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Examining biofeedback with sexual offenders with a learning disability

Submission date
07/06/2017

Recruitment status
No longer recruiting

Registration date
12/06/2017

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Emotional dysregulation (ED) is where a person is unable to properly regulate their emotional responses. It can take a number of forms, including displaying emotions which are incompatible with context, avoidance of emotions, or an excess of an emotional state such as anger. The role of emotional dysregulation in sexual offending individuals has been highlighted. In recent years, mindfulness (a way of becoming more aware of the present moment) and in turn biofeedback (a program that teaches individuals how to control automatic bodily reactions and functions), have been considered as a treatment for a variety of disorders. Biofeedback is commonly achieved using computer based programmes that provide feedback on particular bodily processes through use of sensors. This study aims to evaluate the effectiveness of biofeedback in improving emotional regulation in adult sexual offenders with a learning disability.

Who can participate?
Adult men with a learning disability and a history of sexual offending behaviour

What does the study involve?
All participanrts takes part in the biofeedback programme on a one to one basis, in eight sessions over a period of four weeks. The program is delivered using a computer-based programme which uses a sensor attached to the ear lobe to monitor difference in the amount of time between each heartbeat. The programme itself involves a combination of guided breathing exercises accompanied by images. For example, participants match their breathing cycle to images of a butterfly moving its wings. Participants ae encouraged to complete this breathing practice for 10 minutes. Participants are asked to complete a questionnaire – a modified version of the difficulties in emotion regulation scale – eight weeks before treatment, immediately following treatment, and eight weeks after the last treatment session. Participant's behaviour is also monitored in relation to acts of aggression, and sexually inappropriate behaviours using various scales. These behaviours are monitored from eight weeks before treatment starts through until eight weeks after the last treatment session.

What are the possible benefits and risks of participating?
Biofeedback is thought to help people to manage their emotions better, as a result participants may feel calmer following the treatment. Overall there is thought to be no risk of harm

occurring to the participants. Participants may feel lightheaded or dizzy when they are asked to focus on their breathing. Participants will be supported by the Chief Investigator whilst they are receiving the treatment.

Where is the study run from?
Private Healthcare Low Secure Learning Disability Unit – Essex (UK)

When is study starting and how long is it expected to run for?
October 2015 to December 2017

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Miss Emma Gray

Contact information

Type(s)
Public

Contact name
Miss Emma Gray

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_16-135

Study information

Scientific Title
Examining the effectiveness of biofeedback in improving emotional regulation skills in adult sexual offenders with a learning disability - a feasibility study

Study objectives
The aim of this study is to evaluate the effectiveness of biofeedback in improving emotional regulation in adult sexual offenders with a learning disability (LD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Essex Research Ethics Committee, 08/03/2017, ref: 16/EE/0501

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Emotional regulation in sexual offenders with a learning disability

Interventions
The biofeedback intervention will be delivered to all participants on a 1:1 basis, this will be supervised by the Chief Investigator. The intervention will be delivered on eight occasions over a period of four weeks.

The biofeedback intervention will be delivered using “The Wild Divine” “Relaxing Rhythms”, a biofeedback computer based programme (Wilddivine.com, accessed on 27th April 2016). The Wild Divine utilises a sensor attached to the ear lobe to monitor heart rate variability. Heart rate variability refers to the difference in the amount of time between each heartbeat, with the aim of the biofeedback programme to increase heart rate variability (Wilddivine.com, accessed on 27th April 2016).

The process for delivering the biofeedback intervention will be as follows:
When participants arrive the Wild Divine, Relaxing Rhythms programme will already have been installed on the computer. In addition the IOM Sensor Hardware will already have been connected to the computer. Participants will be seated in front of the computer and asked to attach the sensor to their earlobe. The Chief Investigator will then ensure that the hardware is detecting their heart rate by viewing the indicator lights on the hardware.

Once the sensor is properly attached the Chief Investigator will open the Relaxing Rhythms software programme. The guided training practice event will be selected from step one “Quiet your mind”. The breathing cue visual and breathing cue audio will both be turned on. The breathing cycle will be set to 8 seconds initially, however it may be necessary to adjust this for each participant dependent on their own breathing cycle. Efforts will be made to ensure that the participants are set to a breathing cycle that is comfortable for them.

Participants will be oriented to the butterfly visual, and informed that their breathing cycle should match the moving wings on the butterfly, i.e. breathing out as the wings open, and breathing in and the wings close. They will also be informed of the small chime which sounds on the changing of the breathe cycle, and that they should bring their breathing in line with this sound.

Participants will be encouraged to complete this breathing practice for 10 minutes. Once the breathing practice has started the Chief Investigator will place themselves in the corner of the room, out of sight of the participant, however will remain in the same room throughout and will monitor the wellbeing of the participant throughout the breathing practice.

Upon completion of the 10 minutes the Chief Investigator will close the Relaxing Rhythms programme, and instruct the participant to remove the sensor from their earlobe.

Participants are followed up post-treatment, and eight weeks following the completion of treatment.

Intervention Type
Other

Primary outcome measure
Emotional regulation will be measured using a modified version of the Difficulties in Emotion Regulation Scale (DERS) eight weeks prior to commencing treatment, post-treatment, and eight weeks following the completion of treatment.

Secondary outcome measures
1. Aggression is assessed using The Modified Overt Aggression Scale (MOAS) from a review of the clinical notes in the eight weeks prior to commencing treatment, during the treatment period, and in the eight weeks following the completion of treatment
2. Inappropriate sexual behaviours are recorded objectively using the St Andrews Sexual Behaviour Assessment Scale (SASBA) from a review of the clinical notes in the eight weeks prior to commencing treatment, during the treatment period, and in the eight weeks following the completion of treatment

Overall study start date
01/10/2015

Completion date
30/12/2017

Eligibility

Key inclusion criteria

1. Adult males aged between 18 years and 65 years
2. Learning disability
3. History of sexual offending behaviour (regardless of whether this has resulted in criminal conviction)
4. Already detained in a private healthcare low secure unit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
8

Key exclusion criteria
1. No history of sexual offending behaviour will be excluded from the study
2. No formal diagnosis of a learning disability will be excluded
3. Not already detained in the identified low secure unit
4. Female
5. Younger than 18 or older than 65 years of age
6. Lacking the capacity to consent

Date of first enrolment
01/06/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Private Healthcare Low Secure Learning Disability Unit - Essex
Oaktree Manor
Heath Road
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CO16 0BX

Sponsor information

Organisation
University of Birmingham

Sponsor details
The University of Birmingham
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/07/2018

Individual participant data (IPD) sharing plan
The dataset will not be made available as participants are not being asked to consent to this. The data will be held by the Chief Investigator at the testing site.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/05/2019	10/05/2021	Yes	No
HRA research summary			28/06/2023	No	No