**Full Online Report**

**Virtual Reality Exposure Therapy for the Treatment of Dental Phobia: A Controlled Feasibility Study**

**Running title:** VRET in treatment of dental phobia.

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**ABSTRACT**

**Background:** Virtual Reality Exposure Therapy (VRET) has been used to treat a variety of fears and phobias.

**Aim**: To determine the feasibility (i.e., safety and efficacy) of using VRET to treat dental phobia.

**Method:** Safety was evaluated by determining any adverse events or symptom exacerbation. Efficacy of VRET was evaluated by comparing the reduction in dental anxiety scores (measured 16-times within a 14-week study period, and at six-month follow-up), and its behavioral effects, with that of an Informational Pamphlet (IP) on ten randomized patients with dental phobia using a controlled multiple baseline design. Participants’ heart rate response during VRET, and their experience post-VRET were indexed.

**Results:** No personal adverse events or symptom exacerbation occurred. Visual analysis and post-hoc intention to treat analysis showed a significantly greater decrease in dental anxiety scores [higher PND (Percentage of Non-Overlap Data) scores of 100% and lower POD (Percentage of Overlap Data) of 0%, MDAS, F (1, 8) = 8.61, p = 0.019, and DFS, F (1, 8) = 10.53, p = 0.012], and behavioral avoidance in the VRET compared to the IP group [*d*= 4.2 and -1.4, respectively)]. There was no increase in average heart rate during VRET. Of the nine treatment completers, six (four from the VRET group and two from the IP group) no longer had dental phobia at 6-month follow-up. Four of the five VRET participants, but none of the IP participants, scheduled a dental treatment appointment following the intervention.

**Conclusion:** VRET is a feasible alternative for patients with dental phobia**.**

# **Keywords:** Dental phobia, Dental Anxiety, Diagnostic and Statistical Manual of Mental Disorders, Specific phobia, Virtual Reality Exposure Therapy.

**INTRODUCTION**

Research suggests that about 25% of the population suffers from a fear towards specific dental procedures, whereas about 4% fulfills the criteria for dental phobia (Oosterink, de Jongh, & Hoogstraten, 2009). Because the resultant avoidance towards dental treatment could have considerable impact on both oral and general health (Schuller, Willumsen, & Holst, 2003), timely management of dental phobia is central to improving dental attendance and quality of life.

Cognitive behavioral therapy (CBT), in the form of in vivo exposure therapy (IVET), is the treatment of choice for fearful dental patients (Gordon, Heimberg, Tellez, & Ismail, 2013) (Wide Boman, Carlsson, Westin, & Hakeberg, 2013). More recently, Virtual Reality Exposure Therapy (VRET) has gained acceptance in the treatment of a wide variety of fears and specific phobia (Botella, Baños, Villa, Perpiñá, & García-Palacios, 2000; Garcia-Palacios, Hoffman, Carlin, Furness, & Botella, 2002; Muhlberger, Wiedemann, & Pauli, 2003; Powers & Emmelkamp, 2008). This treatment involves exposure to individual’s fear provoking objects and situations using a computer-generated environment in a well-controlled graded manner, until extinction occurs (Krijn et al., 2004a; Krijn, Emmelkamp, Olafsson, & Biemond, 2004b).

There are a number of potential advantages of VRET over IVET. Firstly, VRET is safe and acceptable as the patients face a credible, virtual counterpart of their fear-eliciting stimuli in a gradual and controlled manner (McLay et al., 2012) at their own pace (Baus & Bouchard, 2014), and under the privacy of the therapist’s office. (North, North, & Coble, 1997). Secondly, VRET is flexible as the therapist can adapt the exposure based on the fear hierarchy of an individual (Gregg 2007). Thirdly, VRET may be a cost-effective therapy as it can be repeated a number of times as per the needs of the patient (Baus & Bouchard, 2014). However, high initial costs of the Virtual Reality (VR) equipment and software, resources for basic training of personnel and cybersickness are some of the potential barriers in the use of VRET (Gregg & Tarrier, 2007; Krijn et al., 2004b).

Regarding the effectiveness of VRET, it has been found that this treatment approach is equally effective (Valmaggia et al., 2016) or slightly more effective than IVET in the treatment of specific phobias. For example, a meta-analysis (Powers & Emmelkamp, 2008) indicated that VRET yielded better results than IVET in the treatment of specific phobias, including fear of flying (Rothbaum et al., 2006), acrophobia (Emmelkamp et al., 2002), social phobia (Klinger et al., 2005), and panic disorders (Botella et al., 2007). However, until now VRET has yielded only limited support as a treatment for dental phobia. Although a recent case study on two patients with dental phobia reported that VRET was effective in reducing avoidance towards dental treatment (Gujjar, Sharma, & de Jongh, 2017), controlled research is lacking.

