Virtual reality relaxation to decrease dental anxiety: immediate effect randomized clinical trial

Lahti S[1,2]

Suominen A[1]

Freeman R[3]

Lähteenoja T[1]

Humphris G[4]

[1] Department of Community Dentistry, University of Turku, Finland;

[2] Turku Clinical Research Centre, Turku University Hospital, Finland

[3] Dental Health Services Research Unit, School of Dentistry, University of Dundee, UK

[4] Division of Populations and Behavioural Science, School of Medicine, University of St Andrews, UK

Abstract word count 250

Total word count 3248

Total number of tables/figures 4 (3/1)

Number of references 41

Key words: dental fear, clinical studies/trials, relaxation technics, virtual reality immersion, dental care, public sector

Running head: Virtual reality relaxation decreases dental anxiety

Corresponding author: Satu Lahti, Department of Community Dentistry, University of Turku, Finland, e-mail: satu.lahti@utu.fi

Knowledge Transfer Statement

Dental anxiety which is a common problem can be reduced with short application of virtual reality relaxation applied pre-operatively in the waiting room. Findings of this study indicate it is feasible and effective procedure to help patients with dental anxiety in normal public dental care setting.

Abstract

INTRODUCTION: Dental anxiety is common and causes symptomatic use of oral health services.

OBJECTIVES: The aim was to study if a short-term virtual reality intervention reduced pre-operative dental anxiety.

METHODS: Randomized controlled single-center trial was conducted with two parallel arms: Virtual Reality Relaxation (VRR) and Treatment As Usual (TAU) in a public oral health care unit. VRR group received a 1–3.5 minute 360°immersion video of a peaceful virtual landscape with audio features and sound supporting the experience. TAU groups remained seated for 3 minutes. Of the powered sample of 280 participants, 255 consented and had complete data. Total and secondary gender specific mixed-effects linear regression models were completed for the post-test dental anxiety (MDAS total score) and its two factors (Anticipatory and Treatment-related dental anxiety) adjusted for the baseline (pre-test) MDAS total and factor scores and age taking into account the effect of blocking.

RESULTS: Total and anticipatory dental anxiety decreased more in VRR compared to TAU groups (β -0.75 p<.001 for MDAS total score; β -0.43 p<.001 for anticipatory anxiety score) in patients of primary dental care clinic. In females dental anxiety decreased more in VRR compared to TAU group for total MDAS score (β -1.08 p<.001) and treatment-related dental anxiety (β -0.597 p=.011). Anticipatory dental anxiety decreased more in VRR compared to TAU group both in males (β -0.217, p<.026) and females (β -0.498, p<.001).

CONCLUSION: Short application of VRR is both feasible and effective to reduce preoperative dental anxiety in public dental care settings. **(**ClinicalTrials.gov NCT03993080**)**

Introduction

One third of Finnish adult are anxious, to some degree, of dental treatment, women more often than men. A tenth are very anxious. The prevalence of dental anxiety has remained stable over the past ten years (Lahti et al. 2007; Liinavuori et al. 2016). These statistics are similar in other countries (Hägglin et al. 1999; Maggirias and Locker 2002; Thomson et al. 2009; Armfield 2010; Hill et al. 2013, Carlsson et al. 2015). People with extreme dental anxiety are more likely to avoid or delay treatment (Pohjola et al. 2007; Thomson et al. 2010; Åstrøm et al. 2011; Hakeberg and Wide Boman 2017; Liinavuori et al. 2019) and Finnish men more often than women (Liinavuori et al. 2019).

Dental anxiety may be managed by psychotherapeutic interventions which enable patients to feel more comfortable when receiving the treatment and help those patients not visiting dentist due to high fear to attend the treatment. These interventions include, relaxation, distraction, exposure and other forms of cognitive behavioral therapy (Armfield and Heaton 2013; Wide Boman et al. 2013; Gordon et al. 2013; Craske et al. 2014). Of these relaxation and distraction are mostly used during dental treatment, whereas exposure therapy including inhibitory learning, and other forms of cognitive behavioral therapy might be needed already before the dental treatment (Armfield and Heaton 2013; Craske et al. 2014). While some of these interventions may be conducted by a dentist, others require support from psychologists (Armfield and Heaton 2013; Wide Boman et al. 2013). Several treatment visits are usually needed to manage dental anxiety, especially for those with extreme dental anxiety, however, a single appointment to reduce dental anxiety has also shown some success (Armfield and Heaton 2013; Wide Boman et al. 2013; Gordon et al. 2013). Based on this research evidence, a brief patient-centered intervention which may be routinely incorporated into daily practice in primary dental care is needed. New technologies have been developed, such as computer assisted cognitive behavioral therapy (CBT) which has shown some potential (Rooskby et al. 2015; Tellez et al. 2015). Technologies based on virtual reality have also been developed for

