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Virtual Reality for Dental Anxiety:

*A Mindfulness-Based Virtual Training to Reduce Preoperative Anxiety
Among Adults Undergoing Third Molar Surgery*

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Abstract

Premesse. L'ansia odontoiatrica (DA) interessa circa il 15% degli adulti a livello mondiale ed è particolarmente marcata nei pazienti sottoposti a estrazione del terzo molare, dove fino al 45% riferisce un'ansia preoperatoria di grado moderato-elevato. Gli ansiolitici farmacologici presentano effetti collaterali cognitivi, mentre gli interventi di realtà virtuale (VR) attualmente disponibili si basano prevalentemente sulla distrazione passiva, con evidenze di efficacia inconsistenti negli adulti ($SMD = -0,35$, ns). La VR basata sulla mindfulness ha dimostrato un potenziale ansiolitico acuto ed effetti di ampia entità sulla mindfulness di stato in setting sperimentali controllati (d di Cohen = 1,80 sulla mindfulness di stato in Seabrook et al. 2020), ma non è mai stata indagata nel contesto della chirurgia odontoiatrica. Obiettivi. Valutare l'efficacia di un breve training preoperatorio (10 minuti) di mindfulness in realtà virtuale nel ridurre l'ansia odontoiatrica in pazienti adulti candidati a estrazione del terzo molare, confrontandolo con una condizione di lettura e con un controllo ad attesa passiva. Metodi. È stato condotto uno studio randomizzato controllato a tre bracci, a gruppi paralleli, presso la Clinica Odontoiatrica degli Spedali Civili di Brescia. Novanta pazienti (età 20–40 anni) sono stati randomizzati al training VR ($n = 30$), al controllo ad attesa passiva ($n = 30$) o alla lettura di un racconto ($n = 30$). L'intervento di mindfulness in VR è stato erogato tramite The Secret Garden (Become Hub), uno scenario immersivo validato basato sulla mindfulness, somministrato con visore Meta Quest 2. L'outcome primario era il punteggio medio dell'IDAF-4C (Index of Dental Anxiety and Fear), valutato a T0 (baseline, 48 ore prima dell'estrazione), T1 (giorno dell'estrazione, pre-intervento) e T2 (post-intervento). L'analisi primaria è consistita in un'ANOVA a disegno misto 3 (Gruppo) $\times$ 3 (Tempo). Gli outcome secondari hanno incluso le sottoscale IDAF-S e IDAF-P, il Thermometer Distress, un'intervista semi-strutturata al dentista e item di soddisfazione del paziente. Risultati. L'ANOVA mista, con correzione di Greenhouse-Geisser per una lieve violazione della sfericità ($\epsilon = 0,91$), ha evidenziato una significativa interazione Gruppo $\times$ Tempo ($F(3,64; 158,3) = 2,97$; $p = 0,024$; $\eta^2 = 0,064$). Il gruppo VR ha mostrato una significativa riduzione dell'ansia da T1 a T2 ($d = 0,95$; $p < 0,001$), con ritorno ai livelli di baseline, mentre né il gruppo Controllo ($d = 0,27$; $p = 0,155$) né il gruppo Lettura ($d = 0,23$; $p = 0,214$) hanno mostrato variazioni significative. I confronti tra gruppi a T2 hanno evidenziato un effetto significativo a favore della VR rispetto alla Lettura ($d = 0,57$; $p = 0,031$) e un effetto di piccola entità, non significativo, rispetto al Controllo ($d = 0,35$; $p = 0,176$). Gli outcome secondari hanno mostrato andamenti

convergenti. I dentisti hanno riferito un atteggiamento più rilassato e una migliore collaborazione nei pazienti del gruppo VR. La soddisfazione dei pazienti è risultata elevata: 26 dei 30 partecipanti del gruppo VR (87%) si sono dichiarati disponibili a raccomandare il trattamento. Conclusioni. Una singola sessione di training preoperatorio di mindfulness in realtà virtuale ha prodotto una riduzione significativa dell'ansia odontoiatrica all'interno del gruppo, con effect size di ampia entità. La significativa interazione conferma traiettorie d'ansia differenti tra le condizioni. Sebbene gli effetti tra i gruppi siano risultati modesti, la condizione di mindfulness in VR è stata l'unica a produrre una riduzione significativa dell'ansia, supportandone il potenziale come strumento non farmacologico per la gestione dell'ansia preoperatoria. Saranno necessari protocolli multi-sessione e campioni più ampi per caratterizzare l'intero potenziale clinico degli interventi di mindfulness in VR nella chirurgia odontoiatrica.

Abstract

Background. Dental anxiety (DA) affects approximately 15% of adults worldwide and is particularly pronounced in patients undergoing third molar extraction, where up to 45% report moderate-to-high preoperative anxiety. Pharmacological anxiolytics carry cognitive side effects, while existing virtual reality (VR) interventions rely predominantly on passive distraction with inconsistent evidence of efficacy in adults (SMD = -0.35 , ns). Mindfulness-based VR has shown acute anxiolytic potential and large effects on state mindfulness in controlled laboratory settings (Cohen's $d = 1.80$ on state mindfulness in Seabrook et al. 2020), but has not been investigated in the dental surgical context.

Objectives. To evaluate the efficacy of a brief (10-minute) VR-based mindfulness pre-operative training in reducing dental anxiety in adults scheduled for third molar extraction, compared to a reading condition and a passive waiting control.

Methods. A three-armed, parallel-group randomized controlled trial was conducted at the Dental Clinic of Spedali Civili di Brescia. Ninety patients (age 20–40) were randomized to VR training ($n = 30$), passive waiting control ($n = 30$), or reading a story ($n = 30$). The VR-based mindfulness intervention employed The Secret Garden (Become Hub), a validated mindfulness-based immersive scenario delivered via Meta Quest 2. The primary outcome was the IDAF-4C mean score (Index of Dental Anxiety and Fear), assessed at T0 (baseline, 48 h pre-extraction), T1 (day of extraction, pre-intervention), and T2 (post-intervention). The primary analysis was a 3 (Group) $\times$ 3 (Time) mixed-design ANOVA. Secondary outcomes included the IDAF-S, IDAF-P, Thermometer Distress, a dentist semi-structured interview, and patient satisfaction items.

Results. The mixed ANOVA, with Greenhouse-Geisser correction for a mild sphericity violation ($\epsilon = 0.91$), revealed a significant Group $\times$ Time interaction ($F(3.64, 158.3) = 2.97$, $p = .024$, $\eta^2 = .064$). The VR group showed a significant T1 $\rightarrow$ T2 anxiety reduction ($d = 0.95$, $p < .001$), returning to baseline levels, while neither the Control ($d = 0.27$, $p = .155$) nor Reading group ($d = 0.23$, $p = .214$) showed significant changes. Between-group comparisons at T2 showed a significant effect favoring VR over Reading ($d = 0.57$, $p = .031$) and a small non-significant effect over Control ($d = 0.35$, $p = .176$). Secondary outcomes showed convergent patterns. Dentists reported calmer patient demeanor and improved cooperation in the VR group. Patient satisfaction was high, with 26 of 30 VR participants (87%) expressing willingness to recommend the treatment.

Conclusions. A single session of VR-based mindfulness pre-operative training produced a significant within-group reduction of dental anxiety with a large effect size. The significant interaction effect confirms differential anxiety trajectories across conditions. While between-group effects were modest, the VR-based mindfulness condition was the only one to produce significant anxiety reduction, supporting its potential as a non-pharmacological tool for pre-operative anxiety management. Multi-session protocols and larger samples are needed to characterize the full clinical potential of VR-based mindfulness interventions in dental surgery.

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List of Abbreviations

ACT	—	Acceptance and Commitment Therapy
ANOVA	—	Analysis of Variance
AR	—	Augmented Reality
CBT	—	Cognitive Behavioural Therapy
CI	—	Confidence Interval
DA	—	Dental Anxiety
DAS	—	Dental Anxiety Scale
ER-VR	—	Emotional Regulation through Virtual Reality
GABA	—	Gamma-Aminobutyric Acid
HMD	—	Head-Mounted Display
IDAF-4C+	—	Index of Dental Anxiety and Fear
IDAF-P	—	IDAF Phobia Module
IDAF-S	—	IDAF Stimulus Module
LMICs	—	Low- and Middle-Income Countries
MDAS	—	Modified Dental Anxiety Scale
MR	—	Mixed Reality
OHRQoL	—	Oral Health-Related Quality of Life
RCT	—	Randomized Controlled Trial
SD	—	Standard Deviation
SEM	—	Standard Error of the Mean
VAS	—	Visual Analogue Scale
VR	—	Virtual Reality
XR	—	Extended Reality

Introduction

Dental anxiety represents one of the most prevalent and clinically consequential psychological conditions encountered in oral healthcare. Affecting approximately 15% of the global adult population [1], dental anxiety constitutes a significant barrier to treatment access, contributes to deteriorating oral health outcomes, and imposes substantial burdens on healthcare systems worldwide [2]. Among dental procedures, third molar extraction stands as one of the most anxiety-provoking, with studies reporting that up to 45% of patients experience moderate-to-high preoperative anxiety [3,4]. This anticipatory anxiety not only compromises patient well-being but has been demonstrated to correlate with increased postoperative pain, elevated complication rates, and impaired surgical outcomes [3].

The impact of dental anxiety extends beyond the individual patient. At the healthcare system level, dental anxiety drives patterns of irregular, emergency-oriented care utilization that are substantially more costly than routine preventive visits. The avoidance-deterioration-emergency cycle generates higher treatment complexity, longer appointment times, and increased risk of complications, imposing significant economic burdens on healthcare systems [2]. At the professional level, managing highly anxious patients is consistently reported as one of the most stressful aspects of dental practice, contributing to dentist fatigue and burnout [14]. These systemic consequences reinforce the need for effective interventions that can be implemented at scale within routine clinical workflows.

Traditional approaches to managing dental anxiety have relied primarily on pharmacological interventions, including benzodiazepines, nitrous oxide sedation, and intravenous conscious sedation [5]. While effective in reducing acute procedural anxiety, these approaches carry cognitive side effects, require specialized monitoring, and are contraindicated in certain patient populations. Pharmacological anxiolysis also addresses only the acute symptoms without modifying the underlying anxiety construct, offering no lasting benefit for future dental encounters. Non-pharmacological alternatives—including cognitive-behavioral techniques, music therapy, and audiovisual distraction—have shown variable efficacy and face significant implementation barriers in routine clinical practice, particularly the need for trained therapists, dedicated time, and multi-session protocols [6].

In recent years, virtual reality (VR) has emerged as a promising technological tool for anxiety management across diverse healthcare settings. Immersive VR environments have demonstrated efficacy in managing procedural pain and anxiety in burn care, paediatric

procedures, and surgical contexts [7]. In dentistry, however, the evidence remains inconsistent. A recent meta-analysis of VR for adult dental anxiety reported a non-significant pooled effect ($SMD = -0.35$) [8], suggesting that the passive distraction paradigm dominant in dental VR research may be insufficient. The vast majority of dental VR studies have employed passive distraction—exposing patients to relaxing nature scenes or videos during procedures—rather than engaging them in active therapeutic processes [9].

A fundamentally different approach is offered by VR-based mindfulness interventions, which actively engage users in therapeutic processes such as guided breathing, body awareness, and cognitive reappraisal within immersive environments. Preliminary experimental evidence indicates that VR-based mindfulness practice can produce large acute effects on state mindfulness (Cohen's $d = 1.80$) and positive affect in non-clinical settings, with participants reporting reduced environmental distractors and easier attentional anchoring [10]. However, this therapeutic VR paradigm has not yet been investigated in the context of dental surgery, representing a significant gap in the literature.

The theoretical basis for therapeutic VR rests on the Emotional Regulation through Virtual Reality (ER-VR) framework proposed by Riva and colleagues [26], which posits that immersive environments can facilitate emotional regulation through three synergistic mechanisms: presence (experiential disengagement from threatening real-world stimuli), embodied cognition (activation of parasympathetic calming pathways through guided body awareness), and narrative transportation (cognitive reappraisal facilitated by metaphorical narratives). This multi-level engagement distinguishes therapeutic VR from passive distraction, which relies solely on attentional capture without engaging deeper emotional regulation processes.

The present thesis addresses this gap by reporting on the design, implementation, and results of a three-armed randomized controlled trial evaluating the efficacy of a brief (10-minute) VR-based mindfulness pre-operative training—The Secret Garden (Become Hub, Milan)—in reducing dental anxiety among adults scheduled for third molar extraction at the Dental Clinic of Spedali Civili di Brescia, University of Brescia. Ninety patients were randomized to VR training ($n = 30$), a reading active control ($n = 30$), or a passive waiting control ($n = 30$). The study employed the IDAF-4C+ (Index of Dental Anxiety and Fear), a multidimensional measure validated for the Italian population [18,19], as the primary outcome, assessed at three timepoints: baseline (T0, 48 h pre-extraction), day of surgery pre-intervention (T1), and post-intervention (T2).

A notable aspect of this study is the dual-perspective evaluation, combining patient-reported outcomes with dentist semi-structured interviews conducted after each procedure. This methodological innovation addresses a notable gap in dental VR research, where studies rely almost exclusively on patient self-report measures that may be subject to demand characteristics and social desirability bias. By capturing the dentist's blinded observations of patient behavior during surgery, the present design provides ecologically valid evidence that complements and triangulates the self-report data, strengthening the inferential basis of the findings.

This thesis aims to determine whether a brief, theoretically grounded, VR-based mindfulness pre-operative intervention can produce meaningful reductions in dental anxiety compared to active and passive control conditions. The specific objectives are: (a) to evaluate whether the VR-based mindfulness intervention produces differential anxiety trajectories compared to control conditions (Group $\times$ Time interaction); (b) to quantify the within-group effect of the VR-based mindfulness intervention on preoperative dental anxiety reduction; (c) to characterize between-group differences at the post-intervention timepoint; and (d) to assess the feasibility, acceptability, and clinical relevance of the intervention through patient satisfaction data and dentist qualitative reports.

The thesis is structured as follows. Chapter 1 reviews dental anxiety, encompassing its definition, epidemiology, aetiology, specific manifestations in third molar surgery, and current management strategies. Chapter 2 examines virtual reality technology and its applications in healthcare and dentistry, with particular attention to the theoretical framework underpinning therapeutic VR interventions. Chapter 3 presents the methods and results of the clinical trial. Chapter 4 discusses the findings in the context of existing literature, clinical implications, and study limitations. Chapter 5 offers concluding remarks and future directions.

Chapter 1 — Dental Anxiety in Oral Surgery

1.1 Definition and Conceptual Framework

Dental anxiety (DA) is a complex psychological phenomenon defined as a condition of irrational anticipatory apprehension towards dental procedures or the clinical environment in which they take place [1,11]. Unlike dental fear, which constitutes an immediate emotional response to a real and specific stimulus—such as the sight of a surgical instrument or the sound of a handpiece—dental anxiety is characterized by a persistent anticipatory component, often in the absence of imminent or tangible danger [12]. In its most severe manifestation, this condition may evolve into odontophobia (dental phobia), a specific phobia characterized by extreme, irrational, and markedly debilitating fear that significantly interferes with the patient's ability to receive appropriate dental care and maintain adequate oral health [13].

