

# The effect of caloric vestibular stimulation on disordered self-related cognition following psychotrauma and forced migration.

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The objective of this pilot is to establish if CVS has any effect on patients with this psychogenic disorder in self-related cognition after psychotrauma and forced migration, and if so, to describe this effect in comparison with the effect CVS has...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30144

### Source

ToetsingOnline

### Brief title

CVS-DSC

### Condition

- Psychiatric disorders NEC

### Synonym

mirror self-misidentification, the mirror sign

### Research involving

Human

### Sponsors and support

**Primary sponsor:** De Gelderse Roos (Wolfheze)

**Source(s) of monetary or material Support:** Ministerie van OC&W, Stichting tot Steun VCVGZ te Arnhem

## **Intervention**

**Keyword:** caloric vestibular stimulation, psychotrauma, refugees, self-related cognition

## **Outcome measures**

### **Primary outcome**

In the CVS experiments so far anosognosia and asomagnosia were assessed using 4 point rating scales. The proposal is to apply a similar scale for the assessment of the level of self alienation induced by confrontation with a mirror.

1. the patient recognises his/her reflection without discrepancy
2. the patient reports a discrepancy between the perceived reflection and his/her self-image but has no doubt it is correct
3. the patient reports doubt as to whether the perceived reflection really belongs to his/her self
4. the patient reports that someone else is gazing back from the mirror

A similar scale can be applied if trauma related memories are induced.

1. the patient reports no reminiscences
2. the patient reports induction of trauma related memories, but does not locate them in the mirror
3. the patient reports induction of trauma related memories, locates them in

the mirror but identifies them as mere imagery

4. the patient reports that persons inside the mirror intend to inflict harm like in the past

The reaction of the patient is rated by the nurse who applies the intervention.

As the aim of this pilot is to assess a so far unknown effect, a qualitative assessment of the experiences of the participants in general following the intervention will also be part of the protocol. After each confrontation the patient will also be asked about his/her experiences in general in an open interview for a more qualitative description of the effect. This part of the assessment will be done by the author, and will, if the patient consents, also be recorded on videotape. This will ensure the transparency of the procedure by making it available to assessment later by independent assessors, as the interviews themselves are for logistic reasons not done by an independent assessor.

### **Secondary outcome**

The fact that the CVS effect is assessed following exposure to a mirror, makes assessment by several independent and blinded assessors, assessing the exact same material also possible. This would be helpful especially in a pilot in which the main purpose is to establish whether there is any effect at all, like this study.

For this the one-way screen of the clinic, acting as a mirror could be used.

The one-way screen will be partly shaded to appear like a common size bathroom mirror, to prevent undue fear possibly caused by a larger reflecting surface.

The confrontation with the mirror could be videotaped from the other side of the one-way screen with a camera. The results can then be shown in random order to independent mental health professionals; the assessors will be simply asked to guess which of the confrontations was baseline, which one followed the control intervention and which the experimental intervention.

Apart from this the author will ask the assessors in an open interview to describe their observations in a qualitative way as well.

## Study description

### Background summary

The Eye Movement Desensitisation Reprocessing (EMDR) technique is at present one of the most effective tools in the treatment of psycho trauma. What makes EMDR that effective is as yet unknown. It is thought that bilateral sensory stimulation induces an orienting response in the brain which activates structures involved in episodic memory processing. More specifically, the self image of the patient encoded in episodic memory seems to be processed allowing self related cognitions biased by the trauma to change into more positive ones. However, the technique also entails prolonged exposure to the traumatic memory, which precludes its use for patients lacking in either psychological or social stability.

Unfortunately this makes EMDR unsuitable for many traumatized asylum seekers, who tend to live in insecure social circumstances and often suffer from co-morbid psychiatric pathology. Yet both psycho trauma and forced migration are likely to affect the self image of these patients in a profoundly negative way. In fact, some patients admitted to a psychiatric clinic specialised in the treatment of asylum seekers were observed to cover the mirrors in their bedrooms out of fear of looking at themselves. When asked about it, a majority of patients indicates that they experience a significant discrepancy between

their self image and their mirror image.