managing dental anxiety. A systematic review concluded they have potential, though more rigorous studies are needed (Gujjar et al. 2019a). Many of them are based on distraction during normal or simulated treatment, or exposure before treatment, and used, for example, natural scenery, games or information on treatment (Frere et al. 2001; Asl Aminabadi et al. 2012; Tanja-Dikstra et al. 2014; Kazancioglu et al. 2015; Padrino-Barrios et al. 2015; Atzori et al. 2018; Niharika et al. 2018; Shetty et al. 2019) while others are based on psychologist-delivered cognitive behavioral therapy (Raghav et al. 2016; Gujjar et al. 2017; Gujjar et al. 2019b). Short virtual reality-based interventions have shown particular promise in reducing preoperative or anticipatory anxiety in secondary care (Ganry et al. 2018). We are unaware, however, of short virtual reality-based relaxation being applied in primary dental care pre-operatively.

Therefore, our research question is: 'Can a short virtual reality-based intervention applied preoperatively be effective in reducing patients' anticipatory and treatment-related dental anxiety for those attending primary dental care?' The aim is to apply short-term virtual reality relaxation to examine if it is effective in reducing anticipatory and treatment-related dental anxiety in primary dental care using an RCT design.

Methods

Design

Randomized controlled single-center trial was conducted with two parallel arms: Virtual Reality Relaxation (VRR) and Treatment As Usual (TAU) groups were randomized, following consent, with an allocation ratio of 1:1. No changes were made to methods after trial commencement.

Participants

Adult (18+ years old) patients who attended for dental treatment (basic, special or emergency dental care, general anesthesia, x-ray), consented, and who were able to complete the Finnish questionnaire without assistance, were eligible for the study.

The study was conducted in the public Oral Health Care Unit of Kalasatama Health and Welfare Center of the City of Helsinki, Finland. Patient recruitment and running the on-site research activities, such as administering the questionnaires and instructing the VR group in the use of appliances, were conducted by 13 students from the Haaga-Helia and Laurea Universities of Applied Sciences. Students were specifically trained for this study by the lead clinician (SL) on site to ensure uniformity of information provided to participants.

Patients were approached in one of the two arrival halls where patients entered the Oral Health Care Unit. Patients were inquired if they had 15 minutes time before their scheduled dental appointment to allow participation in the study. If the patient had the time and volunteered they were told the nature of the study and were given an information leaflet describing the study and about the possibility to win a movie ticket or xylitol products in lottery after participation. If the patient consented s/he was then randomized into one of the two groups.

Interventions

Interventions were conducted in similar settings in small alcoves with a seat and a table. The participants in the TAU group remained seated in the alcove for 3 minutes. Their experience of sitting in the alcove for 3 minutes was identical to that of the VRR group but without the VRR intervention. They were able to use their mobile phones if they so wished.

In the VRR group, participants chose one of the five 1–3.5 minute videos. Still pictures of each video are provided in a supplementary file. The application by MelloVR presented these videos. When the application was launched, clear instructions were displayed on the screen regarding next

steps. These included basic instructions on how to select a video by turning his/her head towards a specific video, using so called gaze selection method without manual controllers. The 360° (resolution range 4096x2010–5120x2560) videos immersed the participants in a peaceful virtual landscape (beach, water fall, underwater, space float, paddling). Videos were played using Samsung Gear VR headset and Samsung Galaxy S7 mobile phone for the MelloVR application attached to the virtual headset with the total weight of approximately 500 grams. Disposable mask was used with the headset for hygienic purposes.

Audio features and sound supported the relaxation experience. The musical ambient track was the same for all video choices. The file format is AAC with 320 kbps quality playing at 48 kHz. It has a tempo of 120 BPM (beats per minute) and fades in smoothly within 10 seconds. The musical instrumentation consists of a smooth synth pad, soft kick drum, and occasional bass and bell notes. White noise can be heard on top of the track which listeners might find relaxing, particularly people with tinnitus. The synth pad looped the same harmony throughout the musical track and the bass supports it. The bell instrument can be heard a few times, but no specific theme is recognized. This is typical of musical productions which are not meant to raise significant attention. The sound was played with on-ear headphones by Pioneer (model SE-M521) to exclude noise. The picture could be adjusted to suit the user's eyesight by using the scroll on top of the glasses and the audio volume could be set accordingly using a control on the side of the glasses.