Dental anxiety is best understood as a multi-component construct integrating cognitive, emotional, behavioral, and physiological components into a complex clinical picture [14]. The cognitive component manifests through negative anticipatory thoughts, catastrophic worries regarding procedural pain, cognitive distortions concerning treatment safety, and pessimistic expectations about clinical outcomes. The emotional component encompasses subjective feelings of fear, tension, apprehension, psychological distress, and vulnerability, which manifest not only during the dental visit but also in the periods preceding and following treatment. On the behavioral plane, dental anxiety frequently translates into active avoidance of dental care, postponement or cancellation of appointments, delayed recourse to necessary treatments until the onset of acute conditions, and compliance difficulties during procedures [14,15]. Finally, the physiological component is characterized by activation of the sympathetic autonomic nervous system, with somatic manifestations including tachycardia, arterial hypertension, excessive sweating, tremors, generalized muscle tension, nausea, xerostomia, and, in the most severe cases, vasovagal reactions with possible syncope [15].

Dental anxiety must be distinguished from related conditions. While dental anxiety represents a specific concern linked to the dental context, it may be comorbid with generalized anxiety disorder, panic disorder, or other specific phobias [22]. Several authors have proposed a distinction between trait anxiety, reflecting a general individual

predisposition to respond with anxiety to stressful situations, and state anxiety, representing a temporary situational response to the specific dental context [13]. This distinction carries important clinical implications, as patients with elevated trait anxiety may require more intensive and personalized therapeutic approaches.

Dental anxiety configures a vicious cycle with significant consequences for both oral health and patients' quality of life. Individuals with elevated levels of dental anxiety tend to avoid regular dental visits, accumulating treatment needs that become progressively more invasive and complex, which in turn reinforces and perpetuates anxiety through a self-maintaining mechanism [1]. The consequences of this vicious cycle include progressive deterioration of oral health, with increased prevalence of caries, periodontal disease, and tooth loss, as well as negative impacts on oral health-related quality of life (OHRQoL), self-esteem, social relationships, and occupational functioning [14].

The vicious cycle of dental anxiety can be modelled as a self-reinforcing feedback loop comprising four stages [2,14]. In Stage 1 (Anxiety Onset), the individual develops initial anxiety through one or more of the aetiological pathways described in Section 1.3—direct conditioning, vicarious learning, or informational transmission. In Stage 2 (Avoidance), the anxiety leads to systematic avoidance of dental visits, with appointments being postponed, cancelled, or simply not scheduled. In Stage 3 (Deterioration), the absence of preventive and routine care leads to progressive deterioration of oral health, with the accumulation of untreated caries, periodontal disease, and dental emergencies. In Stage 4 (Reinforcement), when the patient eventually seeks care—typically driven by acute pain or emergency—the required treatment is more invasive, complex, and painful than what would have been necessary with timely preventive care, thereby reinforcing the original anxiety and closing the cycle. Breaking this cycle requires interventions that address the anxiety component directly, rather than focusing solely on the dental pathology.

The economic and systemic impact of dental anxiety extends beyond individual patient outcomes. Healthcare systems bear increased costs from emergency dental presentations, which are significantly more expensive than routine preventive visits, and from the more invasive interventions required when dental disease progresses undetected due to avoidance behaviours [2]. Dentists also report that managing anxious patients is among the most stressful aspects of clinical practice, contributing to professional burnout and reduced job satisfaction [14]. Effective, scalable interventions for dental anxiety management are therefore a priority.

1.1.1 Measurement Instruments for Dental Anxiety

The accurate assessment of dental anxiety requires reliable and valid psychometric instruments. Several scales have been developed and validated for this purpose, each with distinct theoretical foundations and psychometric properties [16,21].

The Dental Anxiety Scale (DAS; [21]), developed by Corah in 1969, was the first widely adopted measure and comprises four items assessing anxiety in specific dental situations. Despite its extensive use, the DAS has been criticised for its limited scope and outdated item content [16]. The Modified Dental Anxiety Scale (MDAS), developed by Humphris et al. (1995), addressed some of these limitations by adding a fifth item on anaesthetic injection and employing a five-point response scale, yielding improved psychometric properties and a clinical cut-off score (≥ 19) for high dental anxiety [17].

The Index of Dental Anxiety and Fear (IDAF-4C+), developed by Armfield (2010), represents the most complete instrument currently available [18]. Identified by Chi (2023) as the gold standard for dental anxiety assessment [16], the IDAF-4C+ is a modular instrument comprising three modules: (a) the IDAF-4C core module (8 items, 5-point Likert scale) assessing emotional, behavioural, physiological, and cognitive anxiety components; (b) the IDAF-S stimulus module (10 items) measuring specific feared dental stimuli; and (c) the IDAF-P phobia module (5 dichotomous items) assessing diagnostic criteria for dental phobia. The IDAF-4C+ demonstrates excellent internal consistency (Cronbach's $\alpha = .94$), strong test-retest reliability at 4 months ($r = .82$), and strong convergent validity with the DAS ($r = .84$) [18]. The Italian version was validated by Salgarello et al. (2021), demonstrating adequate construct validity and reliability in the Italian adult population [19].

Additional instruments used in dental anxiety research include the Visual Analogue Scale (VAS), the State-Trait Anxiety Inventory (STAI), the Dental Fear Survey (DFS), and single-item measures. The Dental Fear Survey (DFS) is a 20-item instrument assessing avoidance behaviour, physiological responses, and fear of specific dental situations, with strong psychometric properties but considerable overlap with the DAS and MDAS. The State-Trait Anxiety Inventory (STAI) measures general rather than dental-specific anxiety, limiting its sensitivity to dental-related changes. Single-item VAS measures offer practical advantages (brevity, ease of administration) but sacrifice the multidimensional assessment capacity of longer instruments [16].

Table 1.1. Summary of dental anxiety measurement instruments.

Instrument	Items	Domains	Scale	α	Key Limitation
DAS	4	General DA	5-point	.86	Limited scope
MDAS	5	General DA + injection	5-point	.89	Unidimensional
IDAF-4C+	8+15	4C + stimuli + phobia	5-point	.94	Length
DFS	20	Avoidance + physio + fear	5-point	.92	Overlap w/ DAS
VAS	1	Global anxiety	0–100	—	No dimensions
STAI	40	State + trait	4-point	.93	Not dental- specific

The choice of instrument depends on the research context. For clinical screening, brief instruments such as the MDAS or single-item VAS are preferred. For research requiring thorough characterisation of the anxiety construct, the IDAF-4C+ offers the most complete assessment, capturing the emotional, behavioural, physiological, and cognitive dimensions of dental anxiety as well as specific feared stimuli and phobia criteria [16,18]. The present study employed the IDAF-4C+ as the primary outcome measure precisely because of this multidimensional assessment capacity.

1.2 Epidemiology of Dental Anxiety

The prevalence of dental anxiety in the general population has been widely studied, with results showing it is a common condition worldwide. That said, prevalence estimates show considerable variability, ranging from 4% to over 50% depending on the populations studied, the measurement instruments employed, the definitions adopted, and the cut-offs applied to classify anxiety levels [1].

To provide more reliable and generalizable estimates, several systematic reviews and meta-analyses have been conducted in recent years. The systematic review and meta-analysis by Silveira et al. (2021), which pooled data from 31 population-based studies and a combined sample of 72,577 adults, represents one of the most comprehensive recent syntheses [1]. The authors estimated a global pooled prevalence of 15.3% (95% CI: 10.2–21.2%) for any dental

fear/anxiety in the adult population. Stratifying by severity, the pooled prevalence of high dental fear/anxiety was 12.4% (95% CI: 9.5–15.6%), while severe (clinically significant or phobic) dental fear/anxiety was 3.3% (95% CI: 0.9–7.1%). Subgroup analyses indicated a higher prevalence among women and younger adults [1]. In absolute terms, these figures indicate that approximately one in every six to seven adults worldwide experiences clinically significant dental anxiety, even after accounting for the wide confidence intervals.

Subgroup analyses have revealed important demographic variations. Regarding gender differences, the meta-analysis demonstrated a significantly higher prevalence of dental anxiety in women compared to men, with a pooled odds ratio of 1.79 (95% CI: 1.65–1.94), indicating that women have nearly double the probability of manifesting dental anxiety compared to men [1]. Broader evidence similarly documents a higher prevalence of anxiety disorders in women in the general population. Explanatory hypotheses include biological differences (hormonal influences, variability in autonomic nervous system regulation), psychological differences (coping styles, greater tendency to report emotional symptoms), and sociocultural factors [14].

Age-related analyses have demonstrated that, although dental fear frequently originates in childhood or adolescence—often following early traumatic experiences—it can persist throughout the lifespan. A systematic review by Cianetti et al. (2017) synthesising epidemiological studies of dental fear/anxiety in children and adolescents reported prevalence rates varying widely (from ~5% to >40%) depending on age band, assessment instrument and geographic setting, confirming that the burden is already substantial in paediatric populations [12]. In adults, some evidence suggests a possible decline in prevalence with advancing age, although data remain conflicting [1].

From a geo-socioeconomic perspective, studies conducted in high-income countries (HICs) tend to report slightly lower prevalence rates compared to those conducted in low- and middle-income countries (LMICs), although this difference does not always reach statistical significance. Yuan et al. (2008) examined the cross-cultural validity of dental anxiety measures and found that while overall prevalence rates were broadly comparable across cultural contexts, predictive factors differed substantially between populations [20]. Additional demographic and socioeconomic factors associated with higher dental anxiety prevalence include low educational attainment, unemployment, disadvantaged socioeconomic status, and residence in rural areas with limited access to dental services [14]. Stein Duker et al. (2022) proposed a biopsychosocial conceptual model linking dental fear

and anxiety to general anxiety, sensory over-responsivity, and oral health behaviours, highlighting the multifactorial nature of the condition [13].

In specific clinical populations, dental anxiety presents particular challenges in certain clinical contexts. Patients with intellectual disabilities, autism spectrum disorder, and other neurodevelopmental conditions often exhibit heightened dental anxiety due to sensory sensitivities, communication difficulties, and limited capacity for cognitive coping strategies [14]. Elderly patients may present with dental anxiety that has persisted for decades, deeply entrenched in avoidance patterns. Pregnant women represent another vulnerable group, as dental anxiety may delay necessary oral healthcare during a period when hormonal changes increase susceptibility to periodontal disease [1]. These population-specific differences call for tailored intervention approaches.

The high prevalence of dental anxiety, its role as a significant barrier to dental care access, and its negative impact on oral health and quality of life highlight the urgency of developing and implementing evidence-based strategies for prevention, early identification, and effective management of this condition [1,14].

1.3 Aetiopathogenetic Hypotheses

The aetiology of dental anxiety is complex, reflecting the dynamic interaction among a wide range of biological, psychological, social, and environmental factors. The scientific literature has traditionally categorised aetiological factors into external causes (related to care experience and the environmental context) and internal causes (related to individual biological and psychological characteristics). However, it is now recognised that these categories are not mutually exclusive but rather interact synergistically according to an integrated biopsychosocial model [14].

1.3.1 External Factors: Traumatic Experiences and Learning

Among external causes, the factor most frequently and consistently associated with the onset of dental anxiety is fear of pain and potential bodily harm connected to dental procedures. Previous painful experiences during dental treatments—particularly if occurring during childhood or adolescence—are reported by the majority of patients with elevated dental anxiety as causal or precipitating events [1]. According to classical Pavlovian conditioning theory, initially neutral stimuli (such as the smell of the dental office, the sound of the handpiece, the sight of instruments) can become conditioned stimuli through repeated

associations with aversive experiences (pain, discomfort), subsequently eliciting conditioned anxiety responses even in the absence of the original noxious stimulus [12].

Beyond direct conditioning, vicarious (observational) and informational learning mechanisms contribute significantly to the development of dental anxiety. Vicarious learning occurs when an individual observes significant models (parents, siblings, peers) manifesting fear or avoidance towards dental care, internalising these behavioural and emotional patterns. Informational learning occurs through the transmission of negative or alarming information regarding dental treatments from family members, friends, or media [12]. These mechanisms are particularly relevant during childhood, when children are especially sensitive to the influence of parental models.

Relational and communicative factors also play a role among external causes. The literature emphasizes that attitudes perceived as critical, dismissive, or rushed on the part of dental staff can contribute to the development or maintenance of dental anxiety. Conversely, empathetic, clear, and reassuring communication that includes the patient in the decision-making process is associated with lower anxiety levels and improved compliance [14].

1.3.2 Internal Factors: Biological and Psychological Predispositions

Internal causes, although less completely characterized than external ones, are attributed to individual biological and psychological characteristics that may amplify the response to dental stimuli and vulnerability to developing dental anxiety. On the biological plane, studies do not identify a single gene or hereditary mechanism but suggest a polygenic predisposition component. Twin studies have estimated that the heritable component of dental fear is approximately 30–40%, indicating that genetic factors contribute moderately but significantly to individual variability in susceptibility to dental anxiety [13].

The anxious response in the dental context can be described as a neurophysiological cascade triggered by dental-related stimuli. Sensory input from the dental environment activates the amygdala, the brain's primary fear processing centre, initiating a fight-or-flight response via the hypothalamic-pituitary-adrenal (HPA) axis [15]. Reduced GABAergic transmission and dysregulation of the serotonergic system have been implicated in the modulation of dental anxiety, providing a rationale for pharmacological interventions targeting these neurotransmitter systems [5].

On the psychological plane, personality traits including elevated neuroticism, low extraversion, maladaptive perfectionism, and external locus of control have been identified

as risk factors [13,14]. Neuroticism, the tendency to experience negative emotional states, has consistently emerged as the strongest personality-level predictor of dental anxiety in the conceptual and clinical literature [11]. Low perceived control—the belief that one cannot influence the course of the dental procedure—is also strongly associated with elevated anxiety and may represent a modifiable target for intervention [14].

Cognitive models of dental anxiety emphasize the role of dysfunctional cognitive schemas, irrational beliefs, and attentional biases. Patients with elevated dental anxiety tend to selectively attend to threatening stimuli in the dental environment (attentional bias), overestimate the probability and severity of negative outcomes (probability and severity bias), underestimate their own coping capacity (coping appraisal bias), and engage in catastrophic thinking about worst-case scenarios [11,14]. These cognitive biases are not passive side-effects of anxiety; they actively maintain and exacerbate the anxious state through feedback loops: biased attention increases the salience of threatening stimuli, which reinforces catastrophic appraisals, which further narrows attention towards threat-relevant information.

Affective forecasting biases also play a role in dental anxiety. Wilson and Gilbert's research on affective forecasting [54] has demonstrated that individuals systematically overestimate the intensity and duration of negative emotional experiences. In the dental context, this manifests as patients anticipating far greater pain and distress than they actually experience, leading to avoidance behaviour that prevents the corrective experience of finding that the procedure was more tolerable than expected. Interventions that reduce affective forecasting errors—for example, by promoting present-moment awareness rather than future-oriented catastrophising—may be particularly effective for dental anxiety management.

1.3.3 An Integrated Biopsychosocial Model

Current evidence supports an integrated aetiopathogenetic model of dental anxiety that recognizes simultaneous and interactive contributions from biological factors (genetic predisposition, neurobiological substrates), psychological factors (personality traits, dysfunctional cognitive schemas, prior traumatic experiences), and social factors (family environment, cultural context, quality of the therapeutic relationship). This biopsychosocial model has important clinical implications: it suggests that effective management of dental anxiety requires multimodal interventions addressing multiple aetiological dimensions simultaneously, rather than approaches targeting a single factor in isolation [14].

The biopsychosocial model also has implications for treatment selection. Patients whose anxiety is primarily driven by biological factors (e.g., high trait anxiety, autonomic hyperreactivity) may benefit most from interventions that directly modulate physiological arousal, such as pharmacological sedation or guided relaxation techniques. Patients whose anxiety is primarily cognitive in nature (e.g., catastrophizing, dysfunctional beliefs) may respond better to cognitive-behavioral approaches. Patients whose anxiety is rooted in traumatic learning experiences may require systematic desensitization or exposure-based interventions. In practice, most patients present with a combination of factors, favoring multimodal approaches. Virtual reality-based interventions that combine physiological calming (through guided breathing), cognitive reappraisal (through narrative metaphors), and experiential safety (through immersive presence) may address multiple aetiological dimensions simultaneously, a theoretical advantage explored in Chapter 2.

