PIT study: research into the Protocol Imaginary execuTion of self-injury.

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The aim of the research is to investigate whether the "Protocol imaginary execution of self-damaging behavior" leads to a reduction of self-damaging behavior and the urge to self-damaging behavior.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Interventional

Summary

ID

NL-OMON48432

Source
ToetsingOnline

Brief title
PIT study

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
selfharm, self-injury

Research involving
Human

Sponsors and support

Primary sponsor: Fivoor
Source(s) of monetary or material Support: Fivoor

Intervention

Keyword: behavorial intervention, self-injury, urge, working-memory load

Outcome measures

Primary outcome

1. The frequency of self-damaging behavior

2. The duration of the self-damaging behavior

3. The seriousness of the self-damaging behavior

4. The urge for self-damaging behavior

Secondary outcome

How often and for how long patients have practiced the protocol at home.

Study description

Background summary

Self-injury is becoming a bigger problem. Self-injury means: deliberately inflicting damage or pain to one's own body. The International Society for the Study of Self-Injury defines non-suicidal self-injury as follows: the deliberate, self-inflicted damage of body tissue without suicidal intent and for purposes not socially or culturally sanctioned (www.itriples.org). With self-damaging behavior there is always physical injury, which is an expected consequence of the behavior. In the definition, seq. not including suicidal feelings and thoughts. Finally, this definition does not include: behavior that harms the body, but is accepted within society or is part of cultural, spiritual or religious rituals (www.itriples.org). With self-injury, the intention is not to die, but to continue living. Examples of self-injury include deliberate cutting, scratching or burning in one's own skin, hitting itself and banging your head against a wall. Even when someone poisons himself and, for example, deliberately takes more than the prescribed amount of medication, we can speak of self-harm (S. de Klerk, A. van Emmerik, A. van Giezen, 2010). A prerequisite for this is that the action is not intended by the person to die.

Self-damaging behavior occurs in people of all ages, social classes and ethnicities, in both women and men. Given the difference in definitions, the

prevalence figures should be mentioned with caution. Research shows that self-damaging behavior is most common in adolescents and young adults; 18-25% of this group indicate that they have damaged themselves at least once in their lives (www.trimbos.nl, 2017). In the general population, the incidence of self-damaging behavior is between 14 and 600 people per 100,000 per year. Of the psychiatric patients who were admitted, 4.3 - 20% experienced self-damaging behavior and self-damaging behavior occurred relatively more often in women than in men (Claes et al., 2004).

Self-damaging behavior is more common in people who suffer from psychological problems, such as depression, anxiety, eating problems and problems with substance use. However, it also appears that 15-20% of adolescents who harm themselves do not suffer from a mental disorder. People who damage themselves are more sensitive to interpersonal stress and conflicts and have more difficulty regulating their emotions (Andover, MS & Morris, 2014). The DSM-5 mentions self-damaging behavior as a criterion for borderline personality disorder. It has also been added to section III as "a condition requiring further investigation".

There are various reasons and motives for self-damaging behavior self-damaging behavior can have multiple functions. Functions of self-damaging behavior include stopping difficult feelings and thoughts, punishing oneself, getting rest, feeling something even if it is pain, expressing despair, breaking through a dissociation, getting lost, expressing anger, gaining control, getting relief from overwhelming emotions and getting help (Claes & Vandereycken, 2007). Self-damaging behavior is a way to deal with unbearable emotions (Camp, van I., 2014). Self-damaging people often report past abuse.

The rewarding effect of self-damaging behavior ensures that it can become a habit or an addiction. Self-damaging behavior has short-term benefits, namely a rapid but short-term decrease in tension, anxiety, sadness and anger. In addition, some experience the feeling of pain or warm blood on their skin as pleasant. The feelings of shame, guilt and self-hatred increase in the longer term, which means that people experience this behavior as a problem (Claes and Vandereycken, 2006). Self-damaging behavior proceeds through the fixed order of a prior tension build-up, an irresistible urge to hurt oneself in one way or another, and feelings of satisfaction afterwards (Van der Linden & van Oppen, 2002).