Acceptability and feasibility of the VRR application was pilot tested prior to the RCT in 55 primary health care and social welfare clients of Kalasatama Health and Welfare Center. Students who later recruited participants in the RCT invited volunteering clients to try a relaxing virtual reality experience. The virtual reality content and the devices were similar as in the study. Their perceptions were assessed after the virtual reality experience. Of the pilot participants, 98% found the experience relaxing, 87% would like to use it during a potentially anxiety-provoking treatment

procedure and 80% would recommend it to friends. Minor harmful effects, such as feelings of dizziness or nausea, were reported by less than 4%.

Outcomes

The main outcome measure dental anxiety was assessed with validated Finnish version of Modified Dental Anxiety Scale (MDAS) before and immediately after the intervention (Humphris et al. 2000; Yuan et al. 2008; Humphris et al. 2013). The measure has five questions, each with five reply alternatives from not anxious to extremely anxious. The primary outcome variable was the post-test MDAS total score. The secondary outcome variables were post-test scores for the two sub-scales of the MDAS referred to as 'anticipatory' (MDAS items 1 and 2) and 'treatment' dental anxiety (MDAS items 3, 4 and 5). After the intervention and completing post-test MDAS patients reported also their gender (female, male, other) and age in full years before attending their scheduled dental appointment. No personal information or information related to dental appointments after the study were collected.

From MDAS sums for the primary outcome total scale (range 5–25) and for the secondary outcomes anticipatory anxiety (Items 1 and 2: range 2–10) and treatment anxiety (Items 3–5: range 3–15) were calculated.

Sample size

Power calculation was estimated by STATA 'rsquared' routine. The effect of blocking was not introduced, however the effect size was set to a low level to ensure a conservative approach when estimating a sufficient sample size. With a small effect size of 0.04 in favor of the VRR intervention, compared to TAU, would require a sample size of 272 participants at 90% power with alpha set to 0.05, two-sided. This was calculated specifying two control covariates (pre-test MDAS

and participant age in years) and the test random assignment factor, coded as 0=TAU and 1=VR Intervention. Due to the chosen block size of 10 participants, the study required 280 participants.

Randomization

Random allocation sequence was computer generated (by AS) using random number lists in blocks of ten. The blocked randomization was used to keep the numbers of randomized patients in both treatment groups closely balanced during the study and thus homogenize the variation in group allocation due to patient flow in different weekdays and time of day. The block size of ten was big enough to prevent guessing the next randomized treatment group and thus reducing bias (Altman, 1991). The block size of ten was also the multiple of number of treatments and at the same time the required sample size was divisible by block size. The students enrolling the participants administered the randomization of patients, allocating the patient to next free identification number on the randomization list. The patients were blinded until the intervention started. It was not possible to blind the students enrolling the patients.

Statistical analyses

The primary outcome variable post-test MDAS total score was adjusted for the baseline (pre-test) MDAS total score and participant age using mixed-effects regression with inclusion of the random block effect. The analysis method ignoring blocks is more conservative regarding the statistical significance and thus less efficient and powerless (Matts and Lachin 1988). The analyses were repeated for secondary outcome variables the MDAS anticipatory and treatment dental anxiety. Separate analyses were run for males and females. To avoid making assumptions of strict normality and non-heteroscedasticity the ‘robust’ option in the ‘regress’ procedure was applied. Residual plots were inspected for identification of possible violations. Alpha was set to 0.05 (2-sided). Data were analyzed with STATA 15.1 (StataCorp. 2017).

Ethics

Ethical approval was granted by the City of Helsinki, decision number HEL 2018-008940. Trial was registered at ClinicalTrials.gov (NCT03993080).

Results

The flow chart of allocated and analyzed participants is presented in Figure 1. Data collection started 15th October 2018 and was completed 27th February 2019. Recruitment was halted when 277 participants had been collected and participants were analysed by original assigned groups. Means and standard deviations for age and the MDAS total, anticipatory and treatment-related anxiety scores according to gender and intervention group are presented in Table 1. Of the participants 47.5% reported low dental anxiety (MDAS less than 10), 43.9% moderate dental anxiety (MDAS 10-18) and 8.6% high dental anxiety (MDAS 19 or more).