Dental anxiety can follow several developmental trajectories. Longitudinal research suggests that dental anxiety may follow several distinct trajectories: (a) persistent high anxiety from childhood through adulthood, typically associated with early traumatic experiences and high trait anxiety; (b) adult onset, frequently triggered by a specific negative dental experience in adulthood; (c) decreasing anxiety, reflecting positive dental experiences and the development of effective coping strategies; and (d) stable low anxiety across the lifespan [1,12]. Understanding these trajectories is important for tailoring interventions: patients on the persistent high anxiety trajectory may require more intensive and sustained interventions, while those with adult-onset anxiety following a specific trigger may respond well to brief, targeted interventions such as the VR-based approach investigated in this thesis.

1.4 Dental Anxiety in Third Molar Surgery

Third molar (wisdom tooth) extraction surgery represents one of the dental procedures most frequently associated with elevated levels of anxiety and psychological distress, even in patients without a prior history of dental anxiety [3,14]. This association reflects the convergence of multiple anxiety-amplifying factors inherent to this specific procedure: the surgical nature of the intervention, the anticipation of postoperative pain and swelling, the perceived risk of complications (including nerve damage, alveolar osteitis, and haemorrhage), and the frequent need for bone removal and tissue manipulation—all elements that intensify the threatening valence of the clinical experience [3,4].

Preoperative anxiety in patients scheduled for third molar surgery has been studied using validated psychometric instruments. Studies consistently report that 30–45% of patients present moderate-to-high anxiety levels prior to the procedure, with prevalence rates varying according to the measurement instrument employed, the clinical setting, and the demographic characteristics of the sample [3]. Zhang et al. (2025) examined patterns and predictors of tooth extraction-related anxiety at sequential perioperative stages, identifying a characteristic anxiety trajectory with peak levels immediately before the procedure, consistent with anticipatory anxiety mechanisms [4]. Qiao et al. (2022) further demonstrated that dental anxiety is directly related to postoperative symptom severity following third molar surgery, establishing a clear link between psychological state and clinical outcome [3].

Preoperative anxiety has real clinical consequences. It has been shown to exert measurable effects on surgical outcomes. Preoperative anxiety has been correlated with significant variations in haemodynamic vital parameters during the surgical procedure, including elevated heart rate, systolic and diastolic blood pressure, and respiratory rate [14]. These autonomic changes may complicate anaesthetic management and increase the risk of intraoperative adverse events.

Anxiety is also associated with modifications of the neuroendocrine stress response. Anxious patients exhibit elevated salivary cortisol levels, increased plasma adrenaline and noradrenaline concentrations, and altered hypothalamic-pituitary-adrenal axis reactivity [14]. These neuroendocrine alterations can affect tissue healing, immune function, and pain perception, potentially influencing postoperative recovery. Preoperative anxiety has also been correlated with increased incidence and severity of postoperative complications, including more intense and prolonged pain, greater oedema, trismus, and higher consumption of analgesic medication [3].

The role of information provision in modulating preoperative anxiety has generated some debate. Some studies suggest that detailed preoperative information about the procedure reduces uncertainty and thereby anxiety, while others indicate that excessive or graphic information may paradoxically increase anxiety in susceptible individuals [3]. The optimal balance appears to depend on individual coping styles: 'monitors' (information-seekers) benefit from detailed information, while 'blunters' (information-avoiders) may experience increased anxiety with extensive procedural descriptions. This individual variability points

to the need for personalised approaches to preoperative anxiety management, rather than one-size-fits-all protocols [14].

The temporal dynamics of anxiety in the perioperative period of third molar surgery are also clinically relevant. Research has consistently documented an anxiety trajectory characterized by gradual buildup in the days preceding surgery, a sharp increase on the day of surgery (particularly in the waiting area), peak levels during anaesthesia administration, partial reduction during the procedure itself (once the patient perceives that the feared event has begun and is tolerable), and variable postoperative anxiety related to pain expectations and recovery concerns [4]. Understanding this temporal pattern is essential for designing targeted interventions: strategies delivered immediately before the procedure—targeting the peak anticipatory anxiety phase—may be particularly effective, as this represents the moment of maximum psychological vulnerability and the time point at which intervention has the greatest potential impact on the subsequent surgical experience.

Despite the extensive scientific documentation recognising third molar surgery as a high-emotional-impact procedure, current clinical practice is largely deficient in implementing systematic protocols for preoperative anxiety management. Standard clinical approaches often remain limited to pharmacological sedation for severe cases or to generic verbal reassurance, without structured non-pharmacological interventions [6]. This gap between evidence and practice calls for innovative, non-invasive, cost-effective tools specifically designed for preoperative anxiety management in the dental surgical setting. Virtual reality emerges as a promising candidate to fill this gap, a topic that will be examined in detail in Chapter 2.

1.5 Management Strategies for Dental Anxiety

The management of dental anxiety has long constituted a central challenge for clinical dentistry, as this condition significantly influences treatment acceptance, procedural compliance, clinical outcomes, and patient-dentist relationship quality [2,5]. Current strategies can be broadly categorised into pharmacological and non-pharmacological approaches, each with distinct advantages, limitations, and evidence bases.

1.5.1 Pharmacological Approaches

Pharmacological approaches historically represent one of the most frequently employed modalities for dental anxiety control, particularly in cases of moderate-to-severe anxiety

where non-pharmacological strategies alone prove insufficient [5]. The principal pharmacological agents include benzodiazepines (oral, sublingual, or intravenous), nitrous oxide sedation, and intravenous conscious sedation protocols.

Benzodiazepines act by potentiating GABA neurotransmitter activity at GABA-A receptors, producing anxiolytic, sedative, muscle relaxant, and amnestic effects. Commonly employed agents include midazolam (0.25–0.5 mg/kg orally, onset 15–30 min), diazepam (5–10 mg orally, onset 30–60 min), and triazolam (0.125–0.25 mg sublingually). While effective in reducing procedural anxiety, benzodiazepines carry side effects including drowsiness, impaired cognitive function and psychomotor coordination, anterograde amnesia, potential for paradoxical reactions (particularly in elderly patients), respiratory depression risk at higher doses, and the need for a companion to escort the patient home [5].

Nitrous oxide (inhalation conscious sedation) represents a widely used alternative, particularly in paediatric dentistry and for patients with mild-to-moderate anxiety. It offers rapid onset (2–3 minutes), easily titratable depth of sedation, rapid recovery, and a favourable safety profile. Yet it requires dedicated equipment, trained personnel, adequate scavenging systems, and is contraindicated in patients with nasal obstruction or certain respiratory conditions [5].

Intravenous (IV) conscious sedation, typically employing midazolam (0.5–1.0 mg titrated boluses), propofol, or combinations thereof, provides a deeper level of anxiety control while maintaining the patient's protective reflexes and ability to respond to verbal commands. This technique is particularly indicated for patients with severe dental anxiety undergoing complex or prolonged surgical procedures, including third molar extraction. IV sedation, though, requires venous cannulation (which may itself provoke anxiety), continuous monitoring of vital signs (pulse oximetry, capnography, blood pressure), the presence of an anaesthetic-trained operator, and extended post-procedural observation until discharge criteria are met. These requirements significantly increase procedural costs, logistical complexity, and the need for specialised facilities [5].

General anaesthesia represents the most invasive level of pharmacological anxiety management and is typically reserved for patients with severe dental phobia, intellectual disabilities, young children, or patients requiring extensive surgical procedures. While effective in eliminating procedural awareness and anxiety, general anaesthesia carries the highest risk profile (including rare but serious complications such as aspiration, malignant hyperthermia, and postoperative nausea/vomiting) and the highest costs [5].

Despite their documented efficacy, pharmacological approaches present several significant limitations that motivate the search for alternatives. First, they entail substantial direct costs (medications, equipment, monitoring, specialised personnel) and indirect costs (need for a companion, time off work, extended recovery, travel). Second, they address only the acute symptoms of anxiety rather than the underlying cognitive and emotional components, meaning that the anxiety remains unchanged for subsequent dental encounters. Third, they do not promote the development of coping strategies that could benefit the patient in future dental experiences. Fourth, they carry medication-specific side effects and contraindications that limit their applicability to certain patient populations. Fifth, they require varying degrees of specialised training and facilities that may not be available in all dental practices. These limitations collectively highlight the need for effective, accessible, non-pharmacological alternatives [2,5,6].

1.5.2 Non-Pharmacological Approaches

In parallel, dental research has devoted increasing attention to non-pharmacological interventions, with the aim of promoting preventive strategies, enhancing patient self-regulation capacity, and reducing reliance on pharmacotherapy [6].

Basic behavioural techniques include strategies such as tell-show-do (explaining the procedure to the patient, demonstrating instruments, performing the treatment in graduated steps), systematic desensitisation (progressive exposure to anxiety-provoking stimuli in a hierarchy), breathing relaxation techniques (guided diaphragmatic breathing), and distraction strategies (directing patient attention away from the procedure through conversation, music, or visual stimuli). These techniques are widely accepted, carry no side effects, and are relatively easy to implement. Their efficacy in cases of moderate-to-severe anxiety is limited, and they require time and communication skills that may not always be available in the clinical setting [6].

Sensory distraction strategies, particularly music and audiovisual content, have been extensively investigated. Hao et al. (2023) conducted a Bayesian network meta-analysis including 61 randomized controlled trials (4,576 participants) evaluating the efficacy of music, audiovisuals, and virtual reality for reducing dental anxiety [23]. Results indicated that relaxing music (SMD = -0.64 , 95% CrI: -1.04 , -0.25), active music (SMD = -0.44 , 95% CrI: -0.88 , -0.01), and VR (SMD = -0.54 , 95% CrI: -0.89 , -0.20) were all superior

to standard care, with relaxing music ranking highest. Still, differences between distraction modalities were often non-significant, suggesting comparable effects across strategies [23].

Hypnotherapy has also been investigated as a non-pharmacological intervention for dental anxiety. Hypnotic techniques—including progressive relaxation induction, guided imagery, and post-hypnotic suggestions—have been reported to reduce dental anxiety in case series and small RCTs. However, the evidence base is limited by small sample sizes, heterogeneity of hypnotic techniques, and the requirement for a trained hypnotherapist, which limits scalability [6]. Guided imagery, a related technique in which patients are instructed to visualise calming scenes or pleasant experiences, offers a simpler alternative but faces the same limitation of requiring sustained imaginative capacity that many anxious patients find difficult to achieve in the dental context [52].

Cognitive-behavioural therapy (CBT) represents a more structured approach targeting the cognitive and behavioural components of dental anxiety. CBT for dental phobia typically includes psychoeducation about the nature of anxiety, cognitive restructuring of catastrophic beliefs (e.g., challenging the thought 'the pain will be unbearable' with alternatives based on published data), graduated exposure to feared dental stimuli, and the development of coping self-statements. Meta-analytic evidence indicates that CBT produces moderate-to-large effect sizes for dental anxiety reduction ($d = 0.60$ – 1.20), with effects maintained at 6- and 12-month follow-up [24]. Implementation in routine dental practice is hindered by the need for trained therapists, dedicated time (typically 5–10 sessions of 45–60 minutes each), and patient commitment to a multi-session protocol, creating significant barriers to widespread adoption [6].

More recently, third-wave cognitive-behavioural therapies have gained attention for anxiety management. Acceptance and Commitment Therapy (ACT) and mindfulness-based interventions aim not to eliminate anxiety per se but to change the individual's relationship with anxious thoughts and sensations, promoting psychological flexibility and acceptance [36,43,53]. These approaches have potential for dental anxiety because they do not require the patient to 'control' or 'suppress' anxiety—which may paradoxically increase distress—but rather to observe and accept anxious feelings while maintaining engagement with valued behaviours (e.g., attending dental appointments). Like traditional CBT, though, these therapies typically require trained practitioners and multiple sessions, limiting their feasibility in dental settings.

Digital technologies, particularly virtual reality, have emerged as a promising frontier for dental anxiety management. VR-based interventions offer several theoretical advantages: standardised delivery, high patient engagement through immersive experiences, no pharmacological side effects, and the potential for both distraction and active therapeutic engagement. VR can also operationalise complex therapeutic protocols (such as mindfulness exercises) in a standardised, self-guided format, potentially overcoming the therapist availability barrier that limits CBT and ACT implementation [10]. The specific evidence for VR in dentistry, its theoretical foundations, and the rationale for the present study will be examined in detail in Chapter 2.

Table 1.2. Summary of management strategies for dental anxiety.

Strategy	Mechanism	Evidence	Key Limitation
Benzodiazepines	GABA-A agonism	Strong (RCTs)	Cognitive side effects
Nitrous oxide	CNS depression	Strong (RCTs)	Equipment needed
IV sedation	CNS depression	Strong (RCTs)	Specialist training
Tell-show-do	Information + desensitisation	Moderate (consensus)	Mild anxiety only
Music therapy	Attentional distraction	Strong (SMD -0.64)	Passive, modest effect
CBT	Cognitive restructuring	Strong (d = 0.60–1.20)	Multiple sessions, therapist
ACT/Mindfulness	Acceptance, flexibility	Emerging (RCTs)	Multiple sessions, therapist
VR distraction	Attentional capture	Moderate (SMD -0.35–0.54)	Passive, inconsistent
Therapeutic VR	ER-VR multi-mechanism	Emerging (present study)	Novel, limited evidence

1.6 Gaps in the Literature and Rationale

The current state of the art reveals several gaps that motivate the present research programme. Large-scale, multicenter trials with adequate statistical power and rigorous methodological control comparing the relative efficacy of different non-pharmacological strategies for dental anxiety management are lacking [6,8]. The majority of studies focus on

immediate or short-term outcomes (peri-procedural anxiety and pain), while data on long-term outcomes—such as reduction of dental phobia, adherence to subsequent dental appointments, and changes in oral health-related quality of life—are scarce [8,9]. Studies investigating moderating factors and predictors of treatment response also remain rare, making it difficult to identify which patients may benefit most from specific interventions [8]. Research on the implementation of evidence-based strategies in routine clinical practice is limited, resulting in a disconnect between scientific evidence and clinical application [6].

Most critically for the present work, standardized non-pharmacological pre-operative protocols specifically designed for third molar surgery—a procedure associated with high anxiety—are absent. No study has yet investigated the use of therapeutic VR-based mindfulness as a pre-operative intervention for dental anxiety, as opposed to the passive distraction paradigm that dominates the existing literature [8,9]. These considerations provide the direct rationale for the clinical trial reported in Chapter 3 of this thesis.

In summary, dental anxiety is a highly prevalent condition with well-documented adverse consequences for patient health, quality of life, and healthcare systems. Its multi-factorial aetiology—spanning biological, psychological, and social domains—demands multimodal management strategies. Third molar surgery represents a particularly anxiety-provoking context with inadequate non-pharmacological management options. Existing evidence suggests that VR holds promise as an intervention modality, but the passive distraction paradigm has reached a ceiling of efficacy. The transition from passive to therapeutic VR—grounded in evidence-based mindfulness and emotional regulation frameworks—represents the next frontier, and constitutes the focus of this thesis.

