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Comparative Evaluation of Virtual Reality and Behavioural Counselling on Reducing the Anxiety in Patients during the Dental Treatment

Shailendra Yadav [a†], Muskan Fatema Khan [a†], Shreya Makkasare [a†], Kumar Gaurav Chabbra [a*‡] and Priyanka Paul Madhu [a¥]

[a] Public Health Dentistry, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences(DU), Sawangi (Meghe), India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Anxiety is an enthusiastic state of mind which goes before an experience with feared object or circumstances. The main pharmacological treatment for reducing dental anxiety is local anaesthesia but it involves an injection with a needle prick which is refused by quiet patient. Some techniques were put forward to minimize the suffering during dental treatment such as diversion techniques, TV and hypnotism rather than pharmacological means. Virtual Reality (VR) is a three-dimensional domain that provide users a perception of submission, leading them to an interactive area.
Objectives: To distract mind with virtual reality, that has quite less access to handle approaching pain and anxiety signals and to minimize patient discomfort and uneasiness during dental treatment.
Methodology: The study will be conducted among patients reporting to Out Patient Department of Sharad Pawar Dental College and Hospital eligible patients who meet the eligibility criteria will take part in the trial. The study will be conducted between two groups and the anxiety scale will be

[†]BDS Intern;
[‡]HOD;
[¥]Assistant Professor;
**Corresponding author: E-mail: rajsushil.chabbra@gmail.com;*

calculated pre-test and post-test for each patient. One group of patients are given VR and the other group is given behavioural counselling before beginning of dental treatment.
Results: Virtual reality, a diversion is believed to assist users to get through by other unpleasant events during dental treatment. On application of virtual reality considerable decrease in anxiety is expected.
Conclusion: Virtual reality can be used to decrease anxiety during medical and dental treatment which can affect patients desire towards the treatment. Distractions may also have enduring effect in regards to more favourable impression of therapy.

Keywords: Virtual reality; anxiety; distractions.

1. INTRODUCTION

Background and rationale: In medical and dental procedures, patient agony and uneasiness are undesirable, influencing the patient's interest in the treatment and also hampering his/her willingness to treat [1]. Apprehension is an enthusiastic situation which goes before an experience with a feared object or circumstance, though fear refers to the genuine, or 'activated', reaction to the object or circumstance. It is generally the case, in any case, that an individual will have a fear reaction to something that they encounter anxiety around. Both fear and anxiety can include physiological, cognitive, passionate and behavioural components, in spite of the fact that how these are communicated may possibly change from one individual to another [2].

A few strategies, to alleviate patient discomfort and anxiety during dental treatment, both pharmaceutical and psychological interventions can be used [3]. Local anaesthetic is the most often used pharmacological technique to alleviate dental anxiety. Local anaesthetic necessitates a needle injection into the jaw, and be quite patient deny it since they consider the infusion painful and avoids the needle. Vexatious early dental/medical incidences can influence the healthcare experience of patients, during subsequent medical and dental visits, can increase pain and suffering, and can reduce further visits that can also lead to reduced preventive healthcare, impacting lifelong health [16-18]. Ironically, if a patient ignores a dental surgery that was first treated as a tooth filling is remain unattended, it can lead to slow tooth deterioration, necessitating tooth extraction or root canal treatments [4]. Control techniques were suggested to help children and adults suffer less during dental procedures, including distraction, modelling and hypnotism rather than pharmacological means [5,6].

Virtual reality (VR) is a three-dimensional world that has Head Mounted Display (HMD) more completely immerses the subject in virtual world that offers patients a sense of presence by transporting them to a fun and engaging environment [7]. The illusion of a person remains at the centre of interactive virtual reality moving under a three-dimensional artificial world, as if a person were gazing into a virtual world [8,9]. The use of virtual reality for medical and mental health purposes has grown in popularity during the last 20 years [10,11,12]. There are many variables that affect our experience, including our thoughts and feelings.

1.1 Objectives

- To evaluate the anxiety level for dental procedures pre-intervention among participants of both the groups.
- To evaluate the anxiety level of the participants, post-intervention among both the group.
- To evaluate intragroup comparison of the anxiety level on pre-intervention and post-intervention of each group.

To evaluate intergroup comparison of the anxiety level.

2. METHODOLOGY

This randomized controlled trial will be conducted amongst 30 patients, who will visit Sharad Pawar Dental College, Sawangi (Meghe) Dist.-Wardha. The duration taken will be 1 year. It is a single blinded study as the investigator is blinded in the study. The patients who match the study's eligibility requirements will be enrolled. Anxiety scale will be calculated pre- and post-testing for each patient. A randomized controlled trial will be conducted between two groups. One group of patients will be given VR from beginning of dental procedure during the administration of

local anaesthesia until the completion of the treatment. The preferred dental procedures are root canal treatment first visit while access opening. The other group of participants will be given behavioural counselling before the beginning of the dental treatment.

