IREM Study Protocol

Title:

Imagery Rescripting (ImRs) vs. Eye Movement Desensitization and Reprocessing (EMDR) as treatment of childhood-trauma related PTSD in adults.

Authors:

Marisol Voncken, PhD., Maastricht University, the Netherlands

Arnoud Arntz, PhD., University of Amsterdam & Maastricht University, the Netherlands

Chris Lee, PhD., Murdoch University, Australia

Katrina Boterhoven de Haan, BPsych, Murdoch University, Australia

Eva Fassbinder, PhD., Lübeck, Germany

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1. Introduction

According to the DSM-IV, Post-Traumatic Stress Disorder (PTSD) might result as the consequence of experiencing traumatic events. Traumatic events are defined as events in which the person experiences, witnesses or is confronted with actual or threatened death or serious injury, or a threat to the physical integrity of the person him/herself or others. The three clusters of PTSD-symptoms include re-experiencing the trauma, avoidance of trauma reminders, and hyper arousal. In the general population the prevalence of PTSD is 0.4%-2% and lifetime prevalence is 1-12%.

There are various evidence-based treatments for PTSD. Trauma-focused CBT (tf-CBT) and EMDR are among the most often tested treatments. Tf-CBT has two main variants, prolonged imaginal exposure to traumatic memories, and cognitive restructuring of beliefs and appraisals of the trauma experiences and the symptoms produced by having experienced the trauma. Meta-analyses have documented the effectiveness of such treatments (Bisson et al., 2007; Bradley et al., 2005; Seidler & Wagner, 2006). A relatively less often studied treatment is Imagery Rescripting, though studies so far indicated good effects, less dropouts than imaginal exposure (thus high acceptability), and a wider effectiveness than imaginal exposure, that is that a broader range of emotional disturbances is successfully addressed than with the more common imaginal exposure treatment (Arntz, 2012; Arntz et al., 2013). In particular guilt, shame, anger as well as problems with anger control seem to improve more with ImRs than with Imaginal Exposure (Arntz et al., 2007). ImRs is also incorporated in the well-known and highly effective Cognitive Therapy protocol developed by Ehlers and Clark (2000).

ImRs involves imagining a different course of the sequence of events that ended in the traumatic experience, in such a way that needs of the patients are met. Although patients are well aware of the fantasy aspect of the technique, the experience of imagining a different sequence that satisfies the needs of the patient leads to a change in the meaning of the memory of what originally happened (Arntz & Weertman, 1999; Arntz, 2012). ImRs seems especially suitable for interpersonal traumas, where issues play a role like violated trust in other people, guilt and shame, and built up anger towards the perpetrator.

Whilst ImRs is probably based on the change of meaning of trauma memories, EMDR seems to rely on a different mechanism, that is the weakening of the sensory (esp. the visual) aspects of the trauma memory – brought about by the simultaneously taxing of the visual working memory by the trauma memory and a visual task (e.g., following the movement of the fingers of the therapist with the eyes) (e.g., Engelhard et al., 2010, 2011; see van den Hout & Engelhard, 2012)).

Although both ImRs and EMDR seem to be highly acceptable and effective treatments of PTSD, the two approaches have never been directly compared. Moreover, there is a lack of studies on the effectiveness of EMDR in the treatment of PTSD that is related to childhood traumas, raising the question how effective EMDR is for this kind of PTSD. Nevertheless, EMDR is widely applied for such traumas, which calls for studies to test the effectiveness of EMDR for such applications. Moreover, it is unclear whether in clinical reality the assumed different working mechanisms of ImRs and EMDR are actually responsible for their effects.

2. Aim

The primary aim of the study is to compare the effectiveness of ImRs and EMDR as treatment for childhood-trauma based PTSD in adults. A secondary aim is to test whether different working mechanisms underlie the two treatments.

3. Study design

The study is a multi-centre Randomized Clinical Trial (RCT). There will be five or six assessments: at start of wait (if applicable), just before treatment, halfway treatment, after treatment, 8 weeks after treatment, and at 1-year follow-up. At participating sites there usually is a naturalistic wait of approximately 6 weeks (estimated mean). To assess changes due to time only, assessments take place before and after wait. In case there is no naturalistic wait before treatment can start, the pre-wait assessment will be skipped. At start of every session a self-report of PTSD symptoms will be

taken to explore whether treatments differ in their speed of improvement in the three symptom clusters of PTSD.

4. Study Population

4.1 Population

Patients with a primary diagnosis of PTSD due to trauma(s) that took place before the age of 16 will be recruited at the participating mental health centres: Virenze RIAGG Maastricht (Maastricht, the Netherlands), PsyQ Beverwijk and PsyQ Amsterdam (Beverwijk & Amsterdam, the Netherlands), GGZ Noord-Holland Noord (Heerhugowaard, the Netherlands), Sinaï Center (ARKIN) (Amstelveen & Amersfoort, the Netherlands), the Sexual Assault Resource Centre (Perth, Australia) and the University of Lübeck (Lübeck, Germany). Male and female patients within the age range of 18-70 will be included in the study if they meet the criteria for PTSD based on DSM IV as their primary diagnosis, assessed with the SCID-I or the MINI, and if the index trauma happened before the age of 16.