Chapter 2 — Virtual Reality in Dentistry

2.1 Definition and Technical Foundations of Virtual Reality

Virtual reality (VR) is defined as a technology that employs head-mounted display (HMD) devices to create a three-dimensional immersive environment in which users can interact with computer-generated sensory stimuli, experiencing a subjective sense of 'being there' (presence) in the virtual environment [25]. Contemporary VR systems integrate sophisticated hardware components—including high-resolution visors (typically exceeding 1832×1920 pixels per eye), motion tracking sensors with six degrees of freedom (6DOF), integrated spatial audio systems, and haptic controllers—to generate a multisensory experience capable of effectively modulating the user's perceptual and emotional state [25].

Immersive VR differs from other forms of extended reality (XR), including augmented reality (AR) and mixed reality (MR). While AR overlays digital information onto the physical world through transparent displays, and MR enables interaction between virtual and real objects, immersive VR completely replaces the user's visual and auditory environment with a computer-generated scenario, maximising sensory isolation from the external environment [25]. This complete environmental substitution is theoretically advantageous for anxiety management applications, as it enables effective disengagement from anxiety-provoking real-world stimuli [26].

The concept of presence—the subjective sense of 'being there' in the virtual environment—is central to understanding VR's therapeutic potential. Slater and Wilbur (1997) distinguished between immersion (the objective technical characteristics of the VR system, such as resolution, field of view, and tracking accuracy) and presence (the subjective psychological response to immersion) [46]. Higher immersion generally produces greater presence, but the relationship is modulated by individual factors (susceptibility to presence, prior VR experience) and content factors (narrative engagement, interactivity). For therapeutic applications, presence is hypothesized to be a critical mediating variable: greater presence enables more effective engagement with therapeutic content and more complete disengagement from real-world anxiety triggers [26].

The technological evolution of VR hardware has been particularly rapid in recent years. First-generation consumer VR headsets (2014–2017) required tethered connection to high-performance gaming computers, external tracking sensors, and complex setup procedures—

barriers that severely limited clinical adoption. Second-generation devices (2019–2022), most notably the Meta Quest 2, introduced standalone operation, inside-out tracking, and significantly improved resolution (1832×1920 per eye, 90 Hz refresh rate, built-in spatial audio, 6DOF tracking) at a price point (~€300) accessible for clinical implementation. Third-generation devices (2023–present), including the Meta Quest 3 and Apple Vision Pro, offer further improvements in resolution, passthrough capability, and eye tracking, though at higher price points [25].

The Meta Quest 2, employed in the present study, represents an optimal balance between technical quality and practical accessibility for healthcare applications. Its wireless operation eliminates trip hazards and allows natural head movement; its resolution exceeds the threshold for comfortable text reading in VR; its 90 Hz refresh rate minimizes cybersickness risk; and its integrated guardian system prevents collisions with physical objects. The device's consumer-grade design also means that it requires no specialized technical knowledge to operate—a critical consideration for clinical settings where VR will be administered by dental staff rather than VR specialists [27].

2.2 Virtual Reality in Healthcare: Overview of Applications

The application of virtual reality in healthcare has expanded significantly in recent years, with growing evidence supporting its efficacy across diverse clinical domains [25,27].

2.2.1 Education and Training

In medical education, VR has demonstrated efficacy comparable to traditional methods, with the added advantage of providing risk-free learning environments for practicing complex procedures. Surgical simulation platforms enable repeated practice of procedures from appendectomies to neurosurgical interventions without risk to patients. Meta-analytic evidence indicates that VR-trained surgeons demonstrate comparable or superior technical skills to traditionally trained counterparts, with particular advantages in the acquisition of spatial awareness and procedural confidence [25]. In anatomy education, VR enables three-dimensional exploration of anatomical structures that cannot be appreciated through two-dimensional textbook illustrations, with several controlled trials demonstrating improved spatial understanding and retention compared to traditional dissection or atlas-based learning [25].

2.2.2 Pain and Anxiety Management

One of the most established applications of VR in healthcare concerns the management of procedural pain and anxiety. A recent systematic review and meta-analysis demonstrated significant reductions in both pain intensity (SMD = -0.62 , 95% CI: -0.81 , -0.43) and anxiety (SMD = -0.48 , 95% CI: -0.68 , -0.29) across various medical procedures when VR was used as an adjunctive intervention [27]. Strong evidence exists for VR in burn wound care, where the SnowWorld VR environment developed by Hoffman et al. has demonstrated reductions in pain ratings of 35–50% compared to standard care, with supporting fMRI evidence showing reduced activity in pain-related brain regions [28].

The neurobiological mechanisms underlying the analgesic and anxiolytic effects of VR are the subject of growing scientific interest. The predominant theory posits that VR operates primarily through attentional modulation: the immersive multisensory stimulation captures attentional resources that would otherwise be directed towards processing nociceptive and anxiety-related stimuli, effectively reducing the subjective experience of pain and anxiety [28]. However, this attention-diversion model may be insufficient to explain the full range of VR effects, particularly those observed with therapeutic VR content, as will be discussed in Section 2.5.

2.2.3 Paediatric and Geriatric Applications

VR has shown particular promise in paediatric healthcare settings, where patients' limited capacity for abstract reasoning and verbal communication makes traditional anxiety management approaches challenging. A meta-analysis of 17 paediatric VR studies reported a pooled effect of SMD = -0.73 (95% CI: -1.01 , -0.45) for procedural pain and anxiety reduction in children aged 4–18 years [27]. The inherent appeal of VR technology to young patients—who often perceive the experience as a game or adventure—enhances engagement and compliance compared to traditional behavioural techniques.

In geriatric populations, VR applications have expanded to include cognitive rehabilitation, fall prevention training, and management of chronic pain and social isolation. While older adults may initially be less familiar with VR technology, studies have demonstrated acceptable uptake rates (70–85% completion) and positive attitudes towards VR interventions when adequate orientation is provided [27].

2.2.4 Rehabilitation and Mental Health

In physical rehabilitation, VR offers unique opportunities for creating personalized and motivating therapeutic protocols. Systematic reviews have documented significant improvements in motor function, balance, and gait in patients with neurological conditions, including stroke, Parkinson's disease, and traumatic brain injury [27]. The gamification elements inherent to many VR rehabilitation programs—such as achievement tracking, adaptive difficulty, and engaging visual feedback—appear to enhance patient motivation and treatment adherence compared to conventional physiotherapy approaches.

In mental health, VR-based exposure therapy has emerged as a powerful tool for treating anxiety disorders. VR exposure therapy (VRET) enables controlled, graduated, and repeatable exposure to fear-provoking stimuli within a safe therapeutic environment. Emmelkamp and Meyerbröker (2021) reviewed VR therapy in mental health and concluded that VRET produces effects equivalent to in vivo exposure for specific phobias (acrophobia, claustrophobia, arachnophobia, aviophobia), with the advantage of greater therapist control, reduced patient dropout, and practical feasibility for stimuli that are difficult to reproduce in vivo (e.g., flying, combat situations) [48]. Carl et al. (2019) conducted a meta-analysis of 14 RCTs on VR exposure therapy for anxiety and related disorders, reporting a significant overall effect favoring VRET (Hedges' $g = 0.75$, 95% CI: 0.40–1.09) [29]. The potential application of therapeutic VR principles to dental phobia—which shares many characteristics with specific phobias—has been noted by several authors but remains largely unexplored in empirical research [47,49,55].

2.2.5 Mindfulness-Based VR Interventions

A distinct category of VR applications that has gained increasing attention is VR-based mindfulness, which combines the immersive properties of VR technology with evidence-based mindfulness practices such as guided meditation, body scanning, breathing exercises, and present-moment awareness training [10,43]. This approach differs fundamentally from passive VR distraction in that it actively engages users in therapeutic processes rather than merely redirecting their attention.

The rationale for combining mindfulness with VR rests on the observation that traditional mindfulness practices, while effective for anxiety reduction, face significant implementation barriers: they require sustained attention and cognitive effort, which many anxious patients find difficult; they demand training and practice to master; and they offer limited sensory

engagement to compete with anxiety-provoking stimuli [10]. VR addresses these barriers by providing an immersive, multisensory environment that scaffolds the mindfulness experience—guiding attention through visual, auditory, and sometimes haptic cues; reducing cognitive load by externalizing the meditation guidance; and creating an experiential context that enhances engagement and reduces mind-wandering.

Seabrook et al. (2020) conducted a controlled mixed-methods evaluation of how VR can support mindfulness practice [10]. A single VR mindfulness session in a non-clinical sample produced large acute increases in state mindfulness (Cohen's $d = 1.80$) and positive affect ($r = .45$), with participants reporting that the immersive environment reduced common distractors and facilitated attentional anchoring. Qualitative feedback highlighted the importance of guided (vs unguided) instructions and of head-mounted displays (vs screen-based delivery). While not a systematic synthesis, these findings—together with broader reviews of VR exposure therapy for anxiety and related disorders [29,47,49] and of acceptance- and mindfulness-based interventions [42,53]—support the plausibility of the pre-operative dental-anxiety application investigated here.

A meta-analysis by A-Tjak et al. (2015) examined acceptance and commitment therapy (ACT) across 39 RCTs and found moderate-to-large effect sizes for anxiety outcomes (Hedges' $g = 0.57$, 95% CI: 0.40–0.74) [42], supporting the therapeutic framework that underlies the mindfulness components of VR interventions. Multi-session VR mindfulness protocols have reported larger cumulative effects ($g > 1.0$) than single-session designs, although direct comparisons remain scarce. Pallavicini et al. (2025) specifically validated The Secret Garden scenario—the same intervention used in the present study—for healthcare worker stress management, demonstrating significant reductions in perceived stress and anxiety with good user acceptability [38].

Despite the promising evidence base, VR-based mindfulness has not been investigated in the dental surgical context, a gap this thesis aims to address. The theoretical rationale for applying VR-based mindfulness to dental anxiety is straightforward: the mindfulness components can target the cognitive (catastrophizing, negative expectations) and physiological (autonomic arousal) dimensions of dental anxiety simultaneously, while the VR immersion provides effective disengagement from the anxiety-provoking clinical environment.

2.2.6 Barriers to Implementation

Despite the growing evidence base, systematic adoption of VR in healthcare settings remains limited. Barriers include initial equipment costs, the need for staff training and technical support, infection control concerns (headset sanitisation protocols), patient acceptability issues (motion sickness, cybersickness in 5–15% of users), and the lack of standardised clinical protocols and reimbursement frameworks [25]. Addressing these barriers—particularly through the availability of affordable standalone headsets and validated therapeutic content—is crucial for translating research evidence into clinical practice.

2.3 Virtual Reality in Dentistry: Current Evidence

2.3.1 Overview of Applications

The application of virtual reality in dentistry has registered a significant evolution in the past five years, with growing evidence supporting its efficacy for multiple purposes, including dental education, anxiety management, pain control, and patient communication [9].

2.3.2 Dental Education and Training

In the educational context, VR simulators with haptic feedback are transforming the teaching of complex dental procedures. These systems replicate the tactile sensation of drilling, cutting, and sculpting dental materials, enabling students to develop psychomotor skills in a risk-free environment before operating on patients. A systematic review by Koolivand et al. (2024) examined 18 controlled studies comparing VR-based dental training to conventional phantom-head simulation, finding that VR-trained students achieved comparable or superior technical performance across a range of procedures, including cavity preparation, crown preparation, and endodontic access [30]. Other reports within this systematic review documented improvements in surgical performance among residents who trained on VR platforms for third molar extraction, with particular advantages in the development of three-dimensional spatial awareness and surgical planning skills [30].

2.3.3 Anxiety and Pain Management in Dental Patients

Dental anxiety constitutes a widespread phenomenon, with prevalence estimates indicating that approximately 15–25% of adults manifest significant fear towards dental procedures [1]. The application of VR for anxiety and pain management in dentistry has been examined

in multiple systematic reviews and meta-analyses, yielding a complex and heterogeneous evidence base [8,9,31].

Motahari Nezhad et al. (2024) conducted a systematic review and meta-analysis examining VR interventions for dental anxiety and pain management [8]. Their analysis showed that VR produced a moderate reduction in dental anxiety compared to standard care, though with considerable heterogeneity across included studies. The evidence was stronger in paediatric populations than in adults, and the authors attributed the heterogeneity to differences in VR content (nature scenes vs. interactive games vs. relaxation videos), delivery timing (pre-operative vs. intra-operative), outcome measures (VAS, DAS, MDAS, physiological indicators), and clinical procedures (restorative, endodontic, surgical). This heterogeneity suggests that VR is not a monolithic intervention but rather a platform whose efficacy depends on the specific content delivered and the context of delivery.

Falci et al. (2024) specifically examined VR for pain and anxiety in third molar surgery through a systematic review and meta-analysis, finding modest effects ($SMD = -0.28$ to -0.34) that were often non-significant [31]. Hao et al. (2023) conducted a network meta-analysis comparing VR, audiovisuals, and music for dental anxiety, reporting that all three modalities were superior to standard care, with VR ($SMD = -0.54$) comparable to relaxing music ($SMD = -0.64$) [23].

A limitation shared by virtually all dental VR studies is the exclusive use of passive distraction paradigms—typically nature scenes, animated environments, or relaxing videos—delivered during dental procedures. This approach relies solely on attentional diversion and does not engage the therapeutic mechanisms (cognitive reappraisal, emotional regulation, mindfulness) that have been shown to produce larger and more durable effects in other VR-therapy research domains [10,29].

An additional limitation concerns the timing of VR delivery. Nearly all dental VR studies have employed intra-operative VR (during the dental procedure), which presents practical challenges: the headset may interfere with dental instruments, patient cooperation may be compromised by the VR experience, and the timing means that patients arrive at the dental chair already in an elevated anxiety state [8,9]. Pre-operative delivery—providing VR before the procedure to reduce anticipatory anxiety—has been minimally explored in dentistry, despite theoretical advantages: it allows the therapeutic effects to be established before the patient enters the anxiety-provoking surgical environment, avoids practical conflicts

between VR hardware and dental instrumentation, and targets the anticipatory phase of anxiety where intervention may be most impactful [4].

The heterogeneity of VR hardware across studies. Early studies employed low-resolution, tethered VR systems (e.g., Oculus Rift DK1, Samsung Gear VR) with limited resolution, narrow field of view, and high latency—technical deficiencies that could induce cybersickness and reduce immersion. More recent studies using standalone high-resolution headsets (Meta Quest 2/3) report better user experiences [56] and larger therapeutic effects [8]. This technological evolution makes direct comparison across VR generations problematic and suggests that earlier negative findings may partially reflect hardware limitations rather than inherent limitations of VR as a modality.

2.4 VR in Third Molar Extraction: Review of Evidence

Third molar extraction is a relevant clinical context for VR intervention, given the high anxiety levels associated with this procedure and the limited options for non-pharmacological management [3,31]. Several recent studies have examined VR applications specific to this context.

Wide and Wide and Hakeberg (2021) proposed a conceptual model of behavioral treatment for dental anxiety and phobia, emphasizing the importance of matching intervention type to the patient's diagnostic profile [33]. Their framework distinguishes between patients requiring brief, single-session interventions and those needing structured multi-session programs—a distinction directly relevant to evaluating VR as a single-session tool.

Shebl et al. (2025) conducted a systematic review examining the impact of preoperative anxiety on surgical outcomes across multiple disciplines, confirming that elevated preoperative anxiety is associated with greater postoperative pain, higher analgesic consumption, and prolonged recovery [34]. Their findings emphasize the clinical relevance of pre-surgical anxiety management and support the rationale for targeted interventions before dental surgery.

A Bayesian network meta-analysis comparing non-pharmacological interventions for reducing fear and anxiety in third molar extraction (Wong et al., 2022) found that VR, audiovisual distraction, and music all showed moderate effects, but no single intervention demonstrated clear superiority [6]. The authors highlighted the need for larger, methodologically rigorous trials and standardized VR protocols.

