The use of mirror visual feedback with patients with conversion disorder, motor type.

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Primary objective: The main research issue here is whether the intervention with the mirrorfeedback in patients with motor conversion of the arm or hand leads to improvement handgrip strength.Secondary objectives: The secondary research question is...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON36583

Source
ToetsingOnline

Brief title
Mirror visual feedback and motor conversion disorder

Condition

- Somatic symptom and related disorders

Synonym
conversiondisorder, medically unexplained symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Yulius (voorheen RMPI De Grote Rivieren)
Source(s) of monetary or material Support: Door instelling gefinancierd

Intervention

Keyword: conversion, mirror, motortype

Outcome measures

Primary outcome

Gripstrength with the Jamar hand Meter

Using a Handheld Digital Jamar dynamometer, the maximum hand grip strength will be measured daily in the affected hand. The grip strength is expressed digitally (kilograms). The dynamometer is a valid instrument for measuring hand grip strength (Mathiowetz, 2002). In this study at each measurement point three measurements are made, the highest score is taken. The interrater reliability was .82 (Mathiowetz et al, 1984), where the highest of three readings is used. The dynamometer is easy to use and the measurement takes little time (Bellac et al, 2000).

Sensitivity to the Semmes Weinstein filaments

Using monofilaments, the sensibility of all the fingers are determined. Semmes Weinstein filaments will be used, comprising a set of five different weights. This measurement is performed according to the protocol provided by the test. Although the test-retest reliability is better if the measurements are performed by a single tester (Bell-Krotoski & Tomancik, 1987), the test-retest reliability is also good for the five individual filaments as they are taken by different testers.

Secondary outcome

Brunnstrom Fugl-Meyer Assessment (BFM)

The BFM is an instrument for handicrafts, which consists of 55 items scored on an ordinal 3-point scale (0-2). The overall test consists of an examination of the upper (hand and arm) and lower (leg and foot) limb and an examination of the balance. In this study, only the items for the upper extremity are taken. The maximum score for the upper extremity is 66. For the test area of the upper extremity is a high interrater reliability (ranging from .86 to .95) found in several studies (Sanford et al, 1993, Duncan et al, 1983). Construct validity of various studies and compared with several motor sizes ranged from .54 to .94 for the total score for the upper extremity (Sanford et al, 1993).

Range of Motion (ROM)

The normal range of motion is a joint range of motion (ROM) called. It refers to the amount of possible movement during non-assisted voluntary joint movement. The movement is thus provided by an active contraction of the muscles that span the joint. The opposition of the thumb to describe the degree of opposition against the digiti I, II, III, IV, V, and metacarpal V. The score ranges from 0 to 6.

Dissociative Experiences Scale (DES)

The DES (Carlson & Putnam, 1993, Bernstein & Putnam, 1986) is a self-report to measure dissociative symptoms. The questionnaire was translated into Dutch and Draijer by Boon (1993). The list includes 28 items and includes three factors: absorption, amnesia and depersonalization. The patient is asked to indicate on a visual analogue scale to indicate to what extent they experience dissociative

sypmtoms. Several studies (Dubester & Braun, 1995; Frischoltz et al, 1990, Bernstein & Putnam, 1986) have shown that the realiability of the DES is very high. The test-retest reliability ranges from .84 to .93. The reliability over a period of one year showed relatively stable: .78 (Putnam et al, 1992). A meta-analysis (and Schuengel IJzendoorn, 1996) showed that the convergent validity is high compared to other lists and interviews and dissociation, the DES has a high predictive validity.

Somatic Dissociation Questionnaire (SDQ-20)

The Dutch version of the SDQ-20 (Nijenhuis et al, 1996) is a self-report, which measure somatoform dissociation. Item Scores run from 1 to 5 (absent to severe). The reliability (Cronbach's α = .95) and the validity of the scale are good (Nijenhuis et al, 1996). The criterion validity is strong. This is evidenced by the strong discriminatory power of the SDQ-20 among patients with a dissociative disorder (48.14, SD = 15.24) and a control group of general psychiatric patients (23.5, SD = 3.97, p <.0001). The convergent validity compared with the total score and three of the four scales of the DIS-Q is high (.71

Study description

Background summary

The application of the mirror design has been shown in patients with phantom pain, complex regional pain syndrome and people who had loss of motor function after a stroke. In this study we want the applicability of the mirror structure in patients with motor conversion studies. The effect of the mirror feedback in

motor conversion can be explained from different theoretical backgrounds (cognitive dissonance, dissociation and mirror neurons). Also, the reflection of the functioning hand or arm the system of mirror neurons can activate. In addition, the structure generated by the mirror illusion can help the dissociation of patients can break through.

Study objective

Primary objective: The main research issue here is whether the intervention with the mirrorfeedback in patients with motor conversion of the arm or hand leads to improvement handgrip strength.

Secondary objectives: The secondary research question is whether the mirror design leads to improved sensitivity and increased the functionality of the hand or arm. Another exploratory question focuses on whether there is evidence from research that mirror the structure dissociation in patients with motor conversion can be reduced.

Study design

A replicated randomized single-case AB design, with six patients treated. Such designs are particularly appropriate when little is known about a treatment method (such as mirror visual feedback) both with regard to the treatment effect as the required training intensity. Because the outcomes of the patients are repeatedly determined and a baseline measurement is performed, the patients function as their own control (Bulte & Onghena, 2008, Guyatt et al, 1988; Brain & Barlow, 1984). The baseline phase has the same goal as the untreated control group in randomized controlled trials. If the behavior changes after the baseline phase, it can be assumed that the intervention is responsible for this change. Although this design does not allow the validity of the findings to the public directly to determine the possibility of generalising considerably strengthened when a similar effect is observed in several patients. Repetition of the AB design in several patients strengthens the findings. The design of such a study gives reliable results (for an overview see: Yin, 2003, Barlow & Brain, 1984).