Group had statistically significant effect in the total MDAS model and anticipatory anxiety model (Table 2). VRR group showed 0.75 MDAS scale unit decrease in total dental anxiety and 0.43 scale unit decrease in the anticipatory anxiety compared to TAU group. In the secondary gender specific analyses, in females VRR group showed over one MDAS scale unit decrease in dental anxiety compared to TAU group. In males the decrease was not statistically significant. In MDAS anticipatory dental anxiety the VRR group showed a half a scale unit decrease after compared with the TAU group in females and 0.2 unit decrease in males. For treatment-related dental anxiety the decrease in MDAS scores was statistically significant only among females in the VRR group, showing over half a scale unit decrease compared to TAU group. (Table 3.)

The MDAS outcome data showed a significant level of skewness. The 'robust' option in STATA was applied to mitigate this. To check that our analyses were unbiased we repeated the regression

analyses with log-transforms of the dependent variable. All statistical results remained substantively the same.

Discussion

A short preoperative virtual reality relaxation decreased total and anticipatory dental anxiety in those attending a primary dental care clinic. In the secondary gender specific analyses, total and treatment-related dental anxiety decreased among females and anticipatory dental anxiety among males. To our knowledge this is the first study using a short virtual reality relaxation method in a routine dental primary care setting. We found as in Ganry et al. (2018) that even a short application of virtual reality relaxation reduced anticipatory dental anxiety.

It is possible that at least part of the dental anxiety reduction came from distraction which has been shown to be effective especially when applied during dental treatment (Frere et al. 2001; Asl Aminabadi et al. 2012; Tanja-Dikstra et al. 2014; Padrino-Barrios et al. 2015; Atzori et al. 2018; Niharika et al. 2018; Shetty et al. 2019). The virtual reality used in this study was originally developed for relaxation purposes. Regardless of the pathway the use of virtual reality preoperatively reduced dental anxiety.

The strengths of this study are the RCT design and the study population which included participants with all levels of dental anxiety in primary dental care setting. The levels of dental anxiety were similar to the UK population norms (Humphris et al. 2013). We did not aim to maximize the effect of virtual reality relaxation by recruiting participants with high levels of dental anxiety only. Also, the intervention set up was very similar for both groups in terms of seating and possibility for TAU group to use mobile phone thus enabling the effect of virtual reality intervention to be explicitly identified. The study did not assess either dental anxiety levels after dental treatment or the type of

treatment procedures participants were receiving. Neither was the content or length of VRR intervention participants chose assessed, as this was a population study. Thus, the long-term effects and the effects of different VRR interventions as well as of different dental treatments call for further studies.

There are also limitations to the study population. Recruiting took place in a setting with on average 200 patient visits per day. However, most patients arrived just in time for their scheduled appointment and thus, did not have sufficient time to participate in the study (69.5% of those approached and 83.2% of those excluded). This might have led to possible bias in the age distribution as older patients were more likely to arrive ahead of their scheduled appointment and thus to participate the study. Another recruitment bias might be having missed patients with high dental anxiety as they may come at the last minute. However, the percentages of participants with high dental anxiety were similar to the national survey among adults Finns (Liinavuori et al. 2016) and possibly due to the recruitment including patients coming for acute dental care. Only 11.5% of those approached declined to participate for other reasons and 2.5% did not consent after reading the written information. The fact that many patients were unable to seek out VRR treatment due to time constraints needs to be also addressed to ensure successful implementation at the population level.

There was also a lower percentage of men than women in this study, and only three men reporting high dental fear in this study. Men with high dental fear have been underrepresented also in another cohort study where dental anxiety was assessed in conjunction with dental examination (Kankaanpää et al. 2019). This might partly explain the lack of statistical significance of virtual reality relaxation among men and needs to be considered when powering future studies. Thus, results referring to the effect of gender should be interpreted with caution.

The positive findings of this study indicate that a short VRR intervention is feasible, patient accepted, inexpensive and an effective way of reducing preoperative dental anxiety in public dental care setting on a population level. For those who are truly dentally phobic we realize that a more in-depth psychotherapeutic interventions are necessary. We therefore would recommend in future studies that the level of dental anxiety should be carefully inspected. In addition, further studies are needed to understand the effect of this VR intervention more fully and also to assess long-term outcomes.