The purpose of the present study was, therefore, to evaluate the feasibility, in terms of safety and efficacy, of applying VRET on a sample of dental phobic patients. Primary aims were to evaluate safety by determining any adverse events or symptom exacerbation after intervention with VRET and, to determine the efficacy of VRET by comparing the reduction in dental anxiety and its behavioral effects with that of an Informational pamphlet (IP) control condition, using a controlled multiple baseline study design. Secondary aims were to examine the real-time heart rate (HR) response of participants during VRET, and to evaluate patients’ quality of VR experience (presence, realism and cybersickness) post VRET. The first hypothesis of the study was that no adverse events or symptom exacerbation would be reported following VRET. The second hypothesis was that the application of VRET would be associated with a lowered state anxiety, trait dental anxiety and behavioral avoidance compared to IP. We also hypothesized that the application of VRET would be associated with a significant reduction in patients’ mean heart rate, and that participant’s experience high level of presence and realism, with low level of cybersickness post VRET. Also, the proportion of patients meeting DSM-IV criteria for dental phobia and number of patients scheduling dental appointment would be significantly greater in the VRET condition than in the IP condition.

**METHOD**

*Participants and design*

The study protocol was approved by the ethical board of SEGi university, Malaysia (Reference: EC01/14-01). The authors abided by the ethical principles of psychologists and code of conduct as set out by the American Psychological Association while conducting this research. The present study is a pilot feasibility study for a randomized controlled trial which is registered with International Standard Randomized Controlled Trial Number (Identifier: ISRCTN25824611). Participants were recruited from the outpatient service of the Oral Health Centre of the Faculty of Dentistry of the SEGi University in Malaysia. Patients who had not visited the dentist since the past 12 months, or reported anxiety and avoidance of dental procedures or both, were screened for the presence of dental phobia using the Modified Dental Anxiety Scale (MDAS). Patients with a MDAS score ≥ 15 (n=56), who provided informed consent, were interviewed using the Phobia Checklist (Oosterink et al., 2009). The checklist was administered during screening and at 6-month follow-up. The inclusion and exclusion criteria, the participant recruitment process and measures used at different phases of the study are enumerated in Online Figure-1.

Ten participants (six females and four males) were eligible to participate in the present study. Out of ten participants, eight were Chinese, two were Malay and two were Indian. Eligible participants were randomized (1:1 allocation ratio) to either the VRET condition or an informational pamphlet (IP) control condition using a sealed, opaque, sequentially numbered envelopes (SNOSE) allocation concealment method (Doig & Simpson, 2005). Safety of using VRET was evaluated by determining any adverse events or symptom exacerbation after intervention. A non-concurrent multiple-baseline design (Herson & Barlow, 1976) across subjects was used to evaluate the efficacy of the interventions. This design is often employed to study behavior outcomes of ten or fewer participants (Graham, Karmarkar, & Ottenbacher, 2012). The treatment condition is initiated at different time points for different participants, which allows one to conclude that the outcomes are a result of the treatment rather than merely temporal effects (Christ, 2007). Internal validity of the data in multiple baseline study designs is assured by the evaluation of formative data collected at multiple time points (Christ, 2007). In our study, participants from both groups were randomly assigned to one of the baseline periods (5, 6, 7, 8, and 9 weeks) as shown in Online Table 1. After completing the baseline duration, the participants were administered their respective interventions. Participants 1-5 (P1-5) received VRET while, Participants 6-10 (P6-10) received IP.

The outcome measures of interest in this study were state anxiety, measured using a Visual Analogue Scale-Anxiety (VAS-A) (Luyk, Beck, & Weaver, 1988), dental trait anxiety, indexed by both the Modified Dental Anxiety Scale (MDAS) (Humphris, Morrison, & Lindsay, 1995) and the Dental Fear Survey (DFS) (Kleinknecht, Klepac, & Alexander, 1973), and behavioral avoidance, using a behavioral avoidance test (BAT) (Doering, Ohlmeier, de Jongh, Hofmann, & Bisping, 2013). The questionnaires to record state and trait dental anxiety scores were sent via email within a 14-week study period, and once again at 6-month follow-up as shown in Online Table 1. The BAT was administered twice: pre-and post intervention, and the number of situations the participant was able to tolerate was noted as depicted in Online Table 2 and 3. Participants were asked to rate their anxiety repeatedly during the VRET session, from 0 to 10, on the Subjective Unit of Distress Scale (SUDS) (Wolpe, 1969). Each situational cue was repeatedly administered until the participant reported a SUDS score ≤ 2, after which the next cue was introduced (Raghav et al., 2016). The participants were unaware of this criterion. During the VRET intervention, the participants’ HR was continuously monitored. Post VRET, the participants were observed for 15 minutes to preclude any adverse events, and were assessed for the quality of their VR experience namely presence, realism and cybersickness (Hoffman et al., 2001) measured using 11-point Numerical Rating Scales (NRS) as shown in online table 2, where 0= No presence, realism or Cybersickness and 10= Pronounced presence, realism or Cybersickness. Additionally, patients’ intentions to undergo VR therapy in the future and revisiting the dental office for their dental treatment were also evaluated (Yes/No response).