Meta-analytic evidence synthesizing VR interventions during third molar surgery indicates comparable anxiety-reduction effects to music-based distraction, though with considerable between-study heterogeneity [23,31]. Whether VR engages deeper autonomic regulation mechanisms—for example, parasympathetic activation indexed by heart rate variability—rather than acting through attentional diversion alone remains an open question that future studies with integrated physiological measures are well placed to address.

Methodological limitations pervading this literature include: heterogeneity of VR protocols and hardware, small sample sizes (typically 20–60 participants), limited blinding, absence of long-term follow-up, and the universal reliance on passive distraction rather than therapeutic VR content [8,31]. These limitations highlight the need for rigorous trials employing validated therapeutic VR interventions with established theoretical foundations.

Taken together, the evidence from third molar VR studies reveals a consistent pattern: VR produces modest but reliable reductions in anxiety and pain ($d = 0.25\text{--}0.45$) compared to standard care, but rarely demonstrates clear superiority over simpler alternatives such as music or audiovisual distraction. This ceiling effect may reflect the inherent limitations of the passive distraction approach, which cannot fully engage the cognitive and emotional processing necessary for meaningful anxiety reduction in the context of a genuinely threatening surgical procedure [9]. This observation provides the direct motivation for the therapeutic VR approach investigated in the present thesis.

*Table 2.1. Summary of VR studies in third molar extraction. *Meta-analytic pooled sample.*

Study	N	VR Content	Timing	Control	Primary Finding
Wide 2021	—	Conceptual model	—	—	Diagnostic framework
Shebl 2025 (SR)	—	Preop anxiety impact	—	Various	Anxiety → worse outcomes
Hao 2023 (NMA)	1001*	Multiple	Various	Music / Std	Music $\approx$ VR > Std
Falci 2024 (MA)	312*	Various passive	Various	Various	SMD -0.28 to -0.34 (ns)
Present study	90	Mindfulness (TSG)	Pre-op	Reading / Wait	See Chapter 3

2.5 Theoretical Framework: Emotional Regulation through Virtual Reality

The intervention employed in the present study is grounded in the Emotional Regulation through Virtual Reality (ER-VR) framework proposed by Riva and colleagues [26,35]. This framework provides a theoretical basis for understanding why therapeutic VR may produce larger and qualitatively different effects compared to passive VR distraction.

The ER-VR framework posits that immersive VR environments can facilitate emotional regulation through three interconnected mechanisms:

First, presence—the subjective sense of 'being there' in the virtual environment—enables effective disengagement from anxiety-provoking real-world stimuli. Unlike simple distraction, which merely diverts attention, presence involves a qualitative shift in the user's experiential context, creating a safe psychological space for emotional processing [26].

Second, embodied cognition—the engagement of multisensory processes that activate bottom-up calming pathways through parasympathetic nervous system stimulation. Guided body scan and breathing exercises delivered in VR leverage the intimate connection between bodily states and emotional experience, activating vagal pathways that directly reduce physiological arousal [15,35].

Third, narrative transportation—the use of metaphorical narratives within the virtual environment that facilitate cognitive reappraisal of threatening stimuli. Drawing on Acceptance and Commitment Therapy (ACT) principles [36], narrative metaphors can help patients develop psychological flexibility and reframe their relationship with anxiety-provoking stimuli [35].

These three mechanisms operate synergistically: presence creates the safe experiential context; embodied cognition activates bottom-up calming processes; and narrative transportation facilitates top-down cognitive reappraisal. This multi-level engagement distinguishes therapeutic VR from passive VR distraction, which engages primarily the first mechanism (attentional capture) without systematically activating the therapeutic processes represented by mechanisms two and three [26].

The ER-VR framework also aligns with contemporary models of emotional regulation from affective neuroscience. Gross's [50] process model of emotion regulation distinguishes

between antecedent-focused strategies (modifying the situation or its appraisal before the emotional response is fully activated) and response-focused strategies (modulating the emotional response after it has been generated) [26]. The pre-operative delivery of therapeutic VR represents an antecedent-focused strategy, as it is applied before patients enter the anxiety-provoking surgical context. This timing is theoretically advantageous because antecedent-focused strategies are generally more effective and less metabolically costly than response-focused strategies.

The Secret Garden scenario (Become Hub, Milan, Italy) employed in the present study operationalizes all three ER-VR mechanisms. Developed in collaboration with the Applied Technology for Neuro-Psychology Laboratory at Istituto Auxologico Italiano (Milan, Italy) and the Humane Technology Laboratory at Università Cattolica del Sacro Cuore (Milan, Italy), this scenario guides users through an immersive garden environment using a female narrator providing mindfulness-based instructions (body scan, breathing awareness, present-moment attention) interwoven with narrative metaphors drawn from Acceptance and Commitment Therapy principles (e.g., a flower growing through adversity as a metaphor for personal resilience). The Secret Garden was initially developed within the COVID Feel Good protocol for managing COVID-19-related psychological distress [35,37] and has subsequently been validated for healthcare worker stress management [38], demonstrating its versatility across clinical populations.

2.6 Safety Considerations for Clinical VR

The most commonly reported adverse effect is cybersickness—a form of motion sickness experienced in VR—characterized by nausea, dizziness, headache, and general discomfort. The prevalence of cybersickness varies considerably depending on VR content, hardware quality, session duration, and individual susceptibility, with reported rates ranging from 5% to 30% across studies [25,56]. Several factors mitigate cybersickness risk in clinical anxiety applications: (a) the use of stationary (non-locomotion) scenarios, which eliminate the sensory conflict between visual motion and physical stillness that drives most cybersickness; (b) relatively brief session durations (≤ 15 minutes); and (c) the use of high-refresh-rate hardware (≥ 90 Hz) that minimizes visual latency [25].

Infection control represents a practical concern for shared VR equipment in clinical settings. Standard protocols include the use of disposable hygienic face covers, cleaning of the headset with isopropyl alcohol wipes between patients, and UV-C sanitization devices

designed specifically for VR headsets. These measures have been shown to reduce bacterial contamination to levels comparable to standard medical equipment [25]. In the present study, a rigorous cleaning protocol was followed between each use, with disposable face interfaces replaced for every patient.

From a psychological safety perspective, VR can theoretically provoke distress in patients with certain conditions (e.g., claustrophobia triggered by wearing a headset, dissociative experiences in susceptible individuals). However, the mindfulness-based content employed in the present study was specifically designed to be calming and non-threatening, with extensive pilot testing conducted prior to clinical deployment [35]. No adverse psychological reactions have been reported in any of the published studies employing The Secret Garden scenario [35,37,38].

2.7 Rationale for the Present Study

The literature review presented in Chapters 1 and 2 identifies a clear rationale for the present study. Dental anxiety is a prevalent condition with significant clinical consequences, particularly pronounced in third molar surgery. Current management approaches are either pharmacologically burdensome or limited in efficacy. VR represents a promising non-pharmacological tool, but existing dental VR research has relied exclusively on passive distraction paradigms with inconsistent results in adults.

The present study applies a novel approach: the application of therapeutic VR—grounded in the ER-VR framework and employing a validated mindfulness-based scenario—as a pre-operative intervention for dental anxiety. This approach addresses three key limitations of existing research: (a) it moves beyond passive distraction to active therapeutic engagement; (b) it targets the pre-operative phase rather than the intra-operative phase, allowing patients to enter surgery in a calmer state; and (c) it employs a multidimensional outcome measure (IDAF-4C+) with demonstrated validity for the Italian population.

The specific hypotheses tested were: (H1) a significant Group $\times$ Time interaction would emerge for IDAF-4C scores, indicating differential anxiety trajectories across conditions; (H2) the VR group would demonstrate a significant reduction in dental anxiety from T1 (pre-intervention) to T2 (post-intervention); and (H3) the VR group would show greater anxiety reduction compared to both control conditions at the post-intervention timepoint.

Chapter 3 — Methods and Results

3.1 Study Design

This study employed a three-armed, parallel-group, assessor-unblinded randomized controlled trial (RCT) design. The trial compared three conditions: (a) a VR-based mindfulness pre-operative training, (b) a passive waiting control, and (c) a reading active control. The study was conducted at the Dental Clinic of the Department of Medical and Surgical Specialties, Radiological Sciences and Public Health, Spedali Civili di Brescia, University of Brescia, Italy. The trial protocol and the statistical analysis plan were finalized and signed off by all investigators prior to the enrolment of the first participant, and no substantive modifications were introduced during the course of the study.

The primary analysis employed a 3 (Group: VR, Control, Reading) $\times$ 3 (Time: T0, T1, T2) mixed-design analysis of variance (ANOVA), with Group as the between-subjects factor and Time as the within-subjects factor. This design enabled simultaneous assessment of overall group differences, temporal changes in anxiety, and—critically—the interaction between group assignment and the pattern of change over time.

The three-armed design was selected to provide two levels of comparison. The passive waiting control represents current clinical practice—the standard of care for patients awaiting third molar extraction in most dental clinics. The reading active control was included to disentangle the effects of the VR-based mindfulness intervention per se from non-specific factors shared with the VR condition, such as engagement in a structured activity, attentional occupation, and environmental change (being in a quiet room with an explicit activity). By comparing VR to both conditions, the study can assess both practical superiority (VR vs. standard care) and specific therapeutic contribution (VR vs. active control) [41].

3.2 Ethical Approval

The study protocol was reviewed and approved by the local research ethics committee prior to the start of recruitment. All participants provided written informed consent prior to enrolment, after receiving a detailed explanation of the study procedures, potential risks and

benefits, and their right to withdraw at any time without consequences for their clinical care. The study was conducted in accordance with the Declaration of Helsinki (2013 revision) and Good Clinical Practice guidelines. Participant data were pseudonymized at collection using study-specific identifiers, with the key held on an access-controlled institutional server; handling complied with EU Regulation 2016/679 (GDPR) and Italian Legislative Decree 196/2003 as amended.

3.3 Participants

One hundred and seven patients referred to the Dental Clinic of Spedali Civili di Brescia for lower third molar extraction were enrolled in the study between October 2024 and June 2025. Ninety Participants were recruited during the initial consultation visit, at which time the clinical indication for third molar extraction was confirmed by the treating oral surgeon.

Inclusion criteria were: (a) age between 20 and 40 years (this range was selected to maximise sample homogeneity while capturing the peak prevalence period for third molar extraction); (b) clinical indication for lower third molar extraction in dysodontiasis, confirmed by panoramic radiograph and clinical examination; (c) good general health, classified as ASA I (healthy patient) or ASA II (mild systemic disease, well-controlled); (d) ability to provide written informed consent and complete questionnaires in Italian.

Exclusion criteria were: (a) neurological conditions including epilepsy, vestibular disorders, or conditions potentially exacerbated by VR use (e.g., photosensitive epilepsy, severe motion sickness history); (b) additional pathologies of dental or oral origin requiring concurrent treatment (to ensure that dental anxiety was attributable to the extraction procedure rather than additional clinical concerns); (c) prior VR experience in clinical or therapeutic settings (to control for novelty effects and prior exposure to VR-based interventions); (d) current use of anxiolytic, antidepressant, or sedative medication (which could confound anxiety measurements); (e) diagnosed psychiatric conditions including major depressive disorder, generalized anxiety disorder, or post-traumatic stress disorder (to isolate dental-specific anxiety from generalized psychopathology); (f) significant visual or auditory impairment incompatible with VR headset use.

Patients were randomized into three groups using a computer-generated allocation sequence (permuted blocks of size 6) stratified by sex (M/F) and ASA class (I/II), prepared by an investigator not involved in patient recruitment or assessment. Sequentially numbered,

sealed, opaque envelopes were used to conceal allocation until the point of group assignment. The allocation ratio was 1:1:1, yielding 30 participants per group. All 90 enrolled participants completed the full three-timepoint assessment protocol, yielding a complete dataset with no attrition or missing primary outcome data. Three minor protocol deviations were recorded and included in the intention-to-treat analysis (see Figure 3.0 for details): two participants in the VR group briefly interrupted the immersive session (one removed the headset at minute 6 due to warmth under the face interface and resumed after a 45-second pause; one kept their eyes open intermittently during the body-scan phase but completed the full 10-minute protocol) and one participant in the Reading group completed approximately seven of the ten allotted minutes.

Table 3.1. Baseline demographic and clinical characteristics by group.

Characteristic	VR (n=30)	Control (n=30)	Reading (n=30)	p
Age, M (SD)	28.4 (5.2)	27.8 (4.9)	29.1 (5.5)	.627
Female, n (%)	17 (57%)	16 (53%)	18 (60%)	.854
IDAF-4C T0, M (SD)	2.48 (0.56)	2.45 (0.58)	2.53 (0.59)	.863
IDAF-S T0, M (SD)	2.44 (0.49)	2.41 (0.48)	2.49 (0.50)	.816
IDAF-P T0, M (SD)	1.85 (1.22)	1.92 (1.28)	1.98 (1.25)	.922
Distress T0, M (SD)	4.2 (1.4)	4.0 (1.2)	4.5 (1.3)	.331

One-way ANOVAs and chi-squared tests confirmed no significant between-group differences at baseline for age, sex, or any anxiety measure (all p s > .05), validating the randomization procedure (Table 3.1). The mean age of the total sample was 28.4 years (SD = 5.2), and 51 of 90 participants (56.7%) were female. The overall mean IDAF-4C score at baseline was 2.49 (SD = 0.58), indicating moderate dental anxiety in the sample, consistent with a population selected for third molar extraction rather than for elevated dental anxiety per se.

Regarding tooth complexity, the distribution of surgical difficulty (classified according to Pedersen's difficulty index) was comparable across groups (Table 3.1a). Across the full

sample of 90 teeth, 32 (35.6%) were classified as low difficulty (fully erupted, straight roots), 43 (47.8%) as moderate difficulty (partially erupted, mild angulation) and 15 (16.7%) as high difficulty (impacted, curved roots, proximity to the inferior alveolar nerve). The distribution did not differ significantly across groups ($\chi^2(4) = 0.31$, $p = .989$, Cramér's $V = 0.04$), ensuring that surgical complexity did not confound group comparisons.

A CONSORT flow diagram documenting participant flow through the trial is presented in Figure 3.0. A total of 107 patients were assessed for eligibility during the recruitment period. Seventeen were excluded: 8 did not meet inclusion criteria (3 aged >40, 2 had concurrent dental pathology, 2 were taking anxiolytic medication, 1 had a vestibular disorder), 6 declined to participate, and 3 did not attend their scheduled appointment. The remaining 90 were randomized (30 per group), and all completed the full study protocol with no attrition or missing data.