Author Contributions

S. Lahti contributed to conception, design, data analysis and interpretation, drafted and critically revised the manuscript. A. Suominen contributed to design, data analysis and interpretation, drafted and critically revised the manuscript. R. Freeman contributed to conception, design, data interpretation, drafted and critically revised the manuscript. T. Lähteenoja contributed to design, drafted and critically revised the manuscript. G. Humphris contributed to conception, design, data analysis and interpretation, drafted and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work ensuring integrity and accuracy.

Acknowledgements

The authors acknowledge MelloVR limited for providing the virtual reality relaxation equipment, Oral Health Care Unit of Kalasatama Health and Welfare Center of the City of Helsinki for allowing access to their patients and the students of Haaga-Helia and Laurea Universities of Applied Sciences for recruiting the participants. The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

Data can be requested from the corresponding author.

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Figure 1. The CONSORT flow diagram of allocated and analyzed participants

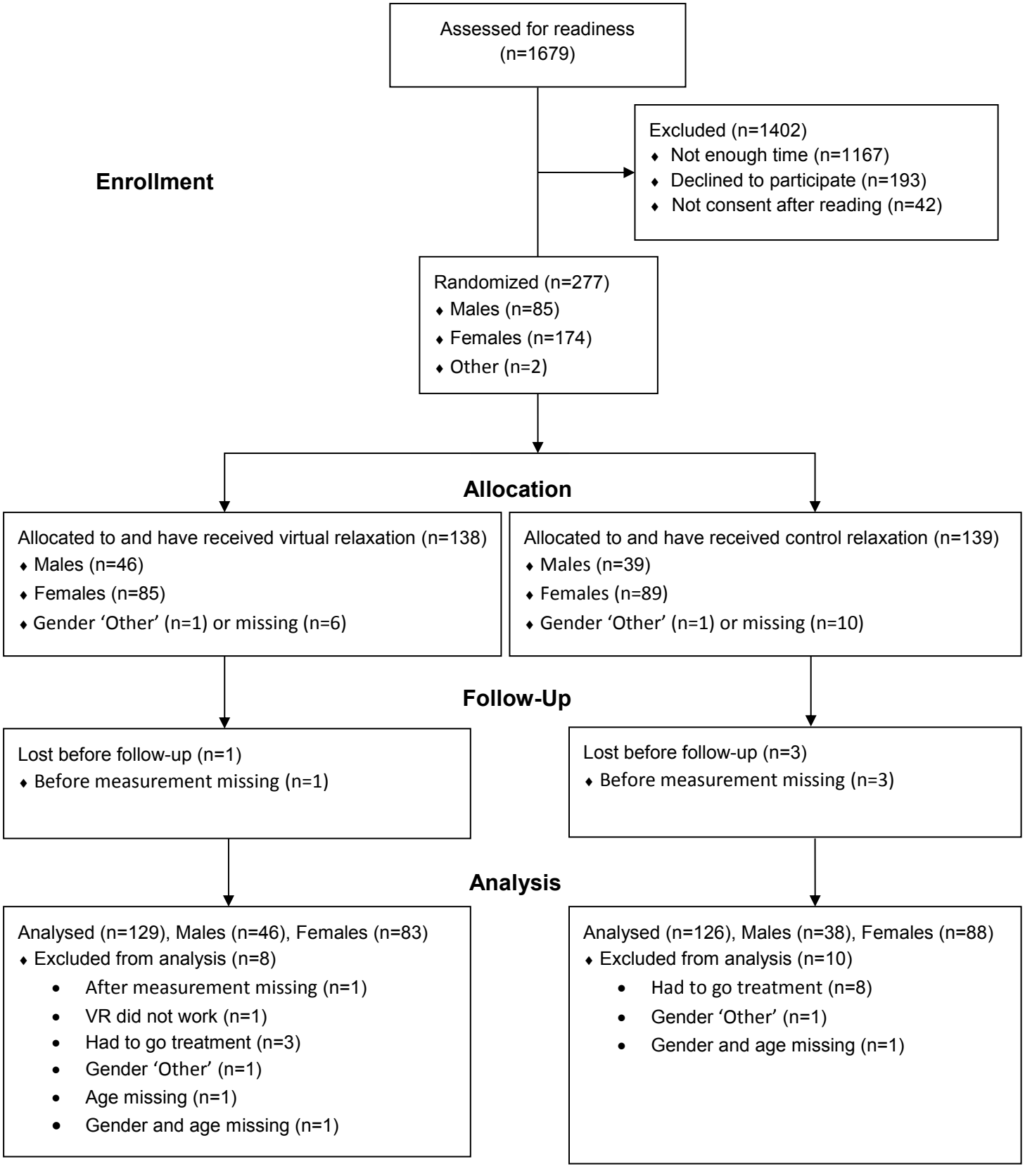

Table 1. Means and standard deviations (SD) for age and dental anxiety and its two factors for males and females and VRR and TAU groups.