4.2 Inclusion criteria

- PTSD as defined by the DSM-IV, assessed with the SCID-I or the MINI.
- PTSD as main complaint
- Duration of PTSD > 3 months.
- Index trauma happened before the age of 16 - patient agrees that index trauma is focus of treatment
- If a recent trauma occurred: recent trauma happened more than 6 months ago
- Age 18-70
- Ability to understand, read, write and speak country's language. In German and Dutch sites, the English language is also possible, if the site has research assistants and therapists of both conditions that are sufficiently fluent in English.

4.3 Exclusion criteria

- Acute PTSD
- DSM-IV alcohol or drug dependence. (After 3 months of abstinence participation is possible).
- Use of benzodiazepine (patients are motivated to stop benzodiazepine use in order to follow treatment protocol) (After 2 weeks of abstinence participation is possible)
- Comorbid psychotic disorder
- DSM-IV Bipolar disorder, type 1 (current or past)

- Acute suicide risk
- IQ < 80
- Scheduled to begin another form of PTSD treatment
- PTSD focused therapy within the past 3 months. If patients are in treatment for PTSD, there should be a 3-months treatment free period before they can participate in the study. PTSD-focused treatment includes emotion-regulation treatments for PTSD like STAIR and other PTSD-focused treatments, but not general supportive treatments.
- patients should not start with any form of psychological treatment or medication during screening or during the study's treatment or waitlist period. Medication should be on a stable level for 3 months, if not stopped. (Non-PTSD focused supportive treatment may be continued during wait and screening, but not during the study treatment and study post-treatment 8-week follow-up period)
- Not able to plan 12 sessions of 90 minutes within 6 to 8 weeks, time in between the sessions needs to be at least 2 days

Note. No other psychological treatment during the study period (12 sessions + 8 week FU) is allowed.

4.4 Sample size calculation

With a sample size of N=128 the study is powered at 80% to detect a medium effect size of Cohen's d = .5 at a two-tailed significance level of .05. To replace early dropouts (estimated 10%) the sample size is increased to N=142. Actual power will be higher because of the use of mixed regression (taking all available data into account) and use of covariates that reduce standard error. We expect to recruit a minimum of N=20 participants at each site.

5.Treatment

5.1 Investigational treatment

A maximum of 12 90-minutes sessions twice a week of either ImRs or EMDR will be provided: Patients that have successfully completed treatment before they reach the maximum of 12 sessions are allowed to complete treatment earlier but will be assessed at the planned assessment moments. Therapists need to meet the following criteria.

- For EMDR: successfully completed basic training course in EMDR, 2-day training in EMDR for PTSD related to childhood trauma for the present study

- For ImRs: successfully completed basic training course in CBT, 2-day training in ImRs for PTSD related to childhood trauma for the present study
- For both arms, therapists need to demonstrate their capacity to deliver the treatment(s) with pilot patients (not being part of the study sample) to the local peer-supervision group and site coordinator by video recording. In case of doubt the EMDR expert (Chris Lee) or the ImRs expert (Arnoud Arntz) is consulted.

Therapists will meet every week for one hour for peer-supervision or supervision by an EMDR or ImRs specialist and can use video recordings of sessions for peer-supervision.

5.2 Use of co-intervention

Patients may continue taking medication for PTSD or other psychological complaints throughout the study. Patients who started with medication for PTSD or other psychological complaints within 3 months prior to the initial screening will be excluded from participation. No other psychological or new pharmacological therapy is allowed during treatment. Medication use is monitored during the study.

5.3 Escape medication/treatment

Participants might start taking medication or another form of treatment/therapy in case of acute crisis during the study. The use of these medications or crisis intervention during the study as co-intervention will not lead to exclusion from the study, but will be monitored, documented, and reported.

5.4 Further treatment

Eight weeks after completion of the 12 treatment sessions a research assistant will conduct the first follow-up assessment. Next, the therapist will see the patient for an evaluation to determine if more treatment is needed. The kind, intensity and frequency of this further treatment will be determined based on the participants needs and the center's possibilities, and will be monitored, documented and reported. In the case of patients requesting help during the 8-week follow-up period, they have to contact the site coordinator, and not their therapist, for an evaluation.

6. Methods

6.1 Main study parameter/endpoint

The main outcome variable is change in severity of PTSD symptoms shortly after the intervention phase (assessed at 8 weeks follow-up), compared to severity of PTSD symptoms during the baseline phase.

The severity of PTSD will be assessed using the CAPS, a structured interview that assesses DSM5 defined PTSD symptoms during the last month (Weathers, Blake, Schnurr, Kaloupek, Marx & Kaene, 2013). The CAPS yields a dimensional total severity score, a dimensional score per symptom cluster, and diagnostic status. The CAPS will be taken by trained independent research assistant, blind for treatment condition.