At 6-month follow-up all participants were reevaluated for dental phobia using the Phobia Checklist (Oosterink et al., 2009) and for any symptom exacerbation. We also determined the number of participants who scheduled a dental appointment following the intervention. All outcome measures and the temporal sequence of these assessments are shown in Online Tables 2 and 3.

*Intervention*

1. VRET group*[[1]](#footnote-1)*

VRET was administered by KR, who was trained in administering VRET by a resource person from Virtual simulations Inc., Québec, Canada (developer of the VRET software). All VRET sessions were videotaped and the coauthors watched the videos to assure treatment integrity.

VRET participants were seated in the dental chair and assisted in wearing the head mounted device (HMD), and the heart rate (HR) wrist band. The baseline HR was recorded for ten minutes with no VRET display. After 10 minutes, the VR system and the HMD were turned ‘ON’ to show a three dimensional (3D) stereoscopic scene of a virtual dental operatory to the participant. The built-in motion tracker in the HMD allowed the participants to look around the virtual dental operatory by turning their head. The participants were also able to see their own virtual counterpart (participant avatar) and a virtual dentist avatar. After making the participants watch the simulated dental environment for two minutes to facilitate orientation, situational cues enacted by the dentist avatar in the VR environment were introduced in the following order:

1. Sitting passively on the dental chair (no tools).
2. Inspection of the oral cavity using mouth mirror.
3. Introduction of an injection.
4. Introduction of drill without sound
5. Introduction of drill with sound

Through scenario #2 to #5, participants were requested to keep their mouth open. All participants received the therapy in one session.

1. *Informational Pamphlet (IP) group*

Participants in the Informational Pamphlet (IP) group received a pamphlet containing information compiled from the Academy of General Dentistry fact sheet on dental anxiety (Academy of General Dentistry, 2010). It included standard information such as a description of dental procedures, and postoperative pain management, to help patients overcome their dental anxiety. Participants were seated in the same area where they completed the self-reported measures, and were given time to review the pamphlet in detail and ask the researcher questions related to their dental anxiety.

**ANALYTIC STRATEGY**

Analysis of primary outcome measures involved the assessment of a) Safety of using VRET by evaluating the participants for any adverse events following therapy and for any symptom exacerbation during the follow-up and b) Efficacy of VRET in comparison with IP, by performing a visual analysis for the dependent measures VAS-A, MDAS and DFS prior to, during and after interventions for measuring changes relative to the baseline phase using the method of Lane and Gast method (Lane & Gast, 2014). Also, BAT scores and steps within the treatment conditions were compared using paired-samples t-tests.

Analysis of secondary outcome measures involved the evaluation of a) trend of mean scores of HR of the different VR scenarios that were graphically plotted and b) VR experience (presence, realism and cybersickness) with descriptive statistics (means and standard deviation). Additionally, the number of participants who no longer met the criteria for dental phobia after 6 months, and the number of participants who had scheduled a dental appointment within the past 6 months, were noted. All analyses were conducted using SPSS (IBM, version 23, Chicago IL, USA).

**RESULTS**

The mean age of the participants was 28.5 years (SD=14.1). All participants completed the study except one (IP group, P-7), who did not respond to the questionnaire that was mailed to the participants after the 9th week of the study.

*Safety of VRET*

No adverse events or symptom exacerbation were reported post-therapy. In addition, no participant dropped out in VRET group.

*Analyses for state anxiety and dental trait anxiety*

All the results from the visual analyses are reported in the Online Tables 4-6 and Online Figures 2-4. The analysis revealed stability of both groups before the intervention (more than 80% of the data were within 25 % of the median) with all dependent measures. There were clear differences in the absolute, relative, median and mean level changes in the VAS-A, MDAS and DFS scores after interventions. Further, the majority of VRET group participants showed higher PND (Percentage of Non-Overlap Data) scores of 100% and lower POD (Percentage of Overlap Data) of 0% compared to IP group. Thus, the results of the visual analysis suggest that VRET intervention caused greater reduction of VAS-A, MDAS and DFS scores compared to the IP intervention.

We performed a post-hoc intention to treat analysis on the dependent measures and alpha was set at 5%. Evaluation of group differences in changes over time using a 2 (pre-treatment *vs* post-treatment) × 2 (VRET *vs* IP) repeated measures MANOVA (on VAS-A, MDAS and DFS simultaneously) revealed a significant main effect of time, F (3, 6) = 6.71, p = 0.024, but no significant interaction between time and group, F (3, 6) = 3.19, p = 0.11. Subsequent univariate testing showed a significant decrease in mean score for the VAS-A, F (1, 8) = 5.91, p = 0.04, the MDAS, F (1, 8) = 24.66, p < 0.001, and DFS, F (1, 8) = 14.24, p = 0.005, from pre-intervention to post-intervention. In addition, and more interestingly, a significant condition by time interaction effect was found for MDAS, F (1, 8) = 8.61, p = 0.019, and for the DFS, F (1, 8) = 10.53, p = 0.012, resulting from the fact that MDAS and DFS scores showed a stronger decrease in the VRET condition. A number of post-hoc comparisons using independent-samples t-tests for mean VAS-A, MDAS and DFS scores revealed no significant differences between the groups. Yet, some of the comparisons showed quite large effect sizes in favor of the VRET group, in particular at follow-up (see Table 1).