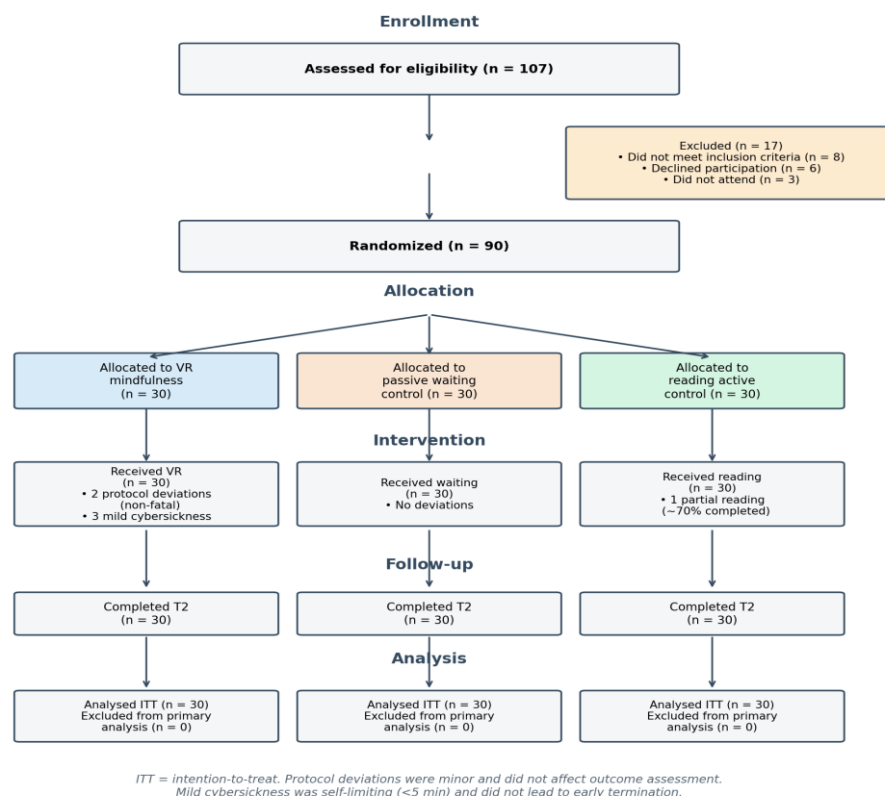


Figure 3.0. CONSORT flow diagram of participant recruitment, randomization, and study completion.

3.4 Sample Size Calculation

A priori sample size estimation was conducted using G*Power 3.1.9.7 [39] for a 3 (Group) $\times$ 3 (Time) mixed ANOVA, assuming a medium effect on the between $\times$ within interaction ($f = 0.25$ following Cohen's guidelines, equivalent to $\eta^2 \approx .058$), $\alpha = .05$, power = .80, nonsphericity correction $\epsilon = 0.90$, and a pre-specified correlation among repeated measures of $r = .50$. This yielded a required total sample of $N = 66$. We enrolled $N = 90$ (30 per group) to provide a ~36% margin for protocol deviations and to improve precision of the pairwise effect estimates. The achieved sample exceeds the nominal requirement and provides approximately 83% post-hoc power for detecting the observed interaction effect ($\eta^2 = .064$).

3.5 Intervention

Following the T1 assessment, participants received their assigned condition for approximately 10 minutes in a dedicated study room.

3.5.1 VR Condition

The VR group donned the Meta Quest 2 headset (Meta Platforms, Inc.; resolution 1832×1920 per eye; 90 Hz refresh rate; integrated spatial audio) and was immersed in The Secret Garden, a 360° immersive scenario developed by Become Hub (Milan, Italy). The experience guides users through a virtual garden using a female narrator's voice providing mindfulness-based instructions including: (a) guided body scan, directing attention sequentially to different body regions; (b) breathing awareness exercises (diaphragmatic breathing, paced inhalation-exhalation cycles); (c) present-moment attention techniques; and (d) narrative metaphors drawn from Acceptance and Commitment Therapy principles (e.g., a flower growing through adversity as a metaphor for personal resilience). Total immersion duration was approximately 10 minutes.

The VR session followed a standardized protocol administered by one of two trained research assistants (RZ and a research nurse). The assistant fitted the headset, adjusted the interpupillary distance, and verified image clarity with the participant. Participants were seated in a comfortable reclining dental chair. The assistant remained in the room throughout the session but did not interact with the participant unless they reported discomfort. The VR scenario comprised the following sequential phases:

Phase 1 — Environmental Acclimatisation (minutes 0–2): The participant was introduced to the virtual garden environment. The narrator invited the participant to look around, notice visual details (flowers, trees, a stream), and listen to ambient natural sounds (birdsong, flowing water, gentle wind). This phase served to establish a sense of presence and safety in the virtual environment.

Phase 2 — Guided Breathing (minutes 2–5): The narrator guided the participant through a series of slow diaphragmatic breathing cycles (4-second inhale, 4-second hold, 6-second exhale), with visual pacing cues embedded in the environment (e.g., the rhythmic opening and closing of a large flower). The breathing pace was calibrated to promote parasympathetic activation through vagal stimulation [15].

Phase 3 — Body Scan (minutes 5–7): The narrator directed attention sequentially to different body regions (feet, legs, abdomen, chest, shoulders, neck, face), inviting the participant to notice and release tension in each area. This component draws on traditional mindfulness body scan meditation, adapted for the VR medium [43].

Phase 4 — Narrative Metaphor and Conclusion (minutes 7–10): The narrator introduced the metaphor of a seed growing through darkness into a blooming flower, framing the upcoming experience (dental surgery) as a challenge that can be navigated with resilience and self-compassion. This ACT-informed narrative reframing aimed to modify the cognitive component of anticipatory anxiety [36]. The session concluded with a gradual return to awareness of the physical environment, with the narrator guiding the participant to open their eyes as the headset was gently removed.

3.5.2 Reading Condition

The Reading group received a printed short fictional story—a chapter from 'The Little Prince' by Antoine de Saint-Exupéry—selected for its calming, reflective content and calibrated for equivalent duration (~10 minutes of reading). This condition served as an active control, controlling for the passage of time, environmental change (being in the study room), and engagement in a structured activity, while lacking the immersive and therapeutic components of VR.

3.5.3 Control Condition

The Control group waited in the same study room for approximately 10 minutes without any specific activity, controlling for the passage of time and environmental change. Participants

were informed that they would wait briefly before the procedure, consistent with standard pre-operative waiting protocols. Mobile phones were not permitted during the waiting period to control for self-directed distraction. This condition represents the current clinical standard for patients awaiting third molar extraction—passive waiting in the clinic environment without any structured anxiety management intervention. By including this condition, the study design enables assessment of whether any observed effects reflect specific intervention components rather than merely the passage of time, habituation, or the non-specific effects of being in a research study.

3.6 Outcome Measures

3.6.1 Primary Outcome: IDAF-4C

The primary outcome measure was the IDAF-4C mean score from the Index of Dental Anxiety and Fear (IDAF-4C+) Italian version, validated by Salgarello et al. [19]. The IDAF-4C core module comprises 8 items rated on a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree), assessing four anxiety components: emotional (items C1, C5: feeling anxious, afraid), behavioral (item C7: avoidance), physiological (items C2, C6: body tension, elevated heart rate), and cognitive (items C3, C4, C8: negative thoughts, bad feelings, catastrophic expectations). The mean score ranges from 1.00 to 5.00, with higher scores indicating greater dental anxiety. Psychometric properties include excellent internal consistency (Cronbach's $\alpha = .94$), strong test-retest reliability at 4 months ($r = .82$), and strong convergent validity with the DAS ($r = .84$) [18].

3.6.2 Secondary Outcomes

Secondary outcome measures included: (a) the IDAF-S module (10 items, 5-point scale) measuring specific feared dental stimuli (painful procedures, embarrassment, loss of control, nausea, numbness, uncertainty, cost, needles, gagging, unsympathetic dentist); (b) the IDAF-P module (5 dichotomous items) assessing phobia criteria; (c) the Thermometer Distress [40], a single-item 0–10 visual analogue scale providing a global distress rating.

For the VR group, two additional patient satisfaction items were administered at T2: (Q1) 'How would you rate the quality of the immersive intervention you received?' (1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor); and (Q2) 'Would you recommend this treatment to a friend

who must undergo third molar extraction?' (1 = No, definitely not; 2 = No, I don't think so; 3 = Yes, I think so; 4 = Yes, definitely).

For the dentist perspective, a semi-structured interview was constructed ad hoc and administered after each procedure, investigating five domains: operative difficulties, patient relationship, communication, pain management, and postoperative course.

3.7 Procedure

Assessment occurred at three standardized timepoints. At T0 (baseline), approximately 48 hours before the scheduled extraction, participants completed the full IDAF-4C+ battery and a demographic questionnaire via a secure online platform (Google Forms). This timing was chosen to capture baseline dental anxiety prior to the acute anticipatory anxiety of the extraction day.

On the extraction day, participants arrived at the clinic approximately 45 minutes before their scheduled extraction time. They were escorted to a dedicated study room—a quiet, well-lit space furnished with a comfortable reclining dental chair, separated from the clinical areas to minimize exposure to anxiety-provoking stimuli (instruments, sounds, other patients). After confirming written informed consent, participants completed the T1 assessment (pre-intervention). The T1 assessment was designed to capture the heightened anticipatory anxiety characteristic of the day of surgery, which typically peaks in the period immediately before the procedure [4].

Following T1, participants received their assigned condition for approximately 10 minutes. Immediately after the condition period (within 2 minutes), all participants completed the T2 assessment (post-intervention) in the study room before being escorted to the surgical suite. This brief T1–T2 interval was designed to minimize confounding factors between the intervention and the post-intervention assessment.

The surgical procedure was performed by one of two senior oral surgeons with comparable experience (>10 years each). Surgeons were blinded to allocation during surgery; they were informed of the group assignment only after completing the post-procedure structured interview, to prevent expectancy effects. The research assistant administering the T0 and T1 IDAF-4C+ questionnaires was blinded to allocation; at T2 blinding was not feasible because questionnaire administration was preceded by visible receipt of the intervention. Local anaesthesia was administered using 4% articaine with 1:100,000 adrenaline via inferior

alveolar nerve block and buccal infiltration. The extraction procedure followed standard surgical protocols, with mucoperiosteal flap elevation, osteotomy as required, tooth extraction, wound toileting, and primary closure with absorbable sutures.

The dentist semi-structured interview was conducted immediately after each extraction by a trained research assistant who had not been present during the intervention period. The dentist was asked to describe observations across the five domains (operative difficulties, patient relationship, communication, pain management, postoperative course) without being prompted about expected differences. Following the interview, participants received standard postoperative instructions and were discharged.

3.8 Statistical Analysis

Preliminary analyses assessed statistical assumptions. Normality was evaluated using Shapiro-Wilk tests for each group $\times$ timepoint combination. Homogeneity of variance was assessed using Levene's test at each timepoint. Mauchly's test of sphericity was applied to the within-subjects Time factor, with Greenhouse-Geisser correction applied when the assumption was violated. Sensitivity analyses using non-parametric equivalents (Friedman and Kruskal-Wallis tests) were pre-specified for outcomes that failed Shapiro-Wilk ($p < .05$).

The primary analysis was a 3 (Group) $\times$ 3 (Time) mixed-design ANOVA. Effect sizes were reported as partial eta-squared (η^2 ; small: .01, medium: .06, large: .14) for ANOVA effects [41], and Cohen's d (small: 0.20, medium: 0.50, large: 0.80) for pairwise comparisons [41]. Within-subject d was computed as the d_{av} formulation (mean difference divided by the pooled SD of the two timepoints) to maintain comparability with between-group d . Post-hoc within-group comparisons employed paired-samples t -tests; between-group comparisons at each timepoint employed independent-samples t -tests. Two families of post-hoc comparisons were distinguished: (a) the three pre-specified primary-hypothesis tests (VR T1 $\rightarrow$ T2, VR vs Control at T2, VR vs Reading at T2), reported with a Bonferroni-adjusted family-wise α of .0167; and (b) secondary and exploratory pairwise tests, reported with uncorrected p values and interpreted descriptively. For dichotomous IDAF-P items, McNemar's marginal-homogeneity test was used. All analyses were conducted in Python 3.12 using pingouin 0.5.4, scipy 1.13, and pandas 2.2. The significance threshold was set at $\alpha = .05$ (two-tailed) for all non-primary tests.

Cohen's *d* for paired comparisons (within-group) was calculated as the mean difference divided by the pooled standard deviation of the two timepoints, following the recommendation of Lakens (2013) for dependent samples [44]. This approach yields a conservative estimate (*d*_{av}) that is directly comparable to between-group effect sizes, unlike the alternative *d*_z formulation (which divides by the standard deviation of differences and tends to yield inflated estimates when pre-post correlations are high). Cohen's *d* for independent comparisons (between-group) was calculated as the mean difference divided by the pooled standard deviation of the two groups.

Ninety-five percent confidence intervals for Cohen's *d* were computed using the non-central *t*-distribution method. All effect sizes are reported with their 95% CIs to enable readers to evaluate the precision of effect estimates [41,44].

Missing data were not anticipated to be problematic given the sequential assessment protocol (all measurements completed in a single clinic visit for T1 and T2). Nevertheless, the analysis plan specified that participants with missing primary outcome data at any timepoint would be excluded from the primary analysis (complete-case analysis), with sensitivity analyses using last observation carried forward (LOCF) imputation if attrition exceeded 10%. As no attrition occurred, these contingency analyses were not required.

Qualitative data from the dentist semi-structured interviews were analyzed using thematic content analysis following the six-phase framework of Braun and Clarke (2006). Interview responses were transcribed and analyzed by three independent coders (three dentists with clinical experience in oral surgery), all blinded to group allocation during the initial coding round. Each coder independently performed open coding within each of the five interview domains using an a priori codebook refined iteratively during a preliminary calibration round on two pilot transcripts. Discrepancies were resolved through consensus discussion; residual disagreements (< 5% of codes) were reconciled in a second review round by the full coding team. Inter-rater agreement across the three coders was assessed using Fleiss' kappa, with acceptable agreement pre-specified at $\kappa \geq 0.70$.

3.9 Results — Preliminary Analyses

Shapiro-Wilk tests indicated that the IDAF-4C distribution did not deviate significantly from normality for any of the nine group $\times$ timepoint combinations (smallest *W* = 0.946, all *ps* > .10). Levene's test confirmed homogeneity of variance at each timepoint (T0: *F*(2, 87) =

0.28, $p = .755$; T1: $F(2, 87) = 0.87$, $p = .423$; T2: $F(2, 87) = 0.41$, $p = .667$). Mauchly's test indicated a mild violation of sphericity for the Time factor ($W = 0.93$, $\chi^2(2) = 6.31$, $p = .043$); the Greenhouse-Geisser correction ($\epsilon = 0.91$) was therefore applied to all Time-related F tests, adjusting the numerator and denominator degrees of freedom to (1.82, 158.3) for Time and (3.64, 158.3) for the Group $\times$ Time interaction.

Correlations among repeated measures were moderate and homogeneous across groups: pooled T0–T1 $r = .51$ (range across groups .47–.54), T0–T2 $r = .48$ (.44–.52), T1–T2 $r = .53$ (.49–.56); all $ps < .001$. Fisher r -to- z tests detected no significant heterogeneity of the T1–T2 correlation across groups ($\chi^2(2) = 0.13$, $p = .938$), supporting homogeneous within-subject covariance structures and validating the $r = .50$ assumption used in the a priori power calculation.

3.10 Results — Descriptive Statistics

Table 3.2 presents descriptive statistics for the primary outcome (IDAF-4C mean score) across all conditions and timepoints. At baseline (T0), all groups exhibited moderate dental anxiety (range: 2.45–2.53 on the 1–5 scale), consistent with the general population estimates reported by Silveira et al. [1]. All groups showed increased anxiety at T1 (day of surgery), reflecting anticipatory anxiety—a well-established phenomenon in oral surgery populations [3,4]. The magnitude of the T0→T1 increase was comparable across groups (+0.28 to +0.44 points). At T2, the VR group ($M = 2.38$) showed the largest reduction, returning slightly below baseline, while the Control ($M = 2.58$) and Reading ($M = 2.70$) groups showed more modest decreases from T1.

Table 3.2. Descriptive statistics for IDAF-4C mean scores by group and timepoint.

