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The effects of virtual reality exposure therapy (VRET) to treat dental anxiety

Submission date
17/10/2015

Recruitment status
No longer recruiting

Registration date
26/10/2015

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dental anxiety is a recognised phobia, which involves a fear of going to the dentist and receiving dental treatment. It is very common and can affect people of any age, ranging from a slight fear to a crippling phobia which means that people avoid going to the dentist at all costs. Virtual reality exposure therapy (VRET) is a type of therapy which is commonly used to treat patients with anxiety disorders, such as phobias. The therapy involves using computers to immerse patients in a virtual world, in which they are exposed to sounds and images which trigger their phobia (fear-inducing stimuli). Over time, patients are exposed to stronger stimuli under the supervision of a therapist. This allows the patient to become “used to” the fear-inducing stimuli, so that eventually they stop triggering anxiety. This type of therapy has shown promising results in treating other phobias as it is safer and less expensive than by directly exposing patients to the things that they are scared of (direct confrontation therapy). The aim of this study is to find out whether VRET is an effective way of helping patients who suffer from dental anxiety.

Who can participate?
Adults who have a dental phobia and are in need of dental treatment which will last for less than 30 minutes.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group (intervention group) take part in the VRET. Participants are exposed to five different scenarios, during which their levels of distress are measured every 35 seconds. Each scenario is repeated until it stops causing the participant distress. Those in the second group (control group) are given an information pamphlet, which includes information about dental anxiety and what to expect from a visit to the dentist for a dental procedure. At the start of the study and then again after 1 week, 3 and 6 months, participants take a number of questionnaires in order to find out whether their anxiety levels have changed. Those in the VRET group are also given a questionnaire about their experiences with the virtual reality therapy.

What are the possible benefits and risks of participating?
A benefit of taking part is that participants will be able to learn more about what causes their anxiety which could help to reduce their level of anxiety and stop them from avoiding dental

visits in the future. There are very few risks of taking part however the virtual reality therapy may cause simulator sickness (a type of motion sickness) in some participants. Precautions against this will be taken by giving patients regular breaks from the therapy.

Where is the study run from?
Oral Health Centre, SEGi University (Malaysia)

When is the study starting and how long is it expected to run for?
March 2014 to June 2016

Who is funding the study?
ACTA Amsterdam (Netherlands)

Who is the main contact?
Dr Kumar Raghav Gujjar

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation and comparison of the effectiveness of Virtual Reality Exposure Therapy (VRET) with an information pamphlet in management of Dental Anxiety patients

Acronym
VRETDA

Study objectives
Virtual Reality Exposure Therapy (VRET) would result in a significantly reduced level of dental anxiety (trait and state anxiety) at 1 week, 3 months and 6 months follow-up compared to the informational pamphlet control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
SEGi University, Research and Innovation Management Centre Ethics Committee, 22/05/2014, ref: EC01/14-01

Study design
Interventional randomised controlled trial with two study arms and single-centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dental anxiety

Interventions
Thirty participants undergo block randomization so that we have equal distribution of participants in both the groups. In order to preserve the allocation concealment, sealed, opaque, sequentially numbered envelopes (SNOSE) are used. Envelopes will be opened serially (next highest number) only after the participant details (patient unique number, date and patient signature) are entered on the envelope.

VRET group: The participants in this group are exposed to five different VR scenarios sequentially in a pre-determined hierarchy (Idle, Mirror, Syringe, Drill with no sound and Drill with sound). During the exposure session the level of discomfort/distress is assessed using Subjective Units of Distress (SUD) scale every 35 seconds. The exposure with each VR scenario is repeated until a SUD score of ≤2 is obtained before proceeding to the next scenario. Also, the

heart rate is monitored continuously during the exposure to determine the physiological response during VRET. Further, the VR experience is evaluated during and following VRET.

Informational Pamphlet control group: Participants in this group will receive a pamphlet of three pages containing information about dental anxiety. The pamphlet will contain details about the standards of care such as patient comfort, description of dental procedures and postoperative pain management. Also, an opportunity is given to the participants to ask the researcher information about dental anxiety.

Intervention Type
Behavioural

Primary outcome measure
Dental anxiety measured using Visual Analogue Scale-Anxiety (VAS-A), Modified Dental Anxiety Scale (MDAS) and Dental Fear Survey (DFS) questionnaires at baseline, after the intervention, 1 week, 3 months and 6 months follow-up.

Secondary outcome measures
1. Avoidance measured using a behavioral test, consisting of observations and an interview asking participants to rate their level of anxiety from 0-10, before and after intervention
2. Physiological arousal measured by recording the heart rate continuously during the VRET session
3. VR-experience measured with questionnaires (presence, sensation of vomiting, intention to use VR googles in the future and about their intention to revisit dental surgery) immediately after the VRET session

Overall study start date
01/03/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years
2. Patients meeting the DSM-4 diagnostic criteria of dental phobia
3. In need of a dental treatment with a planned maximum treatment length of 30 minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Stereoblindness
2. Known other mental disorders such as psychosis, post-traumatic stress disorder, developmental or intellectual disability and cognitive impairment
3. Hearing impairment
4. Visual impairment
5. Nystagmus
6. Known balance disorders such as vertigo and cybersickness
7. Patients with previous history of epileptic seizures
8. Any history of cardiac problems
9. Patients who are undergoing/have undergone any cognitive behavioural therapy (CBT)-based intervention
10. Language impediment (cannot understand English)
11. Patients wearing glasses of greater than plus 3.5 power

Date of first enrolment
28/10/2015

Date of final enrolment
17/03/2016

Locations

Countries of recruitment
Malaysia

Study participating centre
Oral Health Centre, Faculty of Dentistry, SEGi University
No. 9, Jalan Teknologi
Taman Sains Selangor
Kota Damansara
Petaling Jaya
Malaysia
47810

Sponsor information

Organisation
ACTA Amsterdam

Sponsor details
Gustav Mahler Laan 3004
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1081

Sponsor type
Other

ROR
https://ror.org/04x5wnb75

Funder(s)

Funder type
University/education

Funder Name
ACTA Amsterdam

Results and Publications

Publication and dissemination plan
Publication of study results in a peer-reviewed journal.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/02/2016		Yes	No
Results article		01/03/2019	27/10/2022	Yes	No