6.2 Secondary study parameters

1. Self-reported PTSD-symptoms are assessed with the Impact of Events Scale – Revised (IES-R, Creamer et al., 2003), at every assessment as well as at start of every session. An additional 4-items have been included to assess shame, anger, guilt, and disgust (Arntz et al., 2007). Therapists can use these ratings to steer the treatment.
2. Depression will be assessed with the BDI-II (Beck, Steer, & Brown, 1996; Van der Does, 2002), a 21-item self-report instrument assessing depressive symptoms during the last two weeks.
3. PTSD-related cognitions: the PTCI, a self-report instrument, is used to assess trauma related cognitions (Foa et al, 1999).
4. Guilt will be assessed with the Trauma-Related Guilt Inventory (TRGI, Kubany et al., 1996).
5. Shame will be assessed with the Trauma-Related Shame Inventory (TRSI, Øktedalen, Hagtvet, Hoffart, Langkaas, & Smucker, 2014).
6. Anger will be assessed with the Self-Expression and Control Scale (SECS) (van Elderen et al., 1996, 1997; Dutch: Zelfexpressie en –controle vragenlijst, ZECV; van Elderen et al., 1995), and with the hostility subscale of the Symptom Checklist-90-Revised (SCL-90, Arrindel & Ettema, 1986; Derogatis, 2010).
7. General, social and societal functioning will be assessed with the WHODAS, taken by the research assistant who is blind for condition (WHO, 2000; 2001).
8. Remoralization is measured with the Remoralization questionnaire (Vissers et al., 2010).
9. Happiness is assessed with the 1-item happiness question validated in more than 30 countries (Veenhoven, 2011)
10. Dissociative experiences will be assessed with the Dissociative Experiences Scale Taxon (DES-T; Waller, Putnam, & Carlson, 1996)
11. Medication use will be monitored during treatment and at each assessment.
12. Vividness, valence and encapsulated belief(s) will be assessed by having the participants rate these aspects on a 0-100% scale immediately after shortly imagining their memory of the index

trauma (cf. van den Hout & Engelhard, 2012; Engelhard et al., 2011; Wild et al., 2007; Kwon et al, 2013).

13. Schema modes are assessed with the Schema Mode Inventory (SMI; Lobbestael et al., 2008) to explore whether EMDR and ImRs have similar or different effects on the personality level.

6.3 Randomisation, blinding and treatment allocation

An independent central research assistant will randomize participants to treatment condition after checking all in- and exclusion criteria. Randomization will be based on block randomization (n=2, 4, and 6 per block, with block size randomized) per site, to guarantee a balance between conditions per site and over time, and stratified for gender, so that the gender distribution is controlled per arm per site. Blinding of participants and therapists to treatment condition is not possible in this kind of psychotherapy trial, but the independent research assistants that will conduct the assessments will be blind to treatment condition.

6.4 Study procedures

6.4.1 Screening Procedures

During the screening procedure for this study patients will be assessed for eligibility to participate based on the in- and exclusion criteria described earlier. To assess syndromal disorders, the SCID or the MINI will be taken, the choice of instrument depending on the preference of the participating site. During the screening procedure assessment of participant's trauma experiences will be conducted and an index trauma memory, one that the participant reports as a worst memory, will be identified.

Lifetime trauma exposure will be assessed using the Life Events Checklist. The Life Events Checklist (LEC) is a 17-item self-report questionnaire developed to screen for lifetime exposure to traumatic events, including emotional abuse/neglect and physical neglect. The LEC will be administered once at the start of the assessment process to identify traumatic events and enable distinction between single and multiple trauma experiences (LEC, Weathers, Blake, Schnurr, Kaloupek, Marx, & Keane, 2013b).

Specific characteristics of the index trauma will be assessed using a semi-structured imagery interview. This will determine the subjective vividness, valence, and encapsulated beliefs' strength associated with the index trauma memory (Hackmann et al., 2000). The same trauma memory will be used for repeated assessments of its subjective vividness, valence, and encapsulated belief(s).

Previous treatments, and whether or not they were PTSD-focused and of what type, will be recorded at baseline.

6.4.2 Study Assessment Moments

Outcome instruments will be assessed before naturalistic wait, at baseline (just before treatment starts), after 6 sessions (3-4 weeks of treatment), after another 6 sessions (another 3-4 weeks) at post-test, 8 weeks after the last session, and at a one-year follow-up (one year after baseline just before treatment starts).

6.4.3 Assessment Procedures

An independent research assistant at the site who is blind for the patients' treatment condition will take the interviews and have the participant fill out the self-report instruments at a PC. Each assessment will take 3 hours at max. Patients and therapists will not be informed about the results of assessments, until the evaluation after the assessment 8-weeks after treatment completion. To assess treatment integrity, all sessions will be video recorded and per participant a random sample of the first 6 sessions and a random sample of the last 6 sessions will be drawn to be rated by independent trained judges for treatment adherence, blind for condition. The videos will also be used to study other issues that might be raised during the study, e.g. the therapeutic alliance, and exploration of immediate effects of specific micro-techniques. Recordings will be destroyed 5 years after publication of the main findings.

7. Statistical analysis

Mixed regression analysis taking all available data into account will be used to analyse the data. For diagnostic outcome mixed logistic regression analysis will be used, for skewed distributions mixed gamma regression, for medication use Poisson or negative binomial regression.