## **Study objective**

The objective of this pilot is to establish if CVS has any effect on patients with this psychogenic disorder in self-related cognition after psychotrauma and forced migration, and if so, to describe this effect in comparison with the effect CVS has on patients with a neurogenic disorder in self-related cognition.

## **Study design**

The study is intervention-based and blinded, controlled and randomised.

The intervention and the control intervention will follow the baseline mirror confrontation in random order. Assessment of the effect will also be done in random order.

The patients will be only blinded as to which of the interventions is the control. They will however be fully informed on the technical aspects of the CVS intervention, including the assessment by videotape. The nurse applying the vestibular stimulation will be blinded likewise; he or she will be both familiar with the patients however and with possible adverse effects of the intervention like temporary dizziness in order to be able to assist the patients during the intervention and the confrontation. The assessors of the effect of the intervention will also be blinded; when the video material is shown to them, they will not be informed whether they are observing the effect of the intervention, the control or the base line condition.

## **Intervention**

The intervention will consist out of the irrigation of the external canal of the contra lateral (left) ear with room temperature tap water, using a common plastic Luer lock syringe (without needle attached). To check whether the intervention was applied correctly, the nurse applying the intervention will check the presence of a nystagmus (saccadic eye movements) which should normally follow stimulation. Following this the patient will be asked to observe his/her face in a mirror. This confrontation does not need to last longer than a few seconds; the emotional alienation which the patients experience occurs instantly upon looking in the mirror, and so, presumably, would any change.

If the command of Dutch or English is not sufficient in the patients, a professional translator will be asked to provide live translation, as is standard procedure in the clinic.

The intervention will be preceded by baseline mirror confrontation without

prior intervention. Vestibular stimulation of the ipsi lateral (right) ear in the same study object will serve as control intervention.

## **Study burden and risks**

The patients need to:

1. visit the physician to have their eardrums checked and, if necessary, excess earwax removed;
2. do a baseline confrontation with a mirror assisted by a nurse, lasting a few seconds, followed by an open interview by the research psychiatrist lasting about 15 minutes;
3. do the CVS procedure, lasting about 5 minutes, followed a mirror confrontation and an open interview
4. repeat the CVS procedure for the contralateral ear, followed by a mirror confrontation and an open interview

Although the aim of the study is to contribute to the development of therapeutic reprocessing without confrontation with traumatic memory, confrontation with a mirror is still unavoidable for the purpose of this study. Confrontation with a mirror typically induces fear in the study objects; they should therefore be sufficiently stabilised, and preferably still admitted in order to monitor them sufficiently after the experiment. In some cases CVS may induce vertigo that may last a few minutes and that may be accompanied by nausea.

During the otoscopy by the physician the external ear canal can be damaged, and in extreme cases the eardrum may be even perforated.

## **Contacts**

### **Public**

De Gelderse Roos (Wolfheze)

Wolfheze 2  
6874 BE Wolfheze  
Nederland

### **Scientific**

De Gelderse Roos (Wolfheze)

Wolfheze 2  
6874 BE Wolfheze  
Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

#### **Sampling**

The patients should be recruited from sufficiently stabilised inpatients from a psychiatric clinic for asylum seekers and refugees; in addition they should suffer from a psychogenic disorder in mirror self-recognition. The intervention should initially only be applied to patients with minor degrees of fear for mirrors and intact reality testing. If no adverse effects are observed, more severely affected patients could be included later.

### **Exclusion criteria**

#### **Exclusion criteria**

Although the aim of the study is to contribute to the development of therapeutic reprocessing without confrontation with traumatic memory, confrontation with a mirror is still unavoidable for the purpose of this study. Confrontation with a mirror typically induces fear in the study objects; they should therefore be sufficiently stabilised, and preferably still admitted in order to monitor them sufficiently after the experiment.

Patients with organic brain anomalies or injuries are excluded.

Prior to the intervention every patient will be otoscopically assessed by a physician to check if the eardrums are intact (perforation of the eardrum is an exclusion criterium) and to clear away excess earwax if necessary.

The physician will also establish the lateralisation of hand function in the patient (left- or righthandedness); left-handed patients are not excluded, but in their case the intervention is likely to be the control and vice versa.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2006
Enrollment:	10
Type:	Actual

## Ethics review

Approved WMO	
Date:	13-06-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## 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	NL12853.097.06