*Behavioral avoidance*

A paired-samples t-test comparing the pre- and post-intervention BAT scores, and number of steps the patient was able to tolerate, revealed statistically significant differences between pre- and post-scores with large Cohen’s *d* effect sizes (4.2 and -1.4), respectively, in the VRET condition (see Table 1). In contrast, in the IP condition no significant differences were found between the means of the pre-BAT and post BAT scores, or the number of BAT steps, with moderate to large Cohen’s *d* effect sizes (1.0 and -0.4, respectively).

*HR measurement*

As shown in Online Figure 5, the average HR of all VR-participants showed an initial decline from baseline towards the idle phase. After the idle phase, with an increase in anxiety provoking stimuli, there was a slow increase in average HR relative to the idle phase in participants P-1, 3 and 5. However, a steady alleviation of heart rate (relative to baseline) was evident towards the end of VRET in P1-P4. Hence, the confrontation with the increasingly more anxiety eliciting stimuli during VRET did not cause any apparent acceleration in HR during therapy.

*Virtual Reality Experience*

The average presence and the realism experienced by all the participants was 5.4 (SD=1.82) and 6.8 (SD=1.64), respectively. All participants in the VRET condition experienced cybersickness (nausea), except patient P-2. The average cybersickness (nausea) experienced by VRET participants was 4.2 (SD=0.50). Yet, all VRET participants expressed their intentions to undergo similar therapy in the future, and to revisit the dental surgery for treatment.

*Presence of dental phobia*

At the 6-month follow-up, of the nine treatment completers, six (four from the VRET group and two from the IP group) no longer met the diagnostic criteria of dental phobia at 6-month follow-up.

*Dental attendance*

Although all VRET participants showed their interest, four out of five scheduled an appointment and underwent treatment, but none of the IP participants scheduled an appointment for dental treatment following the intervention.

**DISCUSSION**

This is the first controlled feasibility study which evaluated safety and preliminary efficacy of using VRET in dental phobic individuals. Conducting such a pilot study is important to determine any difficulties in timing of measurements and limitations of VRET prior to commissioning the randomized controlled trial. The initial results suggest that VRET is a safe, well-tolerated and acceptable treatment for dental phobia. That is, no symptom exacerbation was reported post-VRET, the confrontation with the anxiety provoking stimuli did not increase patients’ heart rate during therapy, and no participant dropped out during the course of the treatment. Furthermore, our hypothesis that the application of VRET would be associated with a significant reduction in state anxiety, trait dental anxiety, and behavioral avoidance was supported by the present findings. All VRET participants expressed their intentions to undergo similar therapy in the near future and in scheduling an appointment for their dental treatment. The findings of self-reported measures were substantiated by the majority of VRET participants (four out of five) scheduling appointments and undergoing dental procedures such as scaling followed byextractions and fillings. It appeared that six months after the VRET intervention the number of participants who no longer met the criteria of dental phobia was higher in the VRET group compared to the IP group. The above inferences suggest that VRET is a safe and effective treatment alternative for dental phobia.

The significant decrease in behavioral avoidance observed in VRET participants is corroborated by the finding that more participants in the VRET group scheduled their dental appointments and visited the dentist within the 6 months’ follow-up after the intervention. It could be argued that, in vivo exposure to the phobic stimuli during the BAT may have influenced the post-treatment effects by being a part of therapeutic intervention (Cochrane, Barnes-Holmes, & Barnes-Holmes, 2008), notably in VRET. However, the fact that BAT in the IP group showed no difference regarding both avoidance scores, and total BAT steps, after the intervention suggests that exposure to the BAT had only limited influence over the effect of VRET (Krijn et al., 2004a). Despite the fact that the BAT scores, and number of situations the participant was able to tolerate in the IP condition did not decline significantly, the effect size found was moderate to large which may indicate a lack of power to detect a pre-post difference within this group.

We measured both subjective and objective fear response of the VRET participants to determine the feasibility for conducting a RCT. No apparent raise in HR during VRET seems to have occurred. The downward trend observed towards the end of VRET may be suggestive of psychophysiological habituation. However, the results of the HR data should be interpreted with caution as it included the average of the physiologic responses of arousal and habituation which might have occurred with each VR scenario. Additional studies need to be conducted to determine the psychophysiological arousal by comparing the baseline physiologic HR response with the first exposure HR of each VR scenario. Also, physiological habituation may be determined by comparing the first exposure HR response to the last exposure HR response with each VR scenario.