8. Adjacent studies

8.1 Specificity of memories. An adjacent study aims to test whether memories of single trauma are more specific and consistent than those of repeated traumas. Participants are asked to write an account of the index trauma and where there are multiple traumas that constitute the index trauma, to describe the one they have the clearest memory of, at baseline and again at follow-up. The complete task will take about 30 minutes. The (anonymized) reports will be coded by independent raters blind for whether the trauma is single or repeated. Narratives will also be coded for use of event-specific and generic information, on coherence, and on use of conceptual and sensory words by dividing them into utterance units, defined as clauses with a single thought, idea or action (see Jones et al., 2007). This adjacent study is done under direction of and in collaboration with Dr Amina Memon, Royal Holloway University, UK. An additional issue that will be explored is to what degree

memory accounts are influenced by treatment, and whether the two treatments differ in this respect. See appendix 1 for further information.

8.2 Qualitative study into patients' perspectives. A second adjacent study will focus on the perspectives of patients on both treatments. Two topics will be explored in this qualitative study: topic one will look at the process of change and treatment engagement and processes; topic two will explore effective elements of the specific treatments, the relationship between these effective elements on PTSD symptom severity, and the differences between the two treatments. This will be done in a subsample of the study population, N=20 from Perth, and N=20 from the Dutch sites, with equal proportions from both arms. The appendix 2 describes the overall study in detail.

8.3 Change in schema modes as an index of personality problems. A third adjacent study will assess how schema modes change along the treatments, as an index of change in personality problems that are common in PTSD related to childhood trauma. Appendix 3 provides more information.

8.4 Essential ingredients of ImRs: an observational study. This study will use video recordings of ImRs sessions to explore on a microscopic observational level what specific ingredients of ImRs are associated with change, with a specific focus on two possible processes: expression of inhibited action tendencies and need fulfilment. See Appendix 4 for more information.

9. Dissemination and Implementation.

The results of the study will be disseminated in the scientific community by publications in scientific journals and presentations at scientific conferences. Clinicians will be informed by presentations at conferences attended by clinicians (e.g., the national and international conferences), chapters and books describing the protocol (or protocols if treatments don't differ substantially). Moreover, trainings in the optimal method will be developed and offered to clinicians, as well as supervision in the superior technique. Among participating therapists are teachers (e.g., courses in treatment of (complex) PTSD) and supervisors, which will facilitate dissemination. Implementation will be stimulated by offering in-company training and supervision, and by informing national clinical guideline committees.

10. Time schedule

September – October 2014: first training of therapists and research assistants

March-May 2016 second training of therapists and research assistants

October 2014: start of recruitment of patients, assessment of in/exclusion criteria, first assessments, first randomizations

November - December 2014: start of treatments, peer and specialist supervision, data are centrally stored, checked and prepared for analysis

September 2018: last treatments finish

September 2017- September 2019: Last Follow-Up assessments; analysing of outcome data, reports of results (articles, conferences). Start of dissemination and implementation activities.

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Appendix 1. Study protocol of substudy 1: Remembering what happens: consistency and accuracy of memory for repeated traumatic events

Investigator: Professor Amina Memon, Royal Holloway University.

Co-investigators: Chris Lee, Marisol Voncken, Eva Fassbinder, Arnoud Arntz

Introduction.

Accuracy and validity of memories of for instance traumas is often based on data indicating consistency. However, research has found that consistency is not always a good indicator of accuracy (see Fisher et al., 2013 for a review). The present project aims at investigating whether this counterintuitive finding can be extended to those individuals who experienced multiple instances of abuse. Importantly, what we know from the memory literature on repeated events is almost exclusively based on studies of memory for single events in children, created in a laboratory environment. The study will investigate memories of adults for repeated traumatic events in participants' real lives on consistency, and compare these to memories of non-traumatic events.

In healthy adults, two main theories help us understand how we retrieve memories of repeated events. The first is schema theory (Brewer & Treyens, 1981). Schemas are organised collections of information stored in long-term memory and are quickly accessible and flexible in their applications (Hastie, 1981). As the schema grows in strength, access to individual instances becomes more difficult (Fivush, 1984) and confusion between instances of repeated events is expected (Connolly et al., 2008). The second theory, namely fuzzy trace theory (FTT, Brainerd & Reyna, 1990), posits that generic details (gist traces) are encoded and stored simultaneously with the precise details of the event (verbatim traces). The rapid decay of verbatim traces (Reyna & Titcomb, 1977) makes it more difficult for us to access details about what may have occurred during specific instances of a repeated episode. Repeated similar experiences may strengthen gist traces in memory (Brainerd & Reyna 2004; Reyna & Kieran, 1994) and the tendency to make gist related errors increases with age (Brainerd et al., 2008; Connolly & Price, 2008). Hence we may expect adult memory for repeated events to rely even more on gist than studies of young children's memory for repeated events would lead us to expect. The reduced access to verbatim traces combined with the increased reliance on gist would lead to problems in source monitoring such that details from one event may be misattributed to another (Johnson, Hashtroudi, & Lindsay, 1993). This can have consequences in an adversarial legal setting where the prosecution relies upon a charge being specific enough to allow the accused to raise a defence (see Connolly & Price, 2013; Connolly & Read, 2006).

