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The effects of the use of virtual reality (VR) during dental treatment

Submission date
08/07/2013

Recruitment status
No longer recruiting

Registration date
02/08/2013

Overall study status
Completed

Last Edited
23/10/2018

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Dental anxiety and avoidance of dental care due to anxiety cause major problems for both patients and dentists. Various distraction methods are used in daily medical practice to help patients cope with unpleasant procedures, but there is evidence that Virtual Reality (VR) distraction is more effective than other distraction methods. The main aim of the project is to find out if the use of VR during dental treatment can improve the overall dental experience and recollections of treatment for patients, breaking the negative cycle of memories of anxiety leading to further anxiety, and avoidance of future dental appointments. Additionally, the aim is to test whether the use of VR is suitable for dental patients with all levels of dental anxiety. The third aim is to test if the content of the VR distraction can make a difference by comparing two types of virtual environments, a natural area and an urban area.

Who can participate?
Patients who are scheduled to undergo dental treatment will be invited to take part in the study.

What does the study involve?
After the pre-operative treatment appointment or annual check-up, patients will complete an initial questionnaire. During the dental treatment visit, the patient might be asked to wear some special goggles that will enable watching a VR scene. Whether a patient will be allocated to a VR group or a control group will be decided by a process called 'randomisation', which is like a coin toss. Following the appointment the patient will complete a questionnaire about the treatment experience. Patients will receive a phone call one week after treatment and will be asked to answer a few more questions.

What are the possible benefits and risks of participating?
We cannot promise the study will help you, but the information from this study may help improve the care provided to patients who experience anxiety regarding dental treatment in the future. However, some people may find that their dental experience is more pleasant and induces less anxiety than usual. There is little physical risk to participants involved in this project. Using the VR goggles and controller will not be for a long enough period to become a problem. Some people may have feelings of nausea when using the VR system. Patients will be informed

that this may occur and that they should inform the dentist if they start feeling nauseous so the VR session can be stopped. Withdrawal during dental treatment won't affect the dental treatment; it only involves taking the VR goggles off the patient and taking back the controller from the patient. Patients are informed that they are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care they receive.

Where is the study run from?
The study takes place at Torrington Dental Practice in Greater Torrington, UK.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in August 2013 and finish by the end of 2014.

Who is funding the study?
Plymouth University, UK.

Who is the main contact?
Dr. Karin Tanja-Dijkstra
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
The effects of virtual reality distraction during dental treatment: a first test of the elaborated intrusions account

Study objectives
It is hypothesised that exposure to virtual reality during dental treatment will lead to improved recollections of treatment and an overall improved dental experience.

On 06/02/2014 the overall trial end date was changed from 31/12/2013 to 31/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee West Midlands - Coventry & Warwickshire, 10/05/2013, ref: 13/WM/0152

Study design
Three group randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will be randomised to three groups:
Two intervention groups: Two VR interventions will be investigated in this study. The first VR environment consists of a simulation of a natural area. The second VR environment consists of a simulated urban environment.
In both groups, patients will be wearing VR goggles and will use a one-handed controller to navigate the environment.
Control group: The patients in the control group will receive standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The memories of patients about the dental treatment one week after treatment, consisting of
1.1. Remembered pain
1.2. Intrusive thoughts
1.3. Vividness of memories
2. Dental experience
3. Treatment experience
4. VR experience

Key secondary outcome(s)
1. Treatment experience [pain, discomfort, stress - self-reported questionnaire and a physiological indicator (heart rate, measured with a pulse oximeter), time perception, perceived control]
2. Dental experience (communication with dentist, revisit intentions and likeliness of avoidance,

dental anxiety, treatment satisfaction)
3. VR experience (presence, perceived restoration, attractiveness, environmental awareness, nausea, intention to use VR)

All outcomes are measured using self-reported questionnaires.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
All patients, 18 years or older, who are scheduled to undergo dental treatment for fillings and/or extractions with a planned maximum treatment length of 30 minutes are eligible to participate in the study. This includes both referred patients and in-house patients. Both patients who need relative analgesia (RA) and who are treated without sedation will be included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who need intravenous sedation
2. Patients who had epileptic seizures in the past cannot participate in the study due to the very small risk an episode can be triggered by using the HMD, similar to what may happen if they are exposed to a television
3. If a patient is scheduled for more than one treatment during the trial period, the patient will only be included for the first treatment

Date of first enrolment
16/08/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plymouth University
Plymouth
United Kingdom
PL4 8AA

Sponsor information

Organisation
Plymouth University Peninsula Schools of Medicine and Dentistry (UK)

ROR
https://ror.org/04dtfyh05

Funder(s)

Funder type
University/education

Funder Name
Plymouth University (UK)

Alternative Name(s)
University of Plymouth, Plymouth Polytechnic, Polytechnic South West, Exeter College of Art and Design, Seale-Hayne College

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/03/2014		Yes	No
Protocol article	protocol	22/03/2014		Yes	No
HRA research summary			28/06/2023	No	No