The VR environment comprised a routine dental practice set-up with a patient avatar and a male Caucasoid dentist avatar. VRET participants indicated to experience moderate presence and realism regarding this virtual environment. This might explain the reduction in anxiety within the VRET group. To this end, it is assumed that VRET facilitates emotional processing by an activation of people’s underlying fear structure through controlled confrontation with the fearful stimuli without aversive outcomes (Rothbaum, Hodges, Smith, Lee, & Price, 2000), and that one learns that the fear is unfounded, thereby adjusting negative, irrational predictions (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014). This explanation is supported by the finding that one of the participants who experienced lower VR presence during VRET showed no reduction in dental trait anxiety at the end of the study.

Despite the positive findings of our study, some limitations are worth noting. Firstly, a majority of participants who underwent VRET, experienced moderate cybersickness (nausea) post-session. This indicates how important it is to put more effort in reducing cybersickness to increase the acceptability of VRET. We had provided breaks every 20 minutes in the present study. However, as the patients still experienced nausea, we decided to increase the frequency of the breaks in the planned randomized controlled trial (Raghav et al., 2016). Additionally, simulator sickness may be reduced by software improvements which reduce the lag in VR display, using galvanic vestibular stimulation, VIRMO tablets and improving the stability by including a virtual nose in the VR scene, but there is no conclusive evidence to support the use of these adjuncts. Future studies should be conducted to determine their usefulness in reducing the simulator sickness in VRET patients. Secondly, and most importantly, the study had a limited follow-up of 6 months, and a small sample size, clearly restricting the generalizability of the study results. Small ‘N’ study designs such as the present study, allow flexibility in recruiting participants, and are usually employed in the developmental phases of novel interventions (Folke et al., 2015; Graham et al., 2012). Thirdly, we did not measure heart rate response or cybersickness for the IP control group as our primary objective for measuring HR was to ascertain the physiological HR response occurring during the graded exposure to VRET, and not during reading of the informational pamphlet. Similarly, we believe that it was unreasonable to record and compare the HR response between the groups, given the intrinsic differences between the well-defined VRET scenarios and the indistinct educational content of the pamphlet. Lastly, the use of a Caucasoid dentist avatar, given the multi-cultural Malaysian population, could be a limitation of our study. However, the face mask and the head cap worn by the dentist avatar throughout VRET concealed his race to some extent. Moreover, as all three ethnic groups (Chinese, Indian and Malay) were included in the sample, using an avatar for one of these races could have confounded the results. A neutral Caucasoid avatar could have possibly reduced this bias. The findings that participants experienced moderate presence and realism may be suggestive that the race and sex of dentist avatar did not affect the outcome. Regardless of the ethnicity, cultural and religion background of the participants, VRET seemed to be effective in reducing the trait dental anxiety on a limited sample of dental phobic patients of this population. Further research should be conducted to study the influence of VRET with similar and dissimilar combinations of race and sex of the dentist avatar with different populations in the treatment of dental phobia. The role of race, gender and language of the recruiting researcher and the therapist should also be explored in future VRET studies.

In conclusion, the preliminary results of this multiple baseline study are a first indication that it is feasible to use VRET in dental practice, and that this treatment is safe and has the potential to significantly decrease severe dental anxiety and reduce the avoidance tendency compared to IP standard of care among patients with dental phobia without symptom exacerbation. VRET allows patients to face their fear in a controlled and safe environment because the simulation can be stopped, paused, restarted as well as repeated, whenever, and for as many times as necessary (Baus & Bouchard, 2014). To this end, the virtual form of exposure used in the present study was effective and may have formed a useful bridging step between the therapists’ office and real-life (Pastorino & Doyle-Portillo, 2015). Since, VRET does not require any specialized training for the general dentist, it may improve access to wider populations, and result in better overall oral health. Further research is warranted to confirm the effectiveness of VRET on a larger sample of dental phobic patients.

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**TABLES AND FIGURES**

**Table 1. Mean scores, standard deviations and between subgroups effect sizes for the total sample, on all variables.**

|  |
| --- |
| Dental anxiety scores |
|  |  | VRET | IP |  |
|  |  | Mean (SD) | Mean (SD) | Effect Size |
| Baseline | VAS-A | 7.2 (1.4) | 6.4(0.8) | -0.66 |
|  | MDAS | 21.2(1.7) | 19.2(1.1) | -1.35 |
|  | DFS | 69.0(8.7) | 67.2(9.0) | -0.20 |
| Pre-Intervention | VAS-A | 7.9(1.1) | 7.6(1.5) | -0.22 |
|  | MDAS | 21.2(1.7) | 20.4(2.0) | -0.41 |
|  | DFS | 71.6(12.7) | 65.2(15.0) | -0.46 |
| Post-Intervention | VAS-A | 4.2(4.2) | 6.0(2.4) | 0.52 |
|  | MDAS | 14.2(3.1) | 18.6(4.0) | 1.22 |
|  | DFS | 50.4(8.5) | 63.3(16.4) | 0.98 |
| Follow up | VAS-A | 2.0(1.2) | 3.5(2.0) | 0.89 |
|  | MDAS | 11.6(1.6) | 15.0(3.3) | 1.29 |
|  | DFS | 38.2(9.3) | 55.5(14.1) | 1.44 |
| Behavioral Avoidance scores |
|  |  | Pre-Intervention | Post-Intervention |  |
|  |  | Mean (SD) | Mean (SD) | Effect Size |
| VRET | BAT | 41.2 (5.5) | 12.8 (7.5) | 4.2\* |
| BAT STEPS | 3.2 (0.8) | 4.4 (0.5) | -1.43\* |
| IP | BAT | 36.4 (4.9) | 34.4 (6.0) | 1.0 |
| BAT STEPS | 3.2 (0.4) | 3.4(0.5) | -0.4 |
| \*P (<0.05).VRET=Virtual Reality Exposure Therapy, IP=Informational Pamphlet, VAS-A=Visual Analogue Scale-Anxiety, MDAS=Modified Dental Anxiety Scale, DFS=Dental Fear Scale,BAT=Behavioral Avoidance Test, BAT-steps= Behavioral Avoidance Test Steps,  |