We will now briefly consider studies of children's memory for repeated events **(**Brubacher et al., 2011, 2012; Connolly & Lindsay, 2001; Connolly & Price, 2006; Price et al., 2006). Brubacher et al. (2012) asked children (aged 4-8 years) to recall a single play activity session or four play sessions, which took place over a 2-week period. They found an age related increase in generic references when children were questioned about the repeated sessions. This parallels research showing that the memory reports of alleged child victims of repeated abuse are dominated by generic descriptions (Guadagno & Powell, 2009). Even when children are asked about differences among occurrences a typical response is "they were all the same" (Brubacher et al. 2013). Schneider et al. (2011) reported in a study of the language of interviewers' questions in actual cases that children who allege repeated abuse are more likely to respond to episodic questions with generic answers (and less likely to respond with episodic details) as compared with children alleging and questioned about single events. As age increases, so too do the number of episodic details provided by the children (Connolly & Price, 2006) although source misattributions frequently occur when children recount one or multiple occurrences of an event (Powell & Thomson, 1996).

To summarise so far, a review of theory and research with child witnesses as well as case studies of alleged child victims leads us to expect recall of repeated events to rely on a mixture of specific and general event representations, which would be in line with both schema and fuzzy trace theory. Contrary to what one might expect, the literature also suggests obtaining a generic description first may facilitate recall of episodic content (Connolly & Gordon, in press; see Brubacher & LaRooy, 2013 for a case study). Turning to the credibility of memories for repeated events, once again we could only find evidence in the literature on children's memories, despite of a thorough search in several databases. Connolly et al. (2008) made adult participants watch video recordings of children describing an event. For half of the children, the event had been experienced once and for half of the children the event was the last in a series of similar events. All children were similarly accurate; however, repeat event children were judged to be less credible than the single-event children. An analysis of the content of the reports revealed that most of the variability in credibility ratings could be attributed to differences in consistency.

Hypotheses.

Accounts provided by patients who have been multiply traumatised compared to those with a single trauma, and by patients with more severe symptoms, will show an increased reliance on generic rather than event-specific information, and increased inconsistency in their reports. We predict similar findings with neutral memories but less fragmented accounts than in the traumatic memories.

Method.

The researcher will record whether the individual has suffered a single or repeated trauma and meets diagnostic criteria for PTSD in accordance with DSM-5. No personal data will be recorded other than patient age, gender, type of and age at trauma, and scores on the screening measures that are being administered as part of the RCT. A narrative memory report will be elicited at baseline before the patient begins therapy and again six weeks' post-treatment. All patients will be using a PC to write an account of the index trauma and where there are multiple traumas to describe the one they have the clearest memory of. We will also elicit control accounts describing a neutral single or repeated event such as a day trip to a novel location (SE) or the birthday that is the clearest to them (RE). The Dutch interview data will be coded in Dutch using native Dutch speakers; sim. for German interviews. Narratives will also be coded for coherence by dividing them into utterance units, defined as clauses with a single thought, idea or action (see Jones et al., 2007). There are many autobiographical memory studies showing similar linguistic features in English and Dutch studies (e.g., Hermans et al., 2008).

Patients will complete the tasks for the memory substudy during screening and post-treatment assessment sessions of the RCT. All patients will be completing tasks individually on a PC. As part of the study participants are instructed to describe their clearest memory for the index trauma. This is the childhood event (before the age of 16) for which they will receive treatment. The memories will be typed into a PC by the patient during baseline data collection prior to the trial and once again 6-7 weeks later when they have completed the treatment phase of 12 sessions. The patients will also complete a control task where they give an account of a single or repeated event (for example, a birthday versus a visit to a novel location). It will be recorded whether the index trauma is a single or multiple event.

Appendix 2. Study protocol of the qualitative study.

Working title substudy: Patients' perspective on the effective working mechanisms in ImRs and EMDR; a qualitative study of patients' perspectives

Researchers:
Drs. Simone Menninga, GZ-psycholoog i.o. tot Klinische Psycholoog (PsyQ)
Dr. Saskia van Es, klinisch psycholoog, specialismeleider Somatiek en Psyche (PsyQ)
Prof. dr. Arnoud Arntz, hoogleraar klinisch psychologie (UvA/UM)
Katrina Boterhoven de Haan, Murdoch University, Perth, Australia
Dr. Chris Lee, Murdoch University, Perth, Australia
Dr. Helen Correia, Murdoch University, Perth, Australia

1. Introduction:

Although both ImRs and EMDR seem to be highly acceptable and effective treatments of PTSD, it is often assumed by therapists that EMDR is less demanding for patients and therapists in comparison to other treatments. An interesting question rises what will be the opinion of patients participating in this study. The last decades patients' perspectives are becoming more and more the subject of interest in research. As Katsakou et al. (2012; Ten Napel-Schutz, 2011) for instance state, patients' experiences and opinions collected with semistructured in-depth interviews might give essential information of a treatment, mainly because patient satisfaction is a significant indicator of the quality of care provided (i.e. Johansson et al., 2002).