The so-called behavioral addictions are clinically recognized (Van Rooij et al., 2014) and research is also being done. There seems to be a similarity in symptomatology between self-damaging behavior and substance addiction, such as escalation of use, regular relapse, strong desire, and preoccupation with behavior. There are similarities in other areas too: they often concern people with increased impulsivity and psychological or social vulnerabilities (Van Rooij et al., 2014). In addition, preliminary findings from research with brain scans regularly draw comparisons between behavioral addictions, food addiction

and substance-related addictions with regard to the impaired functioning of the brain (Griffiths, 2005; Nijs, Franken & Booij, 2009). In the case of addiction, the trait is an important factor, where emotional distress is leading in self-damaging behavior. From a study by Nixon et. aAl., (2002) shows that self-damaging behavior in adolescents shows addiction characteristics. Patients with internalized aggression have a greater chance of damaging themselves. The endorphins released by self-damaging behavior is one of the factors mentioned as part of the addiction.

There is no specific therapy for the treatment of self-damaging behavior. In general, therapy pays more attention to the underlying problems, with the expectation that self-damaging behavior will also decrease. In the treatment guidelines for, for example, anxiety and depression, suggestions for treating self-damaging behavior are limited. De Klerk, van Emmerik and van Giezen (2010) have the opinion that self-damaging behavior requires specific treatment. The underlying causes can also be investigated on the basis of this.

In the treatment of patients who damage themselves, some therapists use a non-self-injury contract in which the patient makes an agreement to do not harm himself during treatment. Research shows that these contracts are often used to reduce feelings of guilt and / or anxiety in the therapist. Research has not shown that these contracts are effective in reducing self-damaging behavior. Also entering into such a contract prevents the issue of self-damaging behavior from being discussed during the treatment. Patients also do not dare to say that they have damaged themselves due to shame / guilt (de Klerk, van Emmerik and van Giezen, 2010). There are therefore arguments against the use of such a contract. In treatment, it is important that the patient learns skills to ultimately prevent or reduce self-damaging behavior. A bond between the therapist and patient in which support, trust and cooperation is central is important. Research shows that cognitive behavioral therapy, combined with a number of other techniques from other therapies, is effective in the treatment of self-damaging behavior (de Klerk, van Emmerik and van Giezen, 2010).

In this study, Doeksen's "protocol imaginary execution of self-damaging behavior" will be investigated. This protocol is derived from Eye Movement Desencitizition Reprocessing (EMDR), which is a phased form of psychotherapy that is controlled from the adaptive information processing model of Shapiro (1989). This model by Shapiro assumes that psychopathology is based on dysfunctionally stored memories. With EMDR, the emotional charged memories are activated and making the load tangible. Next, a task is offered that loads the working memory. The Working Memory Theory is the theory about the working mechanism of EMDR that currently enjoys the most empirical support (Ten Broeke, de Jongh and Oppenheim, 2016). The premise of this theory is that the human short-term or working memory can perform different tasks simultaneously. Examples include scheduling tasks, solving problems, but also, for example, retrieving and re-recording memories. However, the memory has a limited attention capacity. The consequence of this is that performing one task causes

performance on another task - such as recalling and holding memory images - to come under pressure and be interrupted. Also the attention that is focused on judging a memory image is distracted by the eye movements and at the same time distance is created from the memory image by the instructions given during EMDR. As a result, "decay" (desensitization) of the memory images takes place and the memory increasingly loses the emotional component when it is written to the long-term memory. Research also shows that the bilateral stuimulation in EMDR automatically leads to physical relaxation. The working memory theory has also been investigated in the treatment of addiction. Research has shown that craving for a substance diminishes with a positive flash forward and someone has to perform a double task. The perceived trait with this positive image decreases in intensity and frequency if a visuospatial task is offered at the time of the trek (E. Kemps & M. Tiggemann, 2015).