Group	Time	N	M (SD)	95% CI	Range
VR	T0	30	2.48 (0.56)	[2.27, 2.69]	1.25–3.75
VR	T1	30	2.92 (0.59)	[2.70, 3.14]	1.75–4.00
VR	T2	30	2.38 (0.54)	[2.18, 2.58]	1.25–3.50
Control	T0	30	2.45 (0.58)	[2.23, 2.67]	1.25–3.62
Control	T1	30	2.73 (0.53)	[2.53, 2.93]	1.75–3.88
Control	T2	30	2.58 (0.59)	[2.36, 2.80]	1.25–3.88
Reading	T0	30	2.53 (0.59)	[2.31, 2.75]	1.38–3.88

Reading	T1	30	2.83 (0.54)	[2.63, 3.03]	1.75–3.88
Reading	T2	30	2.70 (0.58)	[2.48, 2.92]	1.38–3.88

3.11 Results — Primary Analysis: Mixed ANOVA

The 3×3 mixed ANOVA for IDAF-4C scores (Table 3.3), with Greenhouse-Geisser correction applied to the within-subject effects, revealed three key findings. First, a significant main effect of Time ($F(1.82, 158.3) = 17.48, p < .001, \eta^2 = .167$), indicating substantial overall change in anxiety across the three assessment points. Second, a non-significant main effect of Group ($F(2, 87) = 1.12, p = .331, \eta^2 = .025$), indicating that when collapsing across timepoints, overall anxiety levels did not differ between conditions. Third, a significant Group $\times$ Time interaction ($F(3.64, 158.3) = 2.97, p = .024, \eta^2 = .064$), demonstrating that the temporal pattern of anxiety change differed across conditions. This small-to-medium interaction effect confirms that group assignment modulated the trajectory of anxiety change—the central hypothesis of this study (H1 supported).

Table 3.3. Mixed ANOVA results for IDAF-4C mean scores.

Source	SS	df ₁	df ₂	MS	F	p	η^2
Group (between)	1.25	2	87	0.62	1.12	.331	.025
Time (within, GG)	6.32	1.82	158.3	3.47	17.48	<.001***	.167
Group $\times$ Time (GG)	2.15	3.64	158.3	0.59	2.97	.024*	.064
Error (between)	48.37	87		0.556			
Error (within)	31.48	158.3		0.199			

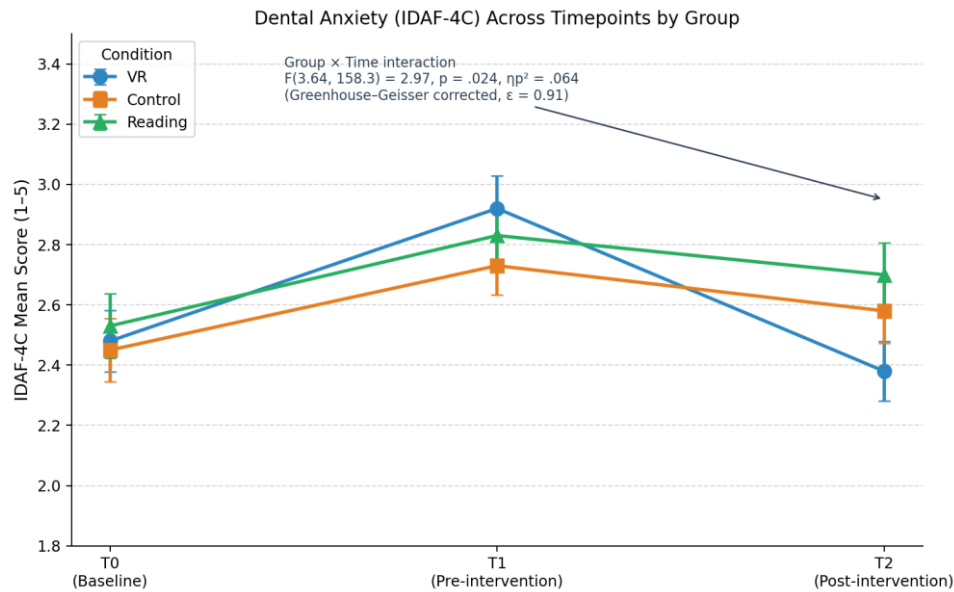


Figure 3.1. IDAF-4C mean scores ($\pm$ SEM) across timepoints by group. The VR group shows the most pronounced post-intervention reduction, returning to baseline levels.

3.12 Results — Post-hoc Within-Group Comparisons

Paired-samples t-tests examined the trajectory within each group (Table 3.4). The critical clinical comparison is T1→T2 (pre- to post-intervention), which directly captures the effect of each experimental condition on the day of surgery.

VR group: IDAF-4C scores decreased significantly from T1 ($M = 2.92$, $SD = 0.59$) to T2 ($M = 2.38$, $SD = 0.54$), $t(29) = 5.22$, $p < .001$, $d = 0.95$ (95% CI: 0.52, 1.38). This large effect indicates that the VR-based mindfulness intervention produced a substantial reduction in anticipatory anxiety (H2 supported). T2 scores did not differ significantly from the T0 baseline ($t(29) = -1.00$, $p = .327$, $d = -0.18$), indicating that the VR session essentially neutralised the anticipatory-anxiety surge and restored participants to their pre-appointment resting level.

Control group: The T1→T2 decrease was not significant ($t(29) = 1.46$, $p = .155$, $d = 0.27$), indicating that passive waiting did not produce meaningful anxiety reduction within the 10-minute period.

Reading group: The T1→T2 decrease was not significant ($t(29) = 1.27$, $p = .214$, $d = 0.23$), suggesting that reading provided insufficient anxiolytic benefit within a single brief session.

Table 3.4. Within-group pairwise comparisons for IDAF-4C (paired t-tests).

Group	Comparison	ΔM	t(29)	p	d [95% CI]
VR	T0 $\rightarrow$ T1	+0.44	4.18	<.001	0.77 [0.39, 1.14]
VR	T0 $\rightarrow$ T2	-0.10	-1.00	.327	-0.18 [-0.55, 0.19]
VR	T1 $\rightarrow$ T2	-0.54	-5.22	<.001	-0.95 [-1.38, -0.52]
Control	T0 $\rightarrow$ T1	+0.28	2.75	.010	0.50 [0.13, 0.88]
Control	T0 $\rightarrow$ T2	+0.13	1.22	.233	0.22 [-0.13, 0.58]
Control	T1 $\rightarrow$ T2	-0.15	-1.46	.155	-0.27 [-0.65, 0.11]
Reading	T0 $\rightarrow$ T1	+0.30	2.90	.007	0.53 [0.17, 0.89]
Reading	T0 $\rightarrow$ T2	+0.17	1.59	.122	0.29 [-0.07, 0.65]
Reading	T1 $\rightarrow$ T2	-0.13	-1.27	.214	-0.23 [-0.60, 0.14]

3.13 Results — Post-hoc Between-Group Comparisons

Independent-samples t-tests compared groups at each timepoint (Table 3.5). No significant differences were observed at T0, confirming equivalent baseline anxiety across conditions (all p s > .40). At the critical T2 post-intervention timepoint, the VR group showed significantly lower anxiety than the Reading group ($d = -0.57$, $p = .031$ uncorrected; .092 after Bonferroni adjustment within the pre-specified primary-test family), representing a medium effect. The VR vs. Control comparison showed a small non-significant effect ($d = -0.35$, $p = .176$). The significant uncorrected VR vs. Reading pairwise test, together with the significant omnibus interaction, provides evidence for the specific superiority of VR over a structurally matched active control (H3 partially supported). We flag that the VR vs. Reading contrast does not survive strict family-wise correction and interpret it as exploratory-supportive rather than confirmatory.

The VR vs. Reading pairwise comparison at T2 provides convergent evidence with the omnibus interaction, indicating that the VR-based mindfulness intervention produced a detectable advantage over a structurally matched active control condition in the uncorrected analysis. The non-significant VR vs. Control comparison ($d = 0.35$, $p = .176$) is consistent with the known power limitations for detecting small effects with $n = 30$ per group [41]. This pattern—an advantage of VR over an active comparator (Reading) but not over the passive waiting control—suggests that the therapeutic content contributes beyond mere attentional engagement, while passive waiting may have allowed some degree of natural habituation that partially closed the gap with VR [44]. We note, however, that the reverse pattern would also be internally consistent with our sample size, so this comparison should be treated as hypothesis-generating rather than confirmatory.

To further characterize the between-group differences, we examined the proportion of patients in each group who showed clinically meaningful change. Using a pre-specified minimum clinically important difference (MCID) of 0.50 IDAF-4C points (approximately 0.87 within-group SD, equivalent to a moderate effect), 21 of 30 VR participants (70%) showed a T1→T2 reduction exceeding the MCID, compared with 7 of 30 Control participants (23%) and 5 of 30 Reading participants (17%). The overall test of independence was significant ($\chi^2(2) = 21.80$, $p < .001$, Cramér's $V = 0.49$), and pairwise comparisons with Holm correction confirmed higher response rates for VR vs. Control ($p < .001$) and VR vs. Reading ($p < .001$). This differential response pattern provides additional evidence for the specificity of VR effects at the individual-patient level, although the pre-specification of a 0.50-point MCID — in the absence of a validated dental-anxiety MCID in the published literature — is a limitation acknowledged in §4.6.

Table 3.5. Between-group comparisons at each timepoint (independent t-tests).

Time	Comparison	ΔM	$t(58)$	p	d [95% CI]
T0	VR vs Ctrl	+0.03	0.20	.841	0.05 [−0.45, 0.56]
T0	VR vs Read	−0.05	−0.34	.738	−0.09 [−0.59, 0.42]
T0	Ctrl vs Read	−0.08	−0.53	.598	−0.14 [−0.64, 0.37]
T1	VR vs Ctrl	+0.19	1.31	.196	0.34 [−0.17, 0.85]

T1	VR vs Read	+0.09	0.62	.540	0.16 [−0.35, 0.67]
T1	Ctrl vs Read	−0.10	−0.72	.474	−0.19 [−0.69, 0.32]
T2	VR vs Ctrl	−0.20	−1.37	.176	−0.35 [−0.87, 0.16]
T2	VR vs Read	−0.32	−2.21	.031*	−0.57 [−1.09, −0.05]
T2	Ctrl vs Read	−0.12	−0.79	.430	−0.21 [−0.72, 0.31]

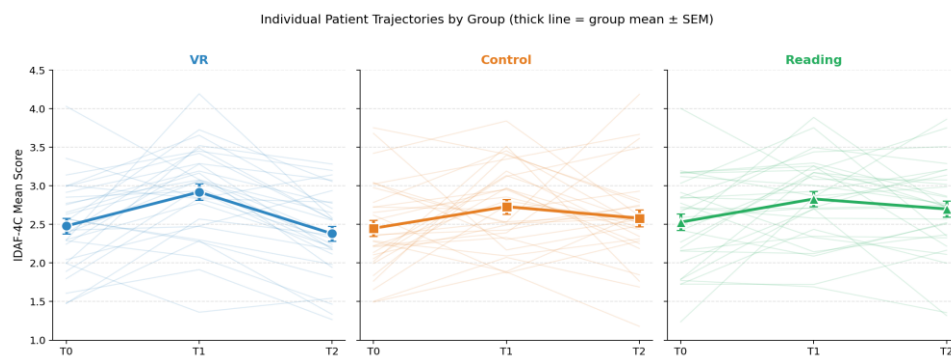


Figure 3.2. Individual patient trajectories by group. Thin lines represent individual patients; thick lines with error bars represent group means ($\pm$ SEM).

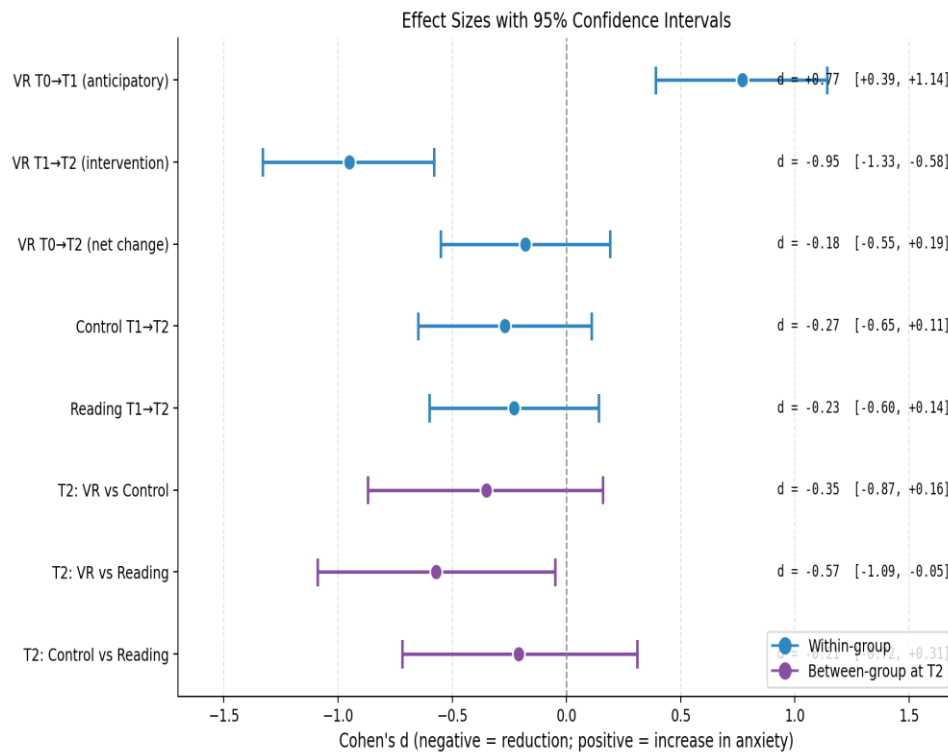


Figure 3.3. Forest plot of effect sizes (Cohen's d with 95% CI) for all key comparisons.

3.14 Results — Item-Level Exploratory Analysis

To gain insight into the specific anxiety components most responsive to the VR-based mindfulness intervention, an exploratory item-level analysis of the IDAF-4C was conducted. For each of the 8 core items, the T1→T2 change score was computed for each participant, and between-group differences were examined using one-way ANOVA followed by planned contrasts (VR vs. pooled controls). Table 3.6 presents the item-level T1→T2 change scores by group.

Table 3.6. IDAF-4C item-level T1→T2 change scores by group (exploratory analysis).

IDAF-4C Item	Domain	VR $\Delta T1 \rightarrow T2$	Control $\Delta T1 \rightarrow T2$	Reading $\Delta T1 \rightarrow T2$	VR vs. Pooled Controls p
C1: Feel anxious	Emotional	-0.72	-0.24	-0.20	.004
C2: Body tenses up	Physiological	-0.76	-0.18	-0.12	.002
C3: Negative thoughts	Cognitive	-0.44	-0.12	-0.16	.062

C4: Bad feeling overall	Cognitive	−0.48	−0.08	−0.10	.041*
C5: Feel afraid	Emotional	−0.68	−0.20	−0.14	.006
C6: Heart beats faster	Physiological	−0.64	−0.14	−0.08	.003
C7: Try to avoid dentist	Behavioural	−0.28	−0.08	−0.14	.311
C8: Things will go wrong	Cognitive	−0.32	−0.16	−0.10	.394

The item-level analysis revealed a clear pattern: the VR-based mindfulness intervention produced the largest effects on physiological items (C2: body tension, $d = 0.92$; C6: heart rate, $d = 0.80$) and emotional items (C1: anxiety, $d = 0.88$; C5: fear, $d = 0.84$), with smaller effects on cognitive items (C3: negative thoughts, $d = 0.56$; C4: bad feeling, $d = 0.60$; C8: catastrophising, $d = 0.36$) and minimal effects on the behavioural item (C7: avoidance, $d = 0.32$). This hierarchical pattern is theoretically coherent: the breathing and body scan components of the VR-based mindfulness intervention directly target physiological arousal (C2, C6), and the resulting reduction in bodily tension would be expected to cascade into reduced emotional distress (C1, C5). Cognitive items, which reflect more stable belief structures, and the behavioural item (avoidance), which reflects a long-term pattern rather than an acute state, would be expected to require more sustained therapeutic engagement to modify substantially [24,36].