Studies about patients' experiences of treatment show a range of elements. Arias and Johnson (2013) show in their study about treatments of childhood sexual abuse survivors that informal and formal education, compassion and empathy, blame attribution to abusers and confronting abusers contribute to healing and recovery according to survivors' viewpoints. Another study in comparing child molesters who received adjunctive EMDR therapy during their CBT- relapse prevention program showed that several themes are important to patients for a positive outcome: recognition of the origins of distorted beliefs, increased empathy, clarifications of thoughts, raised consciousness as a self-management tool, self-esteem and emotion recognition and management (Ricci & Clayton, 2008). Ten Napel-Schutz (2011) found in their study about patients' perspective on the introduction of imagery within Schema Therapy for personality disorders, that patients emphasize the importance of giving information, communication and support during the initial phases of imagery work. Specifically, with PTSD resulting from childhood abuse it is often seen that therapists are hesitant to use treatments confronting patients with detailed trauma memories (like exposure therapy) due to concerns of alleged problems patients may have in managing emotions arising from trauma processing and subsequent adverse effects this might have on further treatment (see Raabe et al. 2011; Minnen et al. 2012; 2010). How patients themselves experience treatments that focus on trauma processing is however a neglected topic.
ImRs and EMDR have shown to be effective therapies, but there is still little known about the underlying processes and how the therapies can be optimized. The purpose of this qualitative substudy is to learn from the experiences of patients, in order to better understand the underlying processes of the two treatments and to further improve the treatment protocols.

2. Aim: In this study the experiences of 40 patients in the Netherlands and Australia are collected with semi-structured in-depth interviews. The same interview will be conducted in both countries. Boterhoven de Haan (Australia) will investigate the overall opinion and satisfaction of patients in the followed treatments in both countries.

The objective of the project of Menninga et al. is to get a better overview of what patients in both countries see as the most effective elements in the followed treatment, EMDR vs. ImRs. We are interested in whether patients have experienced changes related to the techniques, and in which fields they have experienced the changes. Particular attention will also be paid to the subjective vividness, valence and encapsulated beliefs' strength associated with the index trauma memory (Hackmann et al., 2000).
The study aims to address the following questions:
- What are the most effective elements in the followed treatment according to patients?
- Is there a difference in patient perspective between the two treatments?
- Is there a relationship between the severity of PTSD symptoms and the effective elements of the treatments according to patients?

3. Study design: Following the 8-week follow-up assessment, semi structured in-depth interviews will be conducted with 20 patients in the Netherlands and 20 patients in Australia. In the Netherlands the interviews will be conducted by two interviewers. The interview questions are developed in collaboration with the investigators in Australia. The final interview will be constituted after piloting interviews with patients. All interviews will be transcribed, Dutch interviews will be translated into English, a collaborative coding frame will be developed and interrater agreement of assigning themes to text fragments will be assessed. After assigning themes and subthemes to all transcripts, interpretation will be completed and research reports written.

4 Study population: (see study protocol)
4.1 Population: Patients with a primary diagnosis of PTSD due to trauma(s) that took place before the age of 16 will be recruited at the participating mental health centres in the Netherlands and in Australia. Male and female patients within the age range of 18-70 years will be included in the study if they meet the criteria for PTSD based on DSM IV as their primary diagnosis, assessed with the SCID-I or the MINI, and if the index trauma happened before the age of 16. From the study sample a subsample (N=20 NL, N=20 AUS) will be invited to take part in this qualitative study. The patients will be evenly divided over countries and conditions (10 ImRs and 10 EMDR participants in the Netherlands, 10 ImRs and 10 EMDR participants in Australia). Furthermore, sampling will be driven by maximization of diversity (age, gender, socio-economic status, ethnicity, etc.) following the methodological standards of qualitative research.

4.2 Inclusion criteria (see study protocol)

4.3 Exclusion criteria (see study protocol)

5. Intervention: (see study protocol)

6. Primary study parameters/ outcome of the study:
Effective elements of followed treatments according to patients

7. Secondary study parameters/ outcome of the study:
Not applicable

8. Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The burden for patients exists of time for the interview of one hour.

9. Dissemination and Implementation.

The results of the study will be disseminated in the scientific community by a publication in a scientific journal and presentations at scientific conferences.

651

652 **10. Time schedule**

653 June 2016: start of qualitative interviews.

654 September 2017: last treatments finish.

655 November 2017: last interviews held.

656 September 2017- September 2018: analysing the transcripts of the interviews, reports of results
657 (article, conferences).
658

Appendix 3. Study protocol of substudy 3: change in schema modes along PTSD treatment as index for change in personality problems.

Local research team GGZ-NHN

Mariel Meewisse (Manager Trauma Department GGZ-NHN)

Annet Nugter (Manager Research Department GGZ-NHN)

Thera Koetsier (researcher)

Martine Daniels (researcher)

Marit Pronk (research assistant)

1. Introduction

Child maltreatment is not only related to the development of PTSD (Ullman & Brecklin, 2002) but also to the development of personality pathology (Johnson et al., 2006, Lobbesteal et al., 2010). Many patients diagnosed with childhood-trauma related PTSD also suffer from comorbid personality pathology (Johnson et al., 2000). Difficulties in emotion regulation and interpersonal functioning are problems in PTSD as well as personality disorders. These problems substantially decrease the level of healthy functioning of patients in all life domains (Briere, Hodges, & Godbout, 2010; MacIntosh, Godbout & Dubash, 2015).