	All (n=255)	Males (n=84)	Females (n=171)	VRR group (n=129)	TAU group (n=126)
Age in years	52.54 (16.37)	50.17 (16.37)	53.70 (16.30)	51.81 (16.75)	53.28 (16.02)
Baseline					
MDAS total	10.98 (4.67)	9.36 (4.08)	11.77 (4.74)	10.76 (4.54)	11.20 (4.81)
Anticipatory	3.66 (1.95)	3.16 (1.73)	3.91 (2.00)	3.62 (1.93)	3.71 (1.98)
Treatment	7.31 (3.09)	6.20 (2.66)	7.86 (3.14)	7.14 (3.00)	7.49 (3.17)
After treatment					
MDAS total	10.33 (4.55)	9.18 (4.29)	10.89 (4.58)	9.77 (4.32)	10.90 (4.71)
Anticipatory	3.53 (1.94)	3.13 (1.78)	3.72 (1.99)	3.28 (1.88)	3.78 (1.98)
Treatment	6.80 (2.94)	6.05 (2.73)	7.17 (2.98)	6.49 (2.78)	7.12 (3.08)

MDAS, Modified Dental Anxiety Scale; VRR, virtual reality relaxation; TAU, treatment as usual

Table 2. Mixed-effects linear regression model for the post-test dental anxiety (MDAS total score) and its two factors (Anticipatory dental anxiety and Treatment related dental anxiety) adjusted for the baseline (pre-test) MDAS total score, gender, participant age and adapting the blocking.

	All (n=255)		
Total MDAS after	β	95% CI	p
Group (VRR vs. TAU)	-0.752	-1.183 to -0.321	0.001
Total MDAS before	0.889	0.817 to 0.961	<0.001
Gender	-0.443	-0.933 to 0.047	0.076
Age in years	0.003	-0.011 to 0.018	0.642
Anticipatory after	β	95% CI	p
Group (VRR vs. TAU)	-0.429	-0.650 to -0.207	<0.001
Anticipatory before	0.885	0.828 to 0.942	<0.001
Gender	-0.099	-0.343 to 0.146	0.415
Age in years	-0.002	-0.008 to 0.005	0.659
Treatment after	β	95% CI	p
Group (VRR vs. TAU)	-0.338	-0.694 to 0.018	0.062
Treatment before	0.849	0.789 to 0.909	<0.001
Gender	-0.275	-0.677 to 0.127	0.171
Age in years	0.003	-0.008 to 0.014	0.573

β, nonstandardized coefficient; CI, confidence interval. MDAS, Modified Dental Anxiety Scale; VRR, virtual reality relaxation; TAU, treatment as usual

Table 3. Gender specific mixed-effects linear regression models for the post-test dental anxiety (MDAS total score) and its two factors (Anticipatory dental anxiety and Treatment related dental anxiety) adjusted for the baseline (pre-test) MDAS total and factor scores, participant age and adapting the blocking.

	Male (n=84)			Female (n=171)		
Total MDAS after	β	95% CI	p	β	95% CI	p
Group (VRR vs. TAU)	-0.123	-0.517 to 0.270	0.539	-1.084	-1.685 to -0.484	<0.001
Total MDAS before	0.999	0.933 to 1.065	<0.001	0.846	0.761 to 0.932	<0.001
Age in years	0.010	-0.005 to 0.025	0.201	-0.001	-0.018 to 0.016	0.921
Anticipatory after	β	95% CI	p	β	95% CI	p
Group (VRR vs. TAU)	-0.217	-0.409 to -0.025	0.026	-0.498	-0.744 to -0.253	<0.001
Anticipatory before	0.970	0.901 to 1.039	<0.001	0.846	0.744 to 0.948	<0.001
Age in years	0.007	0.001 to 0.014	0.046	-0.006	-0.014 to 0.002	0.128
Treatment after	β	95% CI	p	β	95% CI	p
Group (VRR vs. TAU)	0.091	-0.295 to 0.476	0.645	-0.597	-1.06 to -0.138	0.011
Treatment before	0.953	0.854 to 1.052	<0.001	0.815	0.734 to 0.896	<0.001
Age in years	0.002	-0.010 to 0.014	0.716	0.004	-0.009 to 0.016	0.594