2.1 Eligibility Criteria

2.1.1 Inclusion criteria

- Age: 18-25 years
- Anxiety scale: 5 to 15
- Informed consent
- Dental treatment: Local Anaesthesia and Root canal Treatment

2.1.2 Exclusion criteria

- Anxiety scale: <5 & >15
- Medically compromised

2.2 Interventions

Between two groups, a randomised controlled trial will be undertaken. Anxiety scale will be calculated pre- and post-intervention. One group of patients will be given VR from begging of the procedure. The other group will be given behavioural counselling.

Concurrent care and treatments that are allowed or not allowed during the study.

2.3 Participant Timeline

The duration of study conduction is 1 year.

2.4 Sample Size

Sample size is determined using the following formula:

$$\mathbf{n = (z_{\alpha/2}^2 \times \sigma^2) / E^2}$$

where,

σ= previous expected values=16
E =desired Margin of error = 5
$z_{\alpha/2}$, confidence interval of 90%, z = 1.65
n = sample size

Substituting the values in the formula:

$$\mathbf{Sample\ size\ n = ((1.65)^2 \times (16)^2) / (5)^2 = 27.87}$$

With above mentioned calculation, sample size determination is 27 in number and considering drop outs, the sample size is determined to be 30. The total minimum sample size with 90% of confidence interval is 15 for each group. The study is divided into two groups which will include 15 in each group.

3. METHODS

Allocation: Inclusion Criteria**:**

- Age: 18-25 years
- Anxiety scale: 5 to 15
- Informed consent
- Dental treatment: Local Anaesthesia and Root canal Treatment

The patients from the OPD of Sharad Pawar Dental College will be selected for the study with randomization, in which those patients that agree to participate will be allowed to take part in the study.

Allocation concealment mechanism: The samples are randomly selected from OPD. Patients with Anxiety scale: >5 will be included in both the groups.

Implementation: The patients will be assigned by the assistant of the principal investigator.

Blinding (Masking): The patients who match the study's eligibility requirements will be enrolled. Procedural bias will be avoided by single blinding method.

Data Collection Methods: The outcome will be collected using a questionnaire before and after the intervention which will be enrolled in MS Excel sheet.

4. STATISTICAL METHODS

Analysis Required: It will be statistically analysed by SPSS software version 22. Descriptive analysis and frequency distribution will be done for demographic details. A Paired T test will be done for evaluating the difference between the two groups A and B pre and post intervention. The effectiveness of the VR will be measured by chi square statistics.

1. Intergroup comparison will be done by unpaired 'T' test between group A and group B.

2. Intra-group comparison will be done by paired 'T' test between pre-test and post-test between each group.
3. Descriptive statistics and Chi square analysis to determine association of anxiety reduction with Age, Gender, Education level on application of VR and behavioural counselling method.

Description of any intermediate assessments and terminating procedures, as well as who will have access to these intermediate data and make the final decision to end the experiment.