**Online Table 1.** **Measurement planning (a) Repeated measurements in a Multiple Baseline Design and (b) Measurements at two time points.**

|  |
| --- |
| **Planning of measurements** |
| **1a** | B0 | B1 | B2 | B3 | B4 | **Intervention 5thWk** | F6 | F7 | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F- 6 mos |
| **Pre** | **Post** |
| B0 | B1 | B2 | B3 | B4 | B5 | **Intervention 6thWk** | F7 | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F- 6 mos |
| **Pre** | **Post** |
| B0 | B1 | B2 | B3 | B4 | B5 | B6 | **Intervention 7thWk** | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F- 6 mos |
| **Pre** | **Post** |
| B0 | B1 | B2 | B3 | B4 | B5 | B6 | B7 | **Intervention 8th Wk** | F9 | F10 | F11 | F12 | F13 | F14 | F- 6 mos |
| **Pre** | **Post** |
| B0 | B1 | B2 | B3 | B4 | B5 | B6 | B7 | B8 | **Intervention 9th Wk** | F10 | F11 | F12 | F13 | F14 | F- 6 mos |
| **Pre** | **Post** |
| **2b** | **Two time points** |
| Baseline |  | Follow-up at 6 months |

B\*-Baseline; 5-9 weeks,

F\*\*-Follow-up; 5-9 weeks

a Each baseline phase length was randomly assigned to one participant in the VRET, and to one participant in the informational pamphlet group and assessed for VAS-A, MDAS and DFS.

b For all n=10 patients: Presence of dental phobia was evaluated using phobia check list at B0=Baseline and at 6 months’ follow-up

**Online Table 2. Description of primary and secondary outcome measures.**

|  |
| --- |
| **Primary Outcome measures** |
|  | **Measure** | **Description** |
| 1. | **Safety** | Determined by asking for any adverse events or symptom exacerbation post-VRET. |
| 2 | **Visual analogue scale for anxiety** | VAS-A is a simple, sensitive, fast, reliable and valid tool in state dental anxiety assessment 17. It was recorded by asking the participants to draw a cross mark (X) on a 0-100 mm scale from totally calm (0) and relaxed to worst fear imaginable (100).  |
| 3. | **Modified Dental Anxiety Scale** | MDAS is a 5-item scale assessing anticipatory dental anxiety, fear of dental cleanings, drilling, and injections on a 5-point Likert scale. The possible scores range from 5 to 25, with greater scores indicating higher level of dental anxiety. The test shows high levels of internal consistency and good construct validity 18.  |
| 4. | **Dental Fear Survey** | The Dental Fear Survey (DFS) is a 20-item measure to identify the participants’ emotional and physiological reactions associated with dentistry, as well as avoidance of dental care. Possible scores range from 20 to 100, with greater scores indicating higher levels of dental anxiety. The test has established reliability, validity and sensitivity 19.  |
| 5. | **Behavioural Avoidance Test** | This test was carried out before and after the intervention, by means of standardized observation of behaviour and an interview for both the intervention groups. The participant undergoes several approaching steps towards their anxious stimuli similar to the VRET scenarios and provides a baseline behavioral assessment measure to compare the responses of the patient before and after the interventions. The test contained 5 situational steps that occurred during a dental visit (e.g. sitting in the dental chair, inspection of the oral cavity using two dental mirrors, approaching dental syringe, approaching dental drill without sound and approaching dental drill with sound). Participants were asked to assess his/her level of state anxiety on a scale of 0–10 in each situation. To measure whether the patients was able to tolerate the situation/s the number of steps completed was noted. Both observation and responses to the standardized situations were recorded during the procedure 20. |
| **Secondary outcome measures** |
| 1. | **Psychophysiological parameter** | A HR wrist band was used to record the real time response of the participants during VRET. The device was integrated with the VR software and the output was recorded on exposure with cues during therapy. |
| 2. | **VR experience after VRET**  | **Presence, realism and cybersickness (severity of nausea)** were measured with an 11-point verbal rating scales\* 23. **Intention to use VR goggles again and to revisit the dental surgery** was measured using a yes/no response. |
| \*0= No presence, realism and cybersickness1-3=Mild presence, realism and cybersickness4-6=Moderate presence, realism and cybersickness7-9= Strong presence, realism and cybersickness10= Profound presence, realism and cybersickness |

