineffective treatment outcomes can exacerbate health conditions, leading to increased healthcare costs and a decline in patients' quality of life.

Standard psychological treatment for patients with specific phobias, including needle fear, consists of cognitive behavior therapy, including exposure in vivo and anxiety management techniques. Depending on the presence of a vasovagal reaction, applied tension techniques are learned to prevent patients from fainting [5, 6]. The goal of exposure therapy is to systematically expose patients to their feared stimuli in a controlled environment until they reach a point of realizing that the feared catastrophe does not occur.

Another treatment option is to utilize the 'flashforward procedure', an application of EMDR therapy [7]. EMDR Flashforward (EMDR-FF) focuses on a future fantasy image, typically involving a specific catastrophic outcome resulting from a confrontation with the until then avoided object or situation. The therapy aims to desensitize the image of the feared event in the future, which gives the individual the chance to make a more realistic assessment of the object or situation. For instance, in the case of fear of injections, a patient may harbor a fearful imagination that the next injection will cause unbearable pain. By utilizing EMDR-FF to desensitize this particular image, its emotional intensity decreases, enabling the patient to undergo and persist with the injection treatment more effectively.

Annually, in the Netherlands alone, around 2500 patients with atopic dermatitis use biologicals, which are injected every two weeks. After a brief instruction on how to inject, patients self-administer this injection at home. It is expected that the incidence of fear of injections in this population is underestimated, leading to insufficient attention being paid to treatment to improve therapy adherence. The hypothesis is that one or more session(s) of EMDR flashforward treatment can provide a solution in this regard.

1. Oosterink, F.M.D., A. De Jongh, and J. Hoogstraten, Prevalence of dental fear and phobia relative to other fear and phobia subtypes. European journal of oral sciences, 2009. 117(2): p. 135-143.
2. Duncanson, E., et al., The prevalence and evidence-based management of needle fear in adults with chronic disease: A scoping review. Plos one, 2021. 16(6): p. e0253048.
3. Jenkins, K., II. Needle phobia: a psychological perspective. 2014, Oxford

University Press. p. 4-6.
4. Freeman, D., et al., Injection fears and COVID-19 vaccine hesitancy. Psychological medicine, 2023. 53(4): p. 1185-1195.
5. Ayala, E.S., A.E. Meuret, and T. Ritz, Treatments for blood-injury-injection phobia: a critical review of current evidence. Journal of psychiatric research, 2009. 43(15): p. 1235-1242.
6. Keijsers, G., et al., Protocollaire behandelingen voor volwassenen met psychische klachten. 2017.
7. Logie, R. and A. De Jongh, The *Flashforward procedure*: Confronting the catastrophe. Journal of EMDR Practice and Research, 2014. 8(1): p. 25-32.

Study objective

Primary Objective:
1.1 To assess the prevalence of fear of injections in patients with atopic dermatitis
1.2 To assess the prevalence of fear of injections in the partners of patients with atopic dermatitis, as a proxy for the age-matched general population
1.3 To assess the feasibility and acceptability of EMDR-FF in patients with atopic dermatitis, who are eligible for biological treatment

Secondary Objective(s):
2.1 To investigate if EMDR-FF leads to reduction of fear of injections
2.2 To investigate if EMDR-FF leads to improvement of dermatology-specific quality of life
2.3 To investigate if EMDR-FF leads to reduction of general anxiety

Study design

The current study applies a cross-sectional study to assess the prevalence of fear of injections in patients with atopic dermatitis and their partners (if applicable). Patients with clinically relevant levels of fear of injections will receive one or more session(s) of EMDR-FF (for an explanation, see section 5.1), with a maximum of three sessions. Patients with atopic dermatitis from the dermatology outpatient clinic of the Erasmus University Medical Center are asked to complete a questionnaire about fear of injections. Patients who report clinically relevant levels of fear of injections, and who are eligible for biological treatment, are offered EMDR-FF following a case series design. Feasibility and acceptability through individual structured interviews are determined 4 weeks after the check-up session. The therapy sessions take place in the setting of the dermatology outpatient clinic of the Erasmus University Medical Center. Secondary measurements at baseline (T0), post treatment 1 week after the check-up session (T1) and at follow-up 4 weeks after the check-up session (T2) are administered online. Castor EDC will be used to collect the data.

Intervention

EMDR Flashforward (EMDR-FF) focuses on the adverse image of an imagined future event, typically involving a specific catastrophic outcome resulting from a confrontation with an object or situation that elicits irrational fear [7]. The therapy aims to desensitize the image of the feared event in the future, which gives the individual the chance to make a more realistic assessment of the object or situation that is avoided until then. For instance, in the case of fear of injections, a patient may harbour a fearful imagination that the next injection will cause unbearable pain. By utilizing EMDR-FF to desensitize this image, the emotional intensity decreases, enabling the patient to make a more realistic assessment of the future situation (in this case, the injection treatment).

Working-memory theory offers an explanation for how EMDR(-FF) might work [9, 10]. The theory states that the working memory has a limited attention capacity. As a result, by performing one task, performance on another task comes under pressure. In EMDR-FF, the patient is asked to focus on a distracting stimulus, but at the same time also to focus on the image of the imagined future catastrophe. The hypothesis is that as a result, 'decay' (desensitization) of the fear evoked by the *catastophy image* takes place.

The therapy consists of one to three session(s) of approximately 60 to 90 minutes. EMDR-FF will be applied according to the Dutch version of the standard EMDR Flashforward protocol (version 2023). First the goal of the intervention is explained. Next, the flashforward target image (i.e. an image of the ultimate doomsday scenario) is identified. This flashforward is desensitised using the standard EMDR protocol, followed by the mental video check and future template procedures, to test the extent into which patients perceive themselves as (now) able to face the until then feared situation in real life.

7. Logie, R. and A. De Jongh, The *Flashforward procedure*: Confronting the catastrophe. Journal of EMDR Practice and Research, 2014. 8(1): p. 25-32.
9. 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.
10. 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 reduce fear of injections in patients with chronic skin diseases. Apart from the time investment (to fill out the measurement and to attend the therapy session(s)), no disadvantages are

expected to participate in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Cross-sectional study:
- Age 18 >=
- Moderate to severe atopic dermatitis, or:
- Partner of a patient with atopic dermatitis

Case series study:
- IFS score > 25
- Patients who receive injections (biologicals) as treatment for atopic dermatitis; or

patients who are eligible for biological treatment.

Exclusion criteria

- Insufficient understanding of Dutch language.
- Severe psychiatric disorders that require treatment first, such as delusional disorder or major depression.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	1250
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-09-2024
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	NL86920.078.24