The "Protocol Imaginary Conduct of Self-Harming Behavior" is based on EMDR and working memory theory and developed by Doeksen, clinical psychologist (Doeksen, 2018). Imagination is also used in this protocol, but in a different way than with EMDR. With this protocol, the patient is asked to imagine that he / she is performing the undesirable behavior. The behavior is performed imaginary and at the same time a distracting task is offered, with which the working memory is double burdened. The purpose of this technique is to reduce the patient's unwanted, harmful behavior. Patients receive the homework assignment to do this at home and to distract themselves with, for example, a task such as follow a light balk, tetris or the Stroop task. Doeksen has applied this protocol to different patients with different serious, harmful habits, whose harmful behavior had disappeared after 4 weeks of treatment. Due to successful results, this protocol has also been applied to a patient with self-damaging behavior, furthermore familiar with ADHD and PTSD with dissociative symptoms. Patient damaged himself internally vaginal and anal. After 2 sessions with the protocol there is no longer any question of self-damaging behavior after 10 weeks (Doeksen & ten Broeke, article in preparation).

The above protocol has similarities with the Feeling State Addiction Protocol (FSAP), which has been developed to treat (behavioral) addictions. This protocol is based on the Feeling-State Theory (FST) and this theory assumes that addictions are created when a positive feeling is steadily linked to a specific object or behavior. The linked part between feeling and behavior is called the feeling-state (FS). When the FS is triggered, the entire psychophysiological path is activated. This activation leads to uncontrollable behavior (Miller, 2012).

Because of these positive results that are seen as an important contribution in the treatment of self-damaging behavior, this study will investigate this "Protocol imaginary performance of self-damaging behavior" in a group of 24 patients. There are a number of reasons why this is a useful and important study. There is as yet no specific, effective treatment for self-damaging behavior, but there is a need for this. As long as the self-damaging behavior

persists, the negative self-image continues to be nourished, which often has a stagnating effect in the treatment. The physical consequences of self-damaging behavior can be serious, which means that patients regularly end up with first aid. In addition to the negative feelings that this causes to patients, this also leads to a high cost for health insurers.

Study objective

The aim of the research is to investigate whether the "Protocol imaginary execution of self-damaging behavior" leads to a reduction of self-damaging behavior and the urge to self-damaging behavior.

Study design

This is a single-case experimental design, where the aim is to investigate whether there is a functional relationship between an independent and dependent variable (Horner et al., 2005). The impact of a treatment is investigated by taking many repeated measurements and analyzing this data (Morley, 2018). With single-case, the data is collected within each participant and each participant also serves as his own control group. The term single case does not mean that there is only 1 participant, but it refers to the method of data collection (Neuman & McCormick, 1995). There must be a dependent variable and that is usually observable and measurable behavior. Each measurement moment during the intervention period is compared with an earlier measurement moment (Horner et al., 2005).
The advantage of a single-case design over randomized controlled trials is that the outcomes, such as the course and process of the therapy, can be viewed per participant (Morley, 2018).

This research concerns a non-concurrent multiple baseline design. Multiple baseline designs can handle the data from multiple datasets within a single-case experimental design means (Neuman & McCormick, 1995). Within this design, it is possible to allow participants to enter the study at different times, which is an advantage for this study, since there is a chance that there will not be 24 participants present who can participate in the study.
This design starts with a baseline period ranging from 7 to 21 days, with 5 participants randomly starting after the baseline period on day 8, 5 participants on day 11, 5 participants on day 15, 5 participants on day 18 and 4 participants on day 22 with the intervention period. The baseline period is followed by an intervention period (treatment phase) in which the "protocol imaginary execution of self-damaging behavior" is applied. The starting point of Doeken is that 1 or 2 sessions with the protocol are necessary to teach the patient the technique and to let them experience how the urge can decrease when imagining self-damaging behavior and at the same time performing a work memory task. Given the severness of the personality problem in this target group, which is traumatized and neglected, it is decided in this study to offer a

treatment session with the protocol once a week for 5 weeks, which means a total of 5 sessions. The participants are expected to experience sufficient security and support to apply the protocol themselves. The duration of a session depends on how much urge there is at that moment, but will last a maximum of 60 minutes. During the intervention period, participants receive the homework assignment to practice the technique on a daily basis. Every time the participant feels the urge to hurt himself, the assignment is to apply the protocol.
After the intervention period there is a follow-up period of 4 weeks during which registration is done daily.