**Online Table 3. Overview of timing of outcome measures.**

|  |  |
| --- | --- |
|  | **Measurements** |
| ***Primary outcome*** | ***Secondary outcomes (only with VRET)*** |
| *Safety****(only with VRET)*** | *VAS -A* | *MDAS* | *DFS*  | *BAT* | *Physiological response (HR) (Only with VRET)* | *VR experience (Only with VRET)* |
| **Baseline(B0)** | - | X | X | X | - | - | - |
| **Repeated baseline measures (5-9 weeks).** | - | X | X | X | - | - | - |
| **Intervention** | *Pre-intervention*  | - | X | X | X | X | - | - |
| *During intervention* | - | - | - |  | - | X | - |
| *Post-intervention* | X | X | X | X | X | - | X |
| **Repeated follow-up measures (5-9 weeks)** | - | X | X | X | - | - | - |
| **Follow-up at 6 months** | X | X | X | X | - | - | - |

**Online Table 4. Overview of visual analysis of VAS-A dependent measure.**

|  |  |  |
| --- | --- | --- |
| Participants | Within Condition Analysis | Between Conditions Analysis |
| Level | Trend: | Change in Level | Data Overlap |
| Stability Envelope | Direction change | Stability Change  | Relative Change | Absolute Change | Median Change | Mean Change | PND | POD |
| A | B |
| 1 | Stable | Stable | No Change | None | -0.5 decelerating | -1 Improving | -1 Improving | -1.3 Improving | 30% | 70% |
| 2 | Stable | Stable | Zerocelerating to Decelerating  | None | -6.5 improving | -7 improving | -7 improving | -6.1 Improving | 100% | 0% |
| 3 | Stable | Variable | Zerocelerating to Decelerating  | Stable to Variable decelerating | -3 improving | -3 improving | -3.5 improving | -4.6 Improving | 100% | 0% |
| 4 | Stable | Variable | Zerocelerating to Decelerating | Stable to Variable decelerating | -4 improving | -4 improving | -6 improving | -5.5 improving | 100% | 0% |
| 5 | Stable | Stable | Zerocelerating to Decelerating  | None | -2.5 improving | -3 improving | -2 improving | -2.8 improving | 100% | 0% |
| 6 | Stable | Stable | No Change | None | Slight improving (0.5) | -2 improving | -1 improving | -0.8 improving | 30% | 70% |
| 7 | Stable | Stable | Zerocelerating to accelerating  | None | -2 improving | -2 improving | -2 improving | -1.8 improving | 100% | 0% |
| 8 | Stable | Stable | Zerocelerating to Decelerating  | None | -3.5 improving | -4 improving | -4 improving | -4.1 improving | 100% | 0% |
| 9 | Stable | Variable | No Change | Stable decelerating to Variable decelerating | No change | No change | -0.5 improving | -1.2 improving | 42.80% | 57.14% |
| 10 | Stable | Stable | Decelerating to zerocelerating | None | -1 improving | -1 improving | -1 improving | -1 improving | 66.60% | 33.33% |

**Online Table 5. Overview of visual analysis of MDAS dependent measure.**

|  |  |  |
| --- | --- | --- |
| Participants | Within Condition Analysis | Between Conditions Analysis |
| Level | Trend: | Change in Level | Data Overlap |
| Stability Envelope | Direction change | Stability Change  | Relative Change | Absolute Change | Median Change | Mean Change | PND | POD |
| A | B |
| 1 | Stable | Stable | accelerating to zerocelerating  | None | -10 improving | -9 improving | -10 improving | -19.5 improving | 100% | 0% |
| 2 | Stable | Stable | zerocelerating to decelerating  | None | -5 improving | -5 improving | -6 improving | -16.3 improving | 100% | 0% |
| 3 | Stable | Stable | zerocelerating to decelerating  | None | -4.5 improving | -3 improving | -4.5 improving | -5.7 improving | 100% | 0% |
| 4 | Stable | Stable | decelerating to zerocelerating  | None | -9 improving | -9 improving | -9 improving | -8.7 improving | 100% | 0% |
| 5 | Stable | Stable | zerocelerating to decelerating  | None | -8.5 improving | -9 improving | -9 improving | -9.5 improving | 100% | 0% |
| 6 | Stable | Stable | None | None | -0.5 improving | -2 improving | -1.5 improving | -1.2 improving | 10% | 90% |
| 7 | Stable | Stable | None | None | No change | No change | No change | No change | 0% | 100% |
| 8 | Stable | Stable | None | None | -6 improving | -6 improving | -6.5 improving | -6.4 improving | 100% | 0% |
| 9 | Stable | Stable | accelerating to decelerating  | None | -1 improving | -1 improving | -1 improving | -2 improving | 42.85% | 57.14% |
| 10 | Stable | Stable | None | None | -2 improving | -1 improving | No change | -0.6 improving | 0% | 100% |