MDAS, Modified Dental Anxiety Scale; VRR, virtual reality relaxation; TAU, treatment as usual

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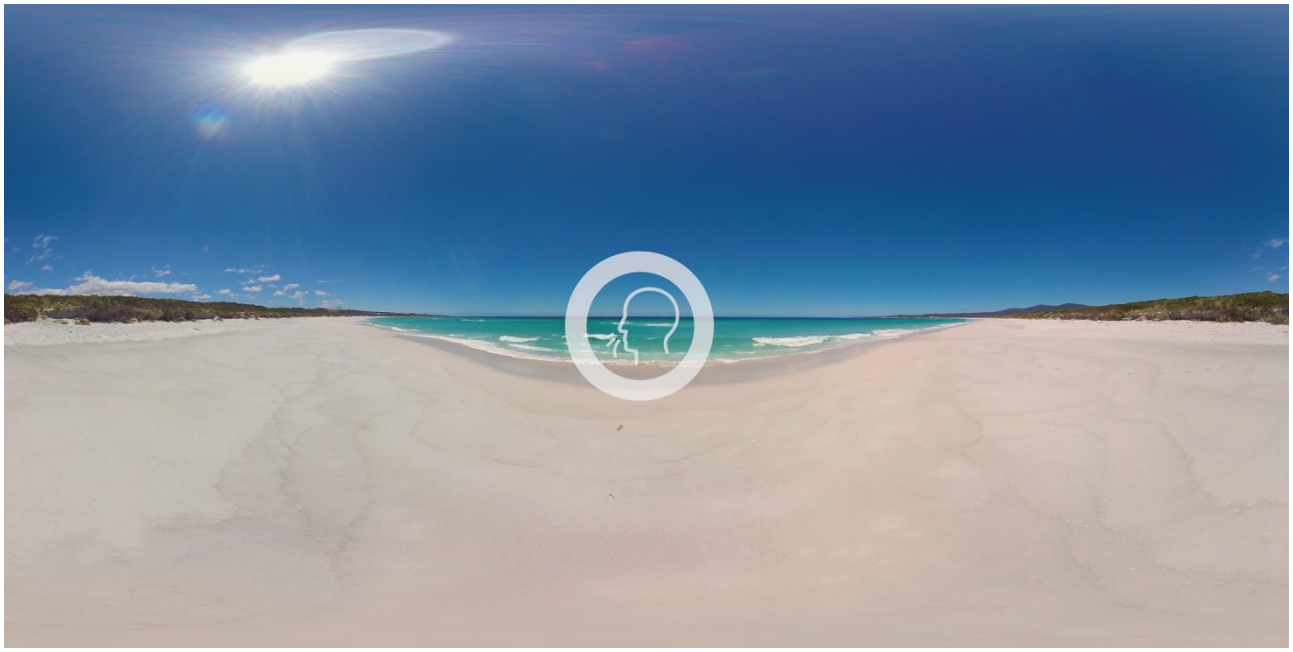
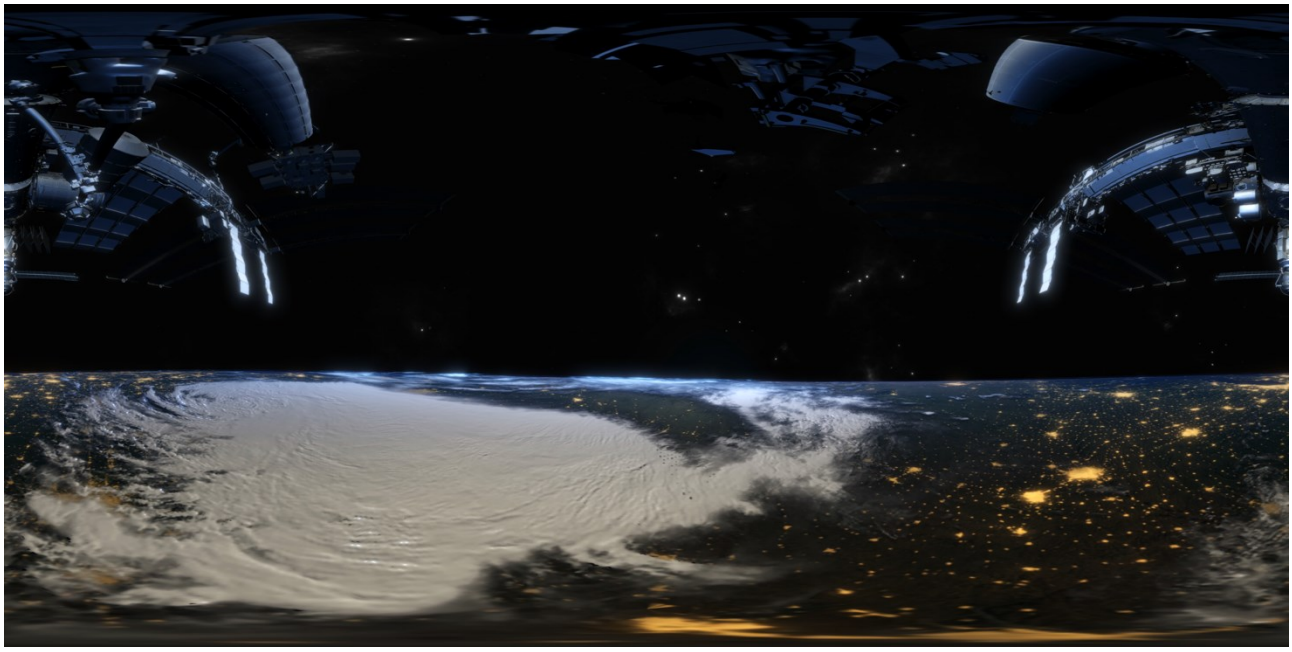
Appendix