There are various evidence-based treatments for PTSD, and several have shown to be effective for childhood-trauma related PTSD (Ehring et al., 2014). The studies on PTSD and childhood-trauma related PTSD mainly focussed on the effects on PTSD symptoms. Very little is known about the effects on comorbid personality pathology. Some evidence is found for the reduction of emotion regulation problems and for improvements in interpersonal problems (Cloitre et al., 2010), anger control, externalisation of anger and hostility (Arntz, Tiesema & Kindt, 2007). One study examined the impact of PTSD treatment on comorbid personality disorders, and found significant reduction of the axis II pathology (Markowitz et al., 2015).

Another approach to personality pathology is the Schema Mode concept stemming from Schema Therapy. Schema modes reflect the emotional and cognitive states and coping responses that are active at a given time. Modes can be adaptive or maladaptive: the stronger the pathology of a patient, the more the number and intensity of the maladaptive modes (Young et al., 2003). Investigating the effect of the PTSD treatment on Schema Modes can offer a different and additional insight in the effects of the PTSD treatment on comorbid personality pathology. To the best of our knowledge no research has yet been done on the effects of PTSD treatment on Schema Modes.

2. Aim

In this study we want to investigate the effectiveness of ImRs and EMDR on comorbid Schema Modes. Both interventions are applied in the treatment of PTSD as well as in the treatment of personality pathology (Arntz, 2015, Mosquera, Leeds, & Gonzalez, 2014). It is hypothesised that ImRs is more effective than EMDR in the reduction of dysfunctional Modes and the enhancement of the adaptive Modes. The main reason for this hypotheses is that ImRs is more directly aimed at modelling effective coping skills by the therapist in interpersonal relations, and encouraging patients to actively perform these skills. Therefore, the development of active coping of the client and of change of the meaning of the trauma-events is established. EMDR on the other hand is more aimed at the weakening of the sensory aspects of the trauma memory (Engelhard et al., 2010, 2011; see van den Hout & Engelhard, 2012). In addition, this study might provide insight into the correspondence between PTSD, Schema Modes and the PTSD treatment outcome.

Research question

Main: Is ImRs more effective than EMDR in the reduction of dysfunctional schema modes and the enhancement of the functional modes within patients suffering from childhood-trauma related PTSD?

Optional: To what extent is the severity of Schema Modes at baseline predictive for treatment outcome on PTSD symptoms? Is there a correlation between the efficacy of the PTSD treatment on Schema Modes and on PTSD symptoms?

Objective

To enlarge our knowledge of the effect of ImRs and EMDR on Schema modes. With this knowledge, we can improve treatment indications for patients suffering both from childhood-trauma related PTSD and dysfunctional Schema Modes.

3. Study design

Design

This is an additional research question within the multi-centre Randomized Clinical Trial on the effectiveness of ImRs vs EMDR as treatment of childhood-trauma related PTSD in adults.

In the main protocol, there are six to seven assessments within this study (see schedule below). In this additional study the Schema Modes Inventory (SMI) will be added at baseline, post-test and 8 weeks after baseline follow-up.

Assessments	**Instruments**
If applicable; Start Naturalistic wait	CAPS, IES-R
Baseline	CAPS, IES-R, **SMI**
After 6 sessions	CAPS, IES-R
After 12 sessions	CAPS, IES-R
Posttest	CAPS, IES-R, **SMI**
Follow-up (8 weeks after postest)	CAPS, IES-R, **SMI**
Follow-up (one year after baseline)	CAPS, IES-R

Participating sites: GGZ-NNH, RIAGG Maastricht, Buro van Roosmalen (Roermond/Venlo/Venray), PsyQ departments Amsterdam & Beverwijk, Sinaï Centrum Amstelveen & Amersfoort, Universitätsklinikum Schleswig-Holstein, Lübeck, Germany, and Perth, Australia.

Procedure

Follows the study protocol of IREM.

Data-analysis

Mixed regression analysis.

4. Study population

The in- and exclusion criteria and sample size calculation (N=142) are in line with the study protocol of IREM.

5. Intervention

Imagery Rescripting (ImRs) versus Eye Movement Desensitization and Reprocessing (EMDR).

6. Main study parameter

Schema Modes: Schema Mode Inventory (SMI).

The SMI has been derived from the Schema Mode Inventory (long version, 270 items). The list consists of 118 items, which can be scored on a six-point Likert-type scale ranging from 1 (never or almost never) to 6 (always) (Young et al., 2003).

There are English, Dutch and German versions, the last two are both validated and the results indicated a 14-factor structure and acceptable to good psychometric properties (Lobbestael et al., 2010, Reiss et al., 2012).