**Online Table 6. Overview of visual analysis of DFS dependent measure.**

|  |  |  |
| --- | --- | --- |
| Participants | Within Condition Analysis | Between Conditions Analysis |
| Level | Trend: | Change in Level | Data Overlap |
| Stability Envelope | Direction change | Stability Change  | Relative Change | Absolute Change | Median Change | Mean Change | PND | POD |
| A | B |
| 1 | Stable | Stable | Zerocelerating to decelerating | No change | -35.5 improving | -37 improving | -36.5 improving | -37.7 improving | 100% | 0% |
| 2 | Stable | Stable | Zerocelerating to accelerating | No change | -21 improving | -25 improving | -21 improving | -20.6 improving | 100% | 0% |
| 3 | Stable | Stable | Zerocelerating to decelerating | No change | -20.5 improving | -21 improving | -21 improving | -19.9 improving | 100% | 0% |
| 4 | Stable | Stable | Accelerating to zerocelerating | No change | -30.5 improving | -27 improving | -29.5 improving | -29.5 improving | 100% | 0% |
| 5 | Stable | Stable | Slow decelerating to rapid decelerating | No change | -29 improving | -28 improving | -37 improving | -35.3 improving | 100% | 0% |
| 6 | Stable | Stable | Decelerating to accelerating | No change | -5 improving | -4 improving | -4.5 improving | -5.8 improving | 80% | 20% |
| 7 | Stable | Stable | No change | No change | -8 improving | -11 improving | -9.5 improving | - 9 improving | 100% | 0% |
| 8 | Stable | Stable | No change | No change | -21.5 improving | -28 improving | -28 improving | -26.8 improving | 100% | 0% |
| 9 | Stable | Stable | No change | No change | 5 deteriorating | 2 deteriorating | No change | -3 improving | 42.85% | 57.14% |
| 10 | Stable | Stable | Accelerating to decelerating | No change | -4.5 improving | -4 improving | -16.5 improving | -8.2 improving | 100% | 0% |

**Online Figure-1 Showing overview of patient flow**

**Screening (n=56)**

**Excluded (n=14)**

1. n=7 were not interested.
2. n=7 were excluded.

- Hearing or visual impairment such as stereoscopy blindness or nystagmus (n=3),

- Known mental disorders such as psychosis, post-traumatic stress disorder, developmental or intellectual disability and cognitive impairment.

- Known balance disorders such as vertigo and cybersickness (n=2).

- Patients with previous history of epileptic seizures.

- Any history of cardiac problems (n=2).

- Patients who are undergoing, or have undergone, any cognitive behavioral therapy (CBT)-based intervention for dental phobia.

- Language impediment (cannot understand English).

- Patients wearing glasses of greater than plus 3.5 power.

**Assessed for eligibility (n=24)**

Avoidance towards dental treatment for more than 12 months, MDAS score ≥ 15, age between 18 to 60 yr, in need of a dental filling or extraction or both with a planned maximum treatment length of 30 minutes per appointment and satisfying “Phobia checklist” criteria of dental phobia.

## Enrollment

**Randomized (n=10)**

## Allocation

Allocated to IP intervention (n=5)

Allocated to VRET intervention (n= 5)

## Baseline phase

**Baseline measurements (n= 10)**

**-** MDAS, VAS-A, DFS.

- MDAS, VAS-A, DFS (Repeated measure 5-9 weeks, till therapy)

## Treatment phase

**Treatment phase measurements:**

-MDAS, VAS-A, DFS, Behaviour test (pre and post interventions)

-Heart rate monitoring and VR experience (VRET group)

## Follow-Up

**Follow-up measurements (n= 10)**

MDAS, VAS-A, DFS (Every week following treatment)

MDAS, VAS-A, DFS, Phobia checklist (after 6 mos)

and after 3 mos (n=10)

-

## Analysis

**Online Figure 2. Graphical representation of VAS-A scores of all participants**

|  |  |
| --- | --- |
|  |  |

**Online Figure 3. Graphical representation of MDAS scores of all participants**

|  |  |
| --- | --- |
|  |  |

**Online Figure 4. Graphical representation of DFS scores of all participants**

|  |  |
| --- | --- |
|  |  |

**Online Figure 5. Mean heart rate of the VRET participants across different VR scenarios.**

1. VRET was conducted utilizing two networked computers of which the VR-simulator computer (Dell XPS-8700 desktop with 4th Generation Intel Core i7-4790 processor (8M Cache, up to 4.0 GHz) and ASUS NVIDIA GEFORCE GTX 750 TI OC 2GB GDDR5 graphic card) rendered the virtual environment and the other User interface-computer allowed the researcher to control and individualize the VR stimuli presented to the patient. An Oculus development kit 2 HMD (Head Mounted Display) with a resolution of 960X1080 per eye was used to immerse the participants in the VR dental environment. A Mio-link wrist band was used to record the HR of the VRET participants in real-time during therapy. [↑](#footnote-ref-1)