Throughout the study period (the baseline period, the intervention period and the follow-up period), patients are asked to record daily (see Annex II) how often they have damaged themselves and how long and severe this was. Patients are also asked to register how strong the urge for self-harm was (on a scale of 0-10). They are also asked how long they have practice the protocol at home.

At the start of the baseline period, before and after the intervention period and after the follow-up period, a self-report questionnaire, the Alexian Brothers urge to s eleven-injury scale (ABUSI), is taken that asks about the urge for self-harm. This questionnaire has been translated from English into Dutch and translated back by a native speaker. The back translation almost corresponded to the original questionnaire and was adjusted on that point. The Self-check questionnaire is also taken at the same time to measure whether the participants experience more self-control after the study than at the start of the study.

Intervention

Protocol Imaginary execution of unwanted habits during work memory load.
Version: self-injury

Rational self-injury
*I'm going to teach you a method right away, so that you learn to hurt yourself in your thoughts and at the same time move your eyes, until you no longer have the urge to hurt yourself.
We call the eye movements Work Memory Task and ensure that you feel less and less urge to really hurt yourself. *

Introduction Procedure Imaginary self-harm.
*I'm going to ask you a few questions about your urge to hurt yourself.
I'm going to ask you to close your eyes and go to that place where you feel the strongest urge to hurt yourself.
I then ask you how strong the urge is to hurt yourself, on a scale of 0 not an urge at all, up to 10 an urge, as strong as possible.
Then I ask you to go to that place and in your mind to hurt yourself as hard as you can; at the same time I ask you to follow my fingers or the lights. "

*After about 32 seconds, I stop with the fingers or the lights and ask how strong the urge to hurt yourself is, on a scale of 0 = no urge at all, up to 10 an urge, as strong as can be ...
Then again I ask you in that place, where the urge is not yet 0, in my mind to hurt yourself, as hard as you can ... and again to follow my fingers or the lights *

*After about 32 seconds, I stop with the fingers or the lights and ask how strong the urge to hurt yourself is, on a scale of 0 = no urge at all, up to 10 an urge, as strong as can be ...
Then again I ask you in that place, where the urge is not yet 0, in my mind to hurt yourself, as hard as you can ... and again to follow my fingers or the lights *

*We keep repeating this until the urge to hurt yourself is completely gone in that place and you can give the urge a 0.
If the urge in that place is 0, I ask you to make that place "white" in your mind, so that you know that the place is quiet and you're done there. "

Then I ask you to close your eyes again to see if you want to hurt yourself in another place.
We will treat that place in the same way: first request a score of the urge from 0 to 10 and then again in thought to hurt yourself, until the urge is 0 and then make the spot white. *
*We will continue until you are here in the room, no longer feel the urge to hurt yourself.
We practice this together in the room so that you can do it exactly the same way at home.
When you feel the urge to hurt yourself at home, go to that place in your mind and move your finger in front of your eyes (or tap / play tetris) to hurt yourself in mind, as hard as you can. Just until the urge is 0, and you can make the place white.
That's how you finish all the places. Every time you want to hurt yourself in real life, you start doing it this way.
Know that practicing at home is very important *.

Protocol
Introduce the eye movements. Consider the good distance and fast pace (as soon as someone can follow) Other forms of Work memory load can of course also.

Step 1: Place of the body to hurt yourself
"I ask you to close your eyes and tell me where you would like to hurt you."
Patient mentions a place in the body

Step 2: Strength of the urge (0-10)
"How strong is the urge to hurt yourself now, in this place, on a scale from 0 to 10, where 0 is no urge to 10, as much as you can."

Patient calls a number above 0.

Step 3: Imaginary pain
Go to that place, hurt yourself (depending on what the patient is doing) .. cut, squeeze, hit ... etc) as hard as you can, do what your body wants to do ... and follow my fingers or the lights.

After about half a minute

Repeat step 2: Strength of the urge
"How strong is the urge to ... ... yourself (cutting, squeezing, biting, hitting ...) now, on a scale from 0 to 10, where 0 is not an urge and 10 is the urge as strong as possible."