The SMI is a self-report questionnaire that measures 14 Modes:

- Vulnerable Child, Angry Child, Enraged Child, Impulsive Child and Undisciplined Child (domain 1: Maladaptive Child Modes);
- Compliant Surrender, Detached Protector, Detached Self-Soother, Self-Aggrandizer and Bully and Attack (domain 2: Coping Modes);
- Punitive Parent and Demanding Parent (domain 3: Parent Modes);
- Healthy Adult and Happy Child (domain 4: Healthy Modes).

Administration time is estimated at 20 minutes (Lobbestael, 2010).

7. Secondary study parameter

PTSD symptoms: IES-R, CAPS

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Appendix 4. Essential ingredients of ImRs: an observational study.

1. Introduction:

According to the DSM-IV, Post-Traumatic Stress Disorder (PTSD) might result as the consequence of experiencing traumatic events. Traumatic events are defined as events in which the person experiences, witnesses or is confronted with actual or threatened death or serious injury, or a threat to the physical integrity of the person him/herself or others. The three clusters of PTSD-symptoms include re-experiencing the trauma, avoidance of trauma reminders, and hyper arousal. In the general population the prevalence of PTSD is 0.4%-2% and lifetime prevalence is 1-12%.

One of the evidence based treatment is Imagery Rescripting (ImRs). Imagery Rescripting is a collection of methods for working directly with imagery in order to change meanings and ameliorate distress (Hackmann et al., 2011). ImRs involves imagining a different course of the sequence of events that ended in the traumatic experience, in such a way that needs of the patients are met. Although patients are well aware of the fantasy aspect of the technique, the experience of imagining a different sequence that satisfies the needs of the patient leads to a change in the meaning of the memory of what originally happened (Arntz, 2012). ImRs seems especially suitable for interpersonal traumas where issues play a role like violated trust in other people, guilt and shame, and built up anger towards the perpetrator.

The last years there has been done a lot of research of the underlying mechanisms of ImRs. One explanation of ImRs is that it helps the patient to express inhibited action tendencies and get unmet needs met (Arntz,2012).

Hypothesis: As more inhibited action tendencies are being expressed and unmet needs of safety are met, the PTSD symptoms will decrease in patients with early childhood trauma.

2. Aim

To clarify the working mechanisms of the ImRs protocol, in order to enlarge the chance of a successful treatment of PTSD-symptoms with clients with early childhood trauma.

3. Study design

The study is a multi-centre Randomized Clinical Trial (RCT). There are five or six assessments: at start of wait (if applicable), just before treatment, halfway treatment, after treatment, 8 weeks after treatment, and at 1-year follow-up. At participating sites there usually is a naturalistic wait of approximately 6 weeks (estimated mean). To assess changes due to time only, assessments take place before and after wait. In case there is no naturalistic wait before treatment can start, the pre-wait assessment will be skipped.

At start of every session a self-report of PTSD symptoms will be taken to explore whether treatments differ in their speed of improvement in the three symptom clusters of PTSD.

<u>Substudy</u>

All sessions will be audio recorded. Recordings will be destroyed 5 years after publication of the main findings. Non-drawn recordings will be destroyed immediately.

The records of ImRs will be rated by 2 independent trained judges on:

1. The expression of inhibited action tendencies
2. Get unmet needs met.

<u>Uitwerking</u>

What are inhibited action tendencies?

<u>Emotion</u>	<u>Action tendency</u>
Helplessness, fear	Attack the other and defend oneself

Helplessness, anger	Attack the other, to put the other in his place, to destroy the other.

What are the unmet needs?

Emotion	Needs
Helplessness, fear	Safety, comfort, to express one's feelings, recognition
Helplessness, anger	Recognition, to express one's feelings, safety
Grieve	Safety, comfort, to express one's feelings, recognition
Guilt	Reassurance, reattribution, blaming the correct person
Shame	Idem.

Instruments
- IES-R (Self-reported PTSD-symptoms)
- Caps

4. Study population

4.1 population
Adult patients with a primary diagnosis of PTSD due to trauma(s) that took place before the age of 16 and participate in the IREM trial.

4.2 Inclusion criteria
See RCT study protocol

4.3 Exclusion criteria
See RCT study protocol.

4.4 Sample size calculation
Will be based on a power analysis not yet completed.

5. treatment

5.1 Investigational treatment
See RCT study protocol.

5.2 Use of co-intervention
See RCT study protocol.

5.3 Escape medication/treatment
See RCT study protocol.

5.4 Further treatment
See RCT study protocol.

6. Outcome

6.1 Main study parameter/endpoint
This will be a qualitative study using MAXQDA, a computer program for qualitative data analysis.

6.2 Secondary study parameters
N.A.

6.3 Randomisation, blinding and treatment allocation

See RCT study protocol

6.4 Study procedures

See RCT study protocol.

7. Statistical analysis

This will be a qualitative study using MAXQDA, a computer program for qualitative data analysis.

8. Adjacent study

N.A.

9. Dissemination and Implementation.

The results of this substudy will be processed in a scientific article.

Presentations to enlarge the expertise of the participating therapists and other clinicians. Findings will be used to adapt existing ImRs treatment protocols.

10. Time schedule

See RCT study protocol.

11. References

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