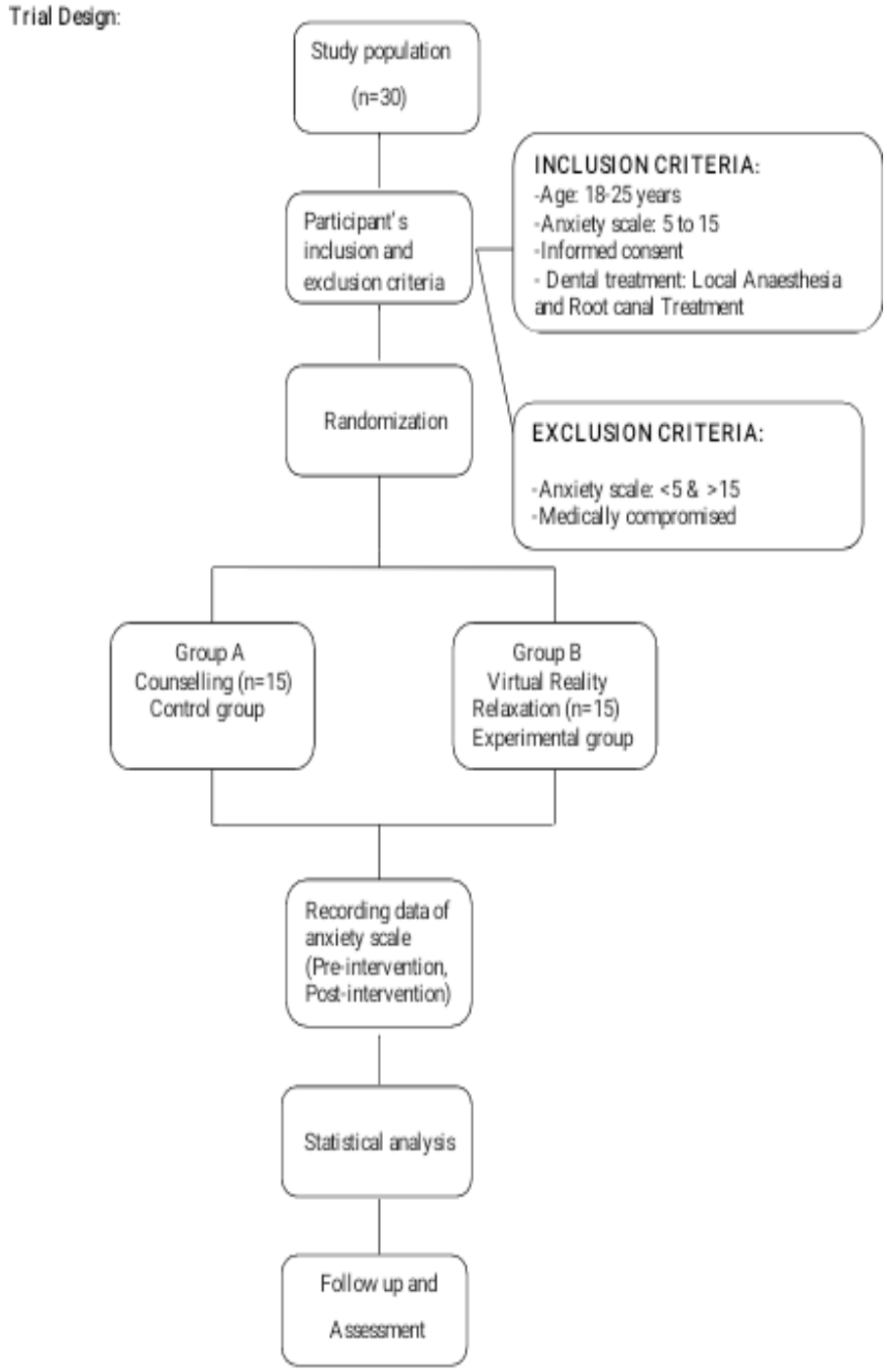

Fig. 1. Trial design

5. EXPECTED RESULTS

On application of virtual reality a paramount remarkable decrease in anxiety is expected, with respect to the theoretical observation and analysis. According to Karin Tanja-Dijkstra et al who performed a research in ICREA-University of Barcelona, Spain on March 12, 2014 which analysed the dental anxiety between the patients and dental profession. This study therefore can indicate that VR diversions may be seen as an important modulation of care cycles where prior meetings impact their behaviour for future opportunities [13].

6. CONCLUSION

Virtual reality can be used in decreasing agony and uneasiness which is undesirable in medical and dental procedures, which can affect the desire of the patient to do the treatment [14-19]. Virtual reality, a diversion is believed to assist user to get through by other unpleasant and is united with relaxation and pleasant images. Distraction may also have enduring effect in regards to more beneficial impressions of therapy and this heading to pronounced readiness to the treatment modalities.

CONFIDENTIALITY

Before, during, and after the study, personal details regarding eligible participants will be gathered, exchanged, and stored in order to ensure confidentiality.

AVAILABILITY TO DATA

The data is accessed by the principal investigator.

CONSENT

Potential study participants or authorised advisers will be asked for consent form or permission by the lead researcher and associate researcher.

ETHICAL APPROVAL

The research has been approved by the Institutional Review Board.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX

MODIFIED DENTAL ANXIETY SCALE:

The severity of dental anxiety of the patients will be assessed using Modified Dental Anxiety Scale which includes following Five Questions [15].

1. If you went to your dentist for treatment tomorrow, how would you feel?
   Not anxious ☐ Slightly anxious ☐ Fairly anxious ☐ Very anxious ☐ Extremely anxious ☐
2. If you were sitting in the waiting room (waiting for treatment), how would you feel?
   Not anxious ☐ Slightly anxious ☐ Fairly anxious ☐ Very anxious ☐ Extremely anxious ☐
3. If you were about to have a tooth drilled, how would you feel?
   Not anxious ☐ Slightly anxious ☐ Fairly anxious ☐ Very anxious ☐ Extremely anxious ☐
4. If you were about to have your teeth scaled and polished, how would you feel?
   Not anxious ☐ Slightly anxious ☐ Fairly anxious ☐ Very anxious ☐ Extremely anxious ☐
5. If you were about to have local anaesthetic injection in your gum, above an upper back tooth, how would you feel?
   Not anxious ☐ Slightly anxious ☐ Fairly anxious ☐ Very anxious ☐ Extremely anxious ☐

Not anxious = 1
Slightly anxious = 2
Fairly anxious = 3
Very anxious = 4
Fairly anxious = 5
Total score is a sum of all five items, range 5-25: cut off is 19 or above which indicate highly dentally anxious patient, possibly dentally phobic.

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