Repeat step 3: Imaginary pain
Go to that place and hurt yourself ..etc. as hard as you can do what you want to do ... and look at my fingers / the lights. *

After about half a minute. Repeat 2 and 3 repeatedly until the urge to pull is 0.

Step 4: Make the place white
*Go to the place that is now 0 and make it white in your mind.
Then we know that you are there now cut ... etc. and that that place is now quiet *.

Repeat from steps 1 to 4 until there is no more place where the patient still feels the urge to hurt themselves.

Step 5: Positive conclusion
*What is the most positive or valuable that you have experienced this session ...
If useful: what does that say about you? What do you call such a person? "

Step 6: Homework
*We have now calmed your entire body.
Now I ask you to practice this at home.
Every time you feel the urge to hurt yourself, you sit down, you go in your mind to that place of your body where you want to hurt yourself and do it in your mind; as hard as you can, you do what your body actually wants to do, while you move your fingers back and forth in front of your eyes and follow your fingers with your eyes.*

Let the patient practice eye movements.
If it is inconvenient for the patient, other forms of work memory load can be practiced; like tapping on the legs, playing Tettris or tables on saying .... etc.

*You can use this registration form to keep track of how long you have hurt yourself in real life each day and how long you have hurt yourself (imaginary). You can take this form with you the next time you come *.
© Do Doeksen version 1-2018

Study burden and risks

One may ask whether patients will not be given more ideas if the treatment will explicitly refer to self-damaging behavior. For a long time in the media there has been a large taboo on self-damaging and suicidal behavior. This dilemma about whether or not to publish about self-damaging and suicidal behavior goes back to 1774, when a book The Suffering of Young Werther was published by Goethe, in which the protagonist robbed himself of life. In response to this book, a wave of suicides in society followed. This is also referred to as the Werther effect.
Self-harm is also a theme that has been taboo on in care for many years. When it came to providing assistance, the motto was: ignore, then it would eventually pass. An important principle in the book "Dealing with self-harm and suicidal behavior" by de Klerk, van Emmerik and van Giezen (2010) is the theme of giving explicit attention to self-damaging behavior instead of ignoring or trivializing it. Herewith the advice of the National Self-harm Foundation to talk about self-damaging behavior is consistent with (National Self-harm Foundation, 2019). The Ivonne van de Ven Foundation also disagrees with the assumption that when you talk to someone about suicide, you bring the person to ideas. Talking about suicidal feelings can actually give the room to express someone's feelings and receive the support that someone needs. The guidelines for the treatment of suicidal patients state that talking about suicidal thoughts is an essential part of the treatment and the guidelines emphasize that talking to a patient about suicide will not lead to a patient being brought to mind, but that this is often wrongly assumed (A. Kerkhof and B .van Luyn, 2016).

The participants are instructed to register daily for a maximum period of 12 weeks. This is a short registration assignment. In addition, participants are expected to participate in 5 sessions with the "Protocol imaginary conduct of self-damaging behavior". This requires effort from the participants, but this is estimated to be feasible in addition to the therapy that they are already receiving. A risk is that the urge for self-damaging behavior will be felt more strongly, but at the same time the participants will also be taught a skill to deal with this.

Contacts

Public

Fivoor

Fenny ten Boschstraat 23
Den Haag 2553PT
NL
Scientific
Fivoor

Fenny ten Boschstraat 23
Den Haag 2553PT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients diagnosed with a specific personality disorder or an unspecified personality disorder by the DSM-IV or the DSM-5;
- patients who harms themselves sometimes to often;
- patients who feel the urge sometimes to often to harm themselves;
- patients who are in treatment at Centrum Intensieve Behandeling, (clinical group therapy, the closed psychiatric department and the Top Referent Trauma Center)
- patients between 18 and 65 years old;
- patients with a Wester and non-Wester origin;
- patients who speak and understand the Dutch language.

Exclusion criteria

- patients who are diagnosed with a disorder with drugs or alcohol by the DSM-IV or DSM-5;

- patients who are acute suicidal;
- patients who are in a psychosis.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2020
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL70386.028.19