Still pictures of the five videos used in the virtual reality relaxation intervention

Video 1. Australian Waterfalls

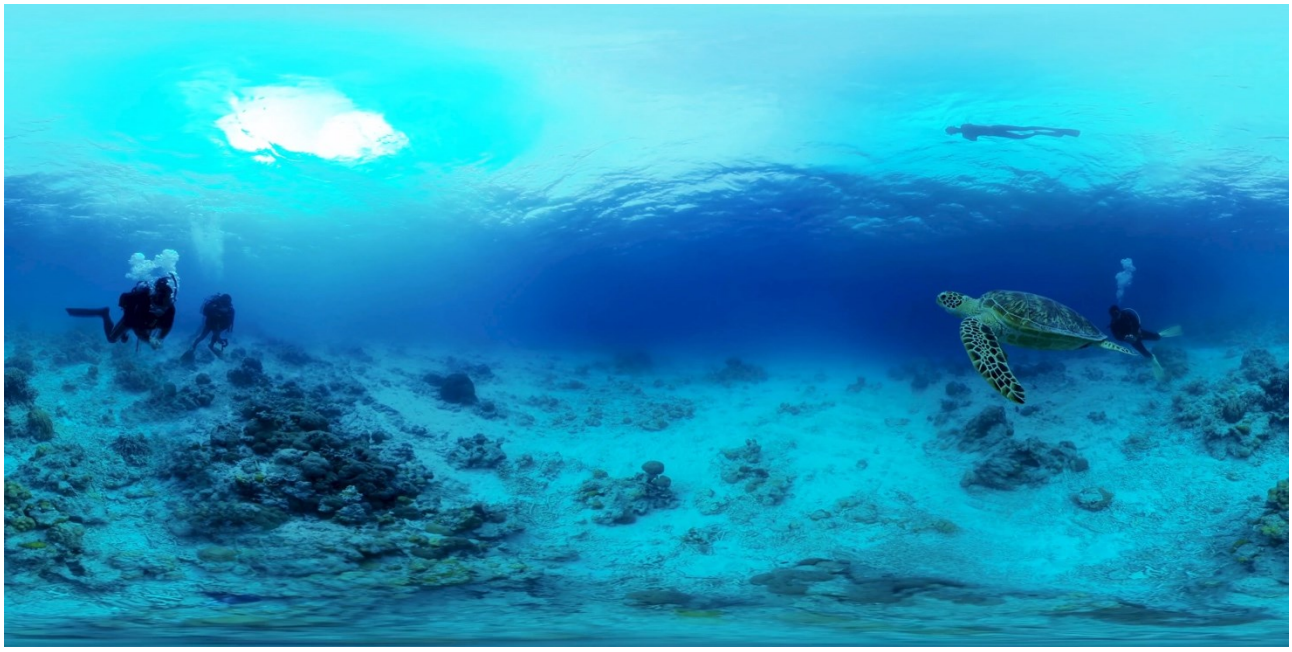


Video 2 Breathing Exercise on Philippine Beach



Video 3. Floating in Space

Video 4. Island Hopping in Thailand



Video 5. Turtle Dive in Bora Bora