Retraining approach bias in forensic sexual offenders and sexual addicts

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Ethical review Approved WMO **Status** Recruiting

Health condition type Impulse control disorders NEC

Study type Interventional

Summary

ID

NL-OMON42202

Source

ToetsingOnline

Brief title

Forensic sexual offenders

Condition

Impulse control disorders NEC

Synonym

sex addiction, sexual preoccupation

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Kwaliteitsinstituut Forensische Zorg

Intervention

Keyword: addiction, approach bias, intervention, sex

Outcome measures

Primary outcome

Approach bias scores at pre-test and post-test.

Secondary outcome

Sexual preoccupation and sexual behavior.

Study description

Background summary

Within the forensic health services there is demand for objective assessment tools. In this study we test an instrument designed to measure approach bias towards sexual stimuli. It is hypothesized that we will find an approach bias among sexual offenders in forensic health care and among those with a sex addiction. Secondly in this project, an intervention designed to reduce approach bias will be tested. It is hypothesized that the intervention, in comparison to the placebo intervention, will lead to a greater reduction in approach bias among both sexual offenders in the forensic healthcare and sex addicts receiving standard addiction treatment.

Study objective

The main objective of this study is the measurement of approach bias in sex offenders and sex addicts, alongside determining whether the approach bias for sexual stimuli differs between these groups. A further objective is to test an intervention designed to train away the approach bias in sex addicts (*avoidance training*), among both those receiving forensic health care and addiction treatment. Secondary objectives are testing whether the training reduces sexual preoccupation and sexual behaviors and testing whether these reductions are related to a reduction in approach bias.

Study design

The study consists of two parts: A. and observational study, and B. an experimental, double-blind, placebo-controlled study.

Intervention

The intervention is a computerized training, the so-called *avoidance training*. In the training, approach bias for sexual stimulus is trained away. The training consists of six sessions spread over a period of three weeks. During each session the participants complete a training of approximately 20 minutes. The training is a computer task in which the participants see sexual images and control images (nature photographs; landscapes, seas, flowers, etc.). The images are tilted either 5 degrees to the left or to the right. The one half of the participants (from the intervention condition and from the control condition) receives the instructions to push images that are tilting to the left away from themselves by pressing a button on the keyboard (by doing so the image gets smaller, creating the illusion that it is moving away from the participant), and to pull images that are tilted to the right towards themselves (the image gets larger in this case). For the other half of the participants the instructions are reversed. The images that the participants in the intervention condition push away from themselves are the sexual images while the images they pull towards themselves are the nature images. In the control condition, half of the sexual images and the half of the nature images are to be pulled towards the participant, the other half are to be pushed away.

It is expected that the consistent pushing away of the sexual stimuli will lead to a reduction in approach bias and thus faster avoidance of the images. In the control group no changes is expected in the approach bias.

Study burden and risks

There are no safety risks associated with carrying out the computer tasks. In the case of a participant experiencing the procedure as too much of a burden, he or she is permitted to prematurely end his or her participation. The training consists of 9 sessions, 2 of which are in the clinic and 7 of which are done at home. The first and last sessions both take 45 minutes to complete and the other 7 sessions last about 20 minutes. Comparable interventions for substance abuse showed diverse effects among patients and healthy groups; behavioral effects were stronger among patients than among healthier groups. It is for that reason that the intervention is specifically being tested among patients.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Heemraadssingel 194

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Rotterdam 3021DM

NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Heemraadssingel 194 Rotterdam 3021DM NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- 18-65 years old
- males
- sexual offenders in a forensic outpatient treatment
- addiction care outpatients with sex addiction

Exclusion criteria

- psychotic disorder, bipolar I disorder, organic mental disorder
- intellectually disabled
- using psychopharmacological drugs and/or anti-androgen medication
- not speaking Dutch properly
- no Internet access

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

Control: Placebo

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 21-12-2015

Enrollment: 104

Type: Actual

Ethics review

Approved WMO

Date: 19-06-2015

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Approved WMO

Date: 17-11-2015

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

CCMO NL51488.078.14