As with clinical trials, randomization in single-case experiments offers a solution to control for (confusing) variables, with respect to time, respondents and setting. Unlike randomized controlled trials (RCTs), the randomisation in single-case designs not include random assignment to a treatment condition. In single-case randomization experiments refers to the purely accidental determining the time of the phase change. Random assignment used in a single-case experiment, obtained on time-based statistical control known and unknown variables. This makes possible a statistical test based on randomization, as in the study design is applied (Ter Kuile et al, 2009, Onghena & Bulte, 2008). To avoid that random distribution would lead to too

little (or no) measurement dates in one of the two phases of a limited randomized phase change is recommended, with a minimum number of measurement dates for each phase is fixed in advance (Bulte & Onghena, 2008) .

The total duration of the study covers seven weeks, with included clinical patients. On the weekends, patients go home (total of 35 working days remain) The baseline phase (A) consists of no treatment and the experimental phase (B) consists of two weeks daily intervention and a possible follow-up period. The start of the experimental phase B (start intervention) for each participant on a purely fortuitous manner determined with the restriction that the baseline phase A at least 1 week (five days) duration and each patient 2 weeks (10 days) consecutive can practice with the mirror design. This means that intervention can begin at any time between the second and sixth week (20 random).

The main outcome measure the strength and the sensitivity is measured daily during the 7 weeks. Because the patients go home on weekends over a period of 7 weeks in total 35 times measured. In this way a comparison can be made in outcome measures between the ranges of the baseline phase and the experimental phase (Ter Kuile et al, 2009; Onghena & Bulte, 2008).

Randomization done with replacement. Because the baseline / control phase lasts at least 5 days and everyone a block of ten days with the mirror design exercise, so there remain twenty days (p =. 05) on the random assignment. The study design is a schematic representation of the design. The table is not included in the template.

Baseline (5 days)
Randomization (20 measuring days), P = 0.05

During this period (day 1 to day 20) is started with random intervention, in a block of ten consecutive (measurement) days.
During the last 10 test days (day 21) could not be randomized.

In one patient, it might be that the fate that after the baseline measurements of five straight starts with the intervention. There then follows a period of ten days, when the protocol is practiced in the mirror design. Then the practice stopped, but is measured daily. The period of twenty days following, is the follow-up period. Patient 2, for example, randomly assigned to eight days after the baseline measurement of five, starting with the intervention. This patient has a total of 12 baseline measurements (fixed + five days seven days assigned by lot) when no intervention takes place. Then started ten days in which the established practice with the mirror setup, after which a period of thirteen days follow-up follows.

Intervention

The intervention includes the addition of practice with the mirror up to the

retirement program. For patients with an affected arm or hand mirror arrangement consists of a vertically positioned mirror that stands between two tables. The healthy and the affected arm to either side of the mirror on the table. The mirror is directed to the poor functioning. The affected arm is shielded, so that these patients are not visible. When the patient looks in the mirror, he sees two arms: the arm functioning and it reflected. Asked the healthy arm to move in the mirror at a reflection of the moving arm. The reflection of the healthy arm creates the illusion that the affected arm move symmetrically along with the healthy arm.
For practicing with the mirror up in the experimental phase, a training protocol was developed. Patients are practicing five times a day for ten consecutive days with. Each training session lasts twenty minutes. Where, in the experimental phase starts with the mirror structure is determined by randomization, as previously described. There is a time twenty minutes practicing with a fixed practisingprotocol.

Study burden and risks

Patients participating in the study are treated following the regular treatmentprogram for patients. The first phase of clinical treatment consists of deactivation. This phase is important in the treatment of motor conversion disorder, because often these patients show long lasting patterns of overburdening. This program requires that patients participate in non-treatment activities in the clinical group, such as meals and coffee. During the low-stimulus program, no treatment modules offered. The rationale behind this program is often the chronic overloading of patients to quit. Many patients do not register bodily or ignore these signals. This is often an important maintaining factor in the disorder. Discontinuation of activities is an initial attempt to reconnect with the physical signals. Patients are asked to record the physical signals. This is monitored by a physiotherapist. This is the main goal in this phase of treatment. The duration of the low-stimulus program is four weeks, depending on the load of the patient. In later stages of the regular treatment graded activity is added, using physical signals to discriminate the limits of activation. During the low-stimulus program patients can participate in the creative actvities, with the aim of leisurement.

As part of this research, the procedures described below was added to the standard treatment offer.

• During the low-stimulus program, somewhere between week 2 and week 6 for ten days twenty minutes five times a day practicing with the mirror structure according to the exercise routine. Both the training protocol as the mirror arrangement already described in Section 6.1.
• grip strength and sensibility are determined on a daily base (35 measurements)
• Weekly, the dissociative symptoms are measured by a psychological assistant and functional dimensions measured.

The risk to patients is negligible. The mirror structure has little negative side effects. Only in a study of Moseley Meaningless sensory experiences are described, which disappear when the intervention was ceased.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Six patients who meet the criteria for a motor conversion disorder according to the DSM-IV classification.
• Patients participating in the low-stimulus program, which is part of the regular treatment
• The motorconversion of the arm is monosymtpomatic (paresis or paralysis)
• Symptoms last between two months and two years.
• Age is between 18 and 65 years.
• Patients are motivated for treatment.

• Sufficient knowledge of Dutch language.

Exclusion criteria

• Co-existence of a somatic condition that influences the conversion disorder
• Psychotic symptoms.
• Mental retardation
• Concurrent treatment for conversion disorder in a different setting.
• A condition which makes patients unsuitable for study participation, according to the researchers

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-09-2011
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	07-11-2011

Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL34890.097.11