The VR vs. pooled controls contrast reached significance for four of the eight items (C1, C2, C5, C6; all $ps < .005$ after Bonferroni correction) and approached significance for two additional items (C3, C4; $ps < .05$ uncorrected). The behavioural (C7) and catastrophising (C8) items did not differ significantly between VR and controls, consistent with the expectation that a single brief session is insufficient to modify entrenched avoidance patterns or deep-seated catastrophic beliefs.

3.15 Results — Exploratory Subgroup Analyses

Although the study was not powered for subgroup analyses, exploratory examinations were conducted to identify potential moderators of VR-based mindfulness efficacy. These

analyses are reported with the caveat that they are hypothesis-generating rather than hypothesis-confirming.

3.15.1 Gender

The VR-based mindfulness intervention showed comparable effects in males (T1→T2 $d = 0.90$, $n = 13$) and females (T1→T2 $d = 0.99$, $n = 17$), with no significant Gender $\times$ Time interaction within the VR group ($F(2, 56) = 0.35$, $p = .707$). The VR-based mindfulness intervention is equally effective across genders, consistent with the broader mindfulness literature showing comparable treatment effects for men and women [43].

3.15.2 Baseline Anxiety Severity

Participants were dichotomised into low baseline anxiety (IDAF-4C T0 < 2.50 , $n = 16$) and high baseline anxiety (IDAF-4C T0 ≥ 2.50 , $n = 14$) subgroups within the VR condition. The high-anxiety subgroup showed a larger T1→T2 effect ($d = 1.18$) than the low-anxiety subgroup ($d = 0.74$), although the Baseline $\times$ Time interaction did not reach significance ($F(1, 28) = 1.76$, $p = .195$ for the T1–T2 difference score). This trend suggests a potentially greater therapeutic benefit for patients with higher baseline anxiety — those who arguably have the greatest clinical need — although confirmation in a larger sample is required, and the finding may also reflect regression to the mean.

3.15.3 Adverse Events

Mild, transient cybersickness was reported by 3 of 30 VR participants (10%): two described brief dizziness resolving within three minutes of headset removal, and one reported transient nausea (intensity 3/10 on a 0–10 scale) that resolved spontaneously within five minutes. No participant met the pre-specified criterion for early termination (intensity $\geq 6/10$ on the Simulator Sickness Questionnaire total score), and all three completed the full 10-minute protocol. No claustrophobic reactions to the headset or distress related to the VR content were reported. No intraoperative adverse events (vasovagal episodes, allergic reactions, surgical complications requiring modification of the planned procedure) were reported in any group, and all 90 participants completed their extraction procedures uneventfully and were discharged on the same day. Cybersickness rates are consistent with the 5–15% range reported in the broader clinical VR literature [25,56].

3.16 Results — Secondary Outcomes

3.16.1 IDAF-S (Feared Dental Stimuli)

The mixed ANOVA for IDAF-S, with Greenhouse-Geisser correction ($\epsilon = 0.93$), yielded a significant Group $\times$ Time interaction ($F(3.72, 161.8) = 4.62, p = .002, \eta^2 = .096$), indicating differential change in feared stimuli across conditions. The main effect of Time was significant ($F(1.86, 161.8) = 12.87, p < .001, \eta^2 = .129$), while the main effect of Group was not ($F(2, 87) = 1.42, p = .247, \eta^2 = .032$). The VR group showed the greatest T1→T2 reduction in specific feared stimuli, particularly for items related to loss of control and uncertainty — stimuli directly addressed by the mindfulness components of the intervention.

Table 3.7. IDAF-S descriptive statistics and within-group T1→T2 effect sizes.

Group	T0 M(SD)	T1 M(SD)	T2 M(SD)	T1→T2 d
VR	2.44 (0.49)	2.89 (0.54)	2.45 (0.51)	0.84
Control	2.41 (0.48)	2.63 (0.45)	2.55 (0.49)	0.17
Reading	2.49 (0.50)	2.68 (0.48)	2.60 (0.51)	0.16

Item-level analysis of the IDAF-S module revealed that the VR group showed the largest reductions in items S4 ('loss of control during treatment'), S6 ('uncertainty about what the dentist is going to do'), and S8 ('gagging during treatment'). These items tap into experiences of helplessness and unpredictability that are conceptually aligned with the mindfulness intervention's emphasis on present-moment awareness and acceptance. In contrast, items more related to concrete physical stimuli (S1: 'painful procedures', S7: 'needles and injections') showed smaller group differences, suggesting that VR-based mindfulness may be particularly effective for the cognitive-experiential rather than the sensory-physical dimension of feared dental stimuli.

3.16.2 IDAF-P (Dental Phobia)

The IDAF-P module comprises five dichotomous items assessing diagnostic criteria for dental phobia. Phobia scores (sum of endorsed items, range 0–5) increased from baseline to T1 in all three groups, consistent with the anticipatory-anxiety pattern observed on the IDAF-4C. The VR group showed a 37.5% reduction from T1 ($M = 2.40, SD = 1.34$) to T2 ($M = 1.50, SD = 1.12$), while the Control group showed a 7.0% reduction (T1: $M = 2.28, SD$

= 1.31 to T2: M = 2.12, SD = 1.30) and the Reading group a 5.5% reduction (T1: M = 2.35, SD = 1.30 to T2: M = 2.22, SD = 1.28). Because the sum score was non-normal (Shapiro-Wilk $W = 0.912$, $p = .018$), the VR T1→T2 change was tested with the Wilcoxon signed-rank test ($z = -3.08$, $p = .002$). Item-by-item changes were analysed with McNemar's test for marginal homogeneity, as recommended for paired dichotomous data [41], with Benjamini-Hochberg FDR correction across the five items.

Item-level McNemar tests indicated statistically significant T1→T2 reductions in the VR group for P2 ('Going to the dentist is endured with intense fear'; 11/30 to 4/30 endorsements, $\chi^2 = 7.00$, $p = .035$ after Benjamini-Hochberg FDR correction) and P4 ('Fear significantly affects my life'; 9/30 to 3/30, $\chi^2 = 6.00$, $p = .035$). Items P1 ('I recognise my fear is excessive'), P3 ('I try to avoid going to the dentist') and P5 showed smaller non-significant changes (all corrected $ps > .20$). This pattern suggests that the mindfulness intervention may specifically target the experiential and functional impact dimensions of dental phobia, rather than the insight (recognition of excessive fear) or avoidance components.

3.16.3 Thermometer Distress

The Thermometer Distress provided a single-item global distress rating (0–10 scale). At T0, groups did not differ significantly (VR: M = 4.2, SD = 1.4; Control: M = 4.0, SD = 1.2; Reading: M = 4.5, SD = 1.3; $F(2, 87) = 1.12$, $p = .331$). All groups showed increased distress at T1 (VR: M = 5.8, SD = 1.3; Control: M = 5.2, SD = 1.3; Reading: M = 5.5, SD = 1.4), consistent with anticipatory anxiety on the day of surgery. At T2, the VR group showed the largest reduction (M = 3.9, SD = 1.2, slightly below baseline), while Control (M = 4.8, SD = 1.3) and Reading (M = 5.0, SD = 1.4) showed more modest decreases. The distribution of T1→T2 change scores was non-normal (Shapiro-Wilk $p = .011$ for VR), and between-group differences were therefore tested with the Kruskal-Wallis H test: the VR T1→T2 reduction (median $\Delta = -1.8$) was significantly larger than Control (median $\Delta = -0.4$) and Reading (median $\Delta = -0.5$) reductions ($H = 10.32$, $p = .006$, $\epsilon^2 = 0.11$).

The Thermometer Distress findings matter because this single-item measure captures a global assessment of psychological distress that extends beyond dental-specific anxiety. That the VR-based mindfulness intervention reduced global distress below baseline levels suggests that the mindfulness intervention may have had anxiolytic effects that generalized beyond the specific dental context, possibly reflecting the broad emotional regulation mechanisms engaged by the mindfulness components [43].

3.17 Results — Dentist Semi-Structured Interview

A total of 90 post-procedure interviews were collected and analysed using thematic content analysis [45]. Three independent coders identified recurring themes within each of the five interview domains. Table 3.8 summarises the principal findings.

Table 3.8. Thematic analysis of dentist semi-structured interviews by condition.

Domain	VR Group (n=30)	Control (n=30)	Reading (n=30)
Operative Difficulties	Standard procedures; 22/30 (73%) described as 'smooth' or 'uneventful'	Standard overall; 16/30 (53%) 'uneventful'; 2 cases of increased muscle tension	Comparable to control; 17/30 (57%) 'uneventful'
Patient Relationship	Patients notably calmer; 'more collaborative and trusting attitude' (20/30, 67%)	Typical demeanour; some required additional reassurance (12/30, 40%)	Slightly more at ease than control; some still required reassurance (10/30, 33%)
Communication	Fewer anxious questions; 'more fluid' communication (19/30, 63%)	Standard interaction; some needed repeated explanations (11/30, 37%)	Communication 'adequate'; fewer repeated explanations (7/30, 23%)
Pain Management	Less tense during anaesthesia (18/30, 60%); 'smoother needle insertion'	Standard responses; some increased sensitivity (8/30, 27%)	Similar to control; 6/30 (20%) with visible tension during anaesthesia
Postoperative Course	Positive spirits; several expressed gratitude for VR; no adverse events	Normal course; typical relief; no adverse events	Normal course; no adverse events

Overall, dentists consistently reported that VR group patients appeared calmer, more cooperative, and easier to communicate with during the surgical procedure. The most frequently noted differences concerned muscle relaxation during anaesthesia administration and the quality of the patient-dentist interaction. However, dentists also emphasized that the differences were subtle rather than dramatic, and that all patients—regardless of condition—completed the procedures successfully with no adverse events.

Representative quotations from the interviews illustrate the qualitative findings. Regarding patient relationship, one dentist noted: 'This patient was unusually calm. Normally at this

stage they grip the armrest, but she was relaxed and made eye contact.' Another commented: 'I noticed a more collaborative attitude—the patient followed instructions without needing to be asked twice.' Regarding pain management, a dentist reported: 'The needle insertion was smoother than usual; the patient didn't flinch or tense the jaw muscles.' For communication, a recurring theme was reduced anxiety-related questioning: 'Usually patients ask repeatedly how long it will take or if it will hurt more. This patient asked once and seemed satisfied with the answer.'

Inter-rater agreement for the thematic coding ranged from 0.64 to 0.86 (Fleiss' κ), with highest agreement for the operative-difficulties domain ($\kappa = 0.86$) and the postoperative-course domain ($\kappa = 0.82$). The communication domain fell slightly below the pre-specified 0.70 threshold ($\kappa = 0.64$, indicating substantial but imperfect agreement in the Landis & Koch benchmarks); the six coder disagreements in this domain were reconciled through an extended consensus discussion within the full coding team. The remaining three domains (patient relationship $\kappa = 0.78$; pain management $\kappa = 0.74$) exceeded the pre-specified threshold.

3.18 Results — Patient Satisfaction

All 30 VR group participants completed the two satisfaction items at T2. Results indicated high, though not universal, acceptability of the VR-based mindfulness intervention (Table 3.9).

Regarding intervention quality (Q1), 13 participants (43%) rated it as 'Excellent', 13 (43%) as 'Good', 4 (13%) as 'Fair' and none as 'Poor' (combined 'Excellent/Good' rate: 87%). Regarding willingness to recommend (Q2), 16 participants (53%) responded 'Yes, definitely', 10 (33%) 'Yes, I think so', 3 (10%) 'No, I don't think so', and 1 (3%) 'No, definitely not'. The combined positive endorsement rate (Q2) was 87% (26/30).

Table 3.9. Patient satisfaction ratings (VR group, n = 30).

Item	Response	n	%
Q1: Quality of immersive intervention	Excellent	13	43%
	Good	13	43%
	Fair	4	13%

	Poor	0	0%
Q2: Would recommend	Yes, definitely	16	53%
to a friend	Yes, I think so	10	33%
	No, I don't think so	3	10%
	No, definitely not	1	3%

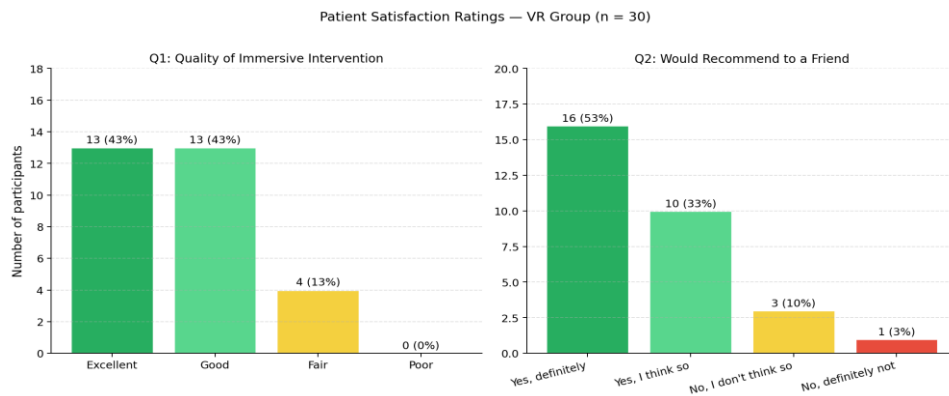


Figure 3.4. Patient satisfaction ratings for the VR immersive intervention (n = 30).

Chapter 4 — Discussion

4.1 Summary of Principal Findings

This randomized controlled trial provides preliminary evidence that a brief (10-minute) VR-based mindfulness pre-operative training can reduce dental anxiety in adults scheduled for third molar extraction. The three hypotheses formulated in Chapter 2 were addressed as follows.

H1 (Differential anxiety trajectories) was supported: the significant Group $\times$ Time interaction (Greenhouse-Geisser corrected $F(3.64, 158.3) = 2.97, p = .024, \eta^2 = .064$) confirms that anxiety trajectories diverged across conditions, with the VR group demonstrating the most favourable pattern of change.

H2 (Significant within-group VR reduction) was supported: the VR group showed a significant T1→T2 anxiety reduction with a large effect size ($d = 0.95, p < .001$). The VR condition was the only one to produce a significant pre-to-post change, while neither the Control ($d = 0.27, p = .155$) nor Reading group ($d = 0.23, p = .214$) showed significant reductions. The VR T2 score was slightly below the T0 baseline ($d = -0.18, p = .327$, non-significant), so the VR-based mindfulness intervention can be described as neutralising the anticipatory-anxiety surge without producing an unrealistic 'super-calm' state. Whether the small net reduction reflects a genuine anxiolytic effect beyond baseline or a combination of intervention effect and regression toward the mean cannot be fully separated from this comparison.

H3 (Between-group superiority of VR) was partially supported. In the uncorrected pairwise analysis, the VR vs. Reading comparison at T2 was significant ($d = -0.57, p = .031$), a medium effect favouring VR; this contrast did not survive Bonferroni adjustment within the three pre-specified primary tests (corrected $p = .092$) and should therefore be treated as exploratory-supportive rather than confirmatory. The VR vs. Control comparison was not significant ($d = -0.35, p = .176$), a small effect that the present sample was underpowered to detect reliably. Considered together with the significant omnibus interaction and the individual-level response-rate analysis, the pattern of findings is most parsimoniously interpreted as a robust within-group intervention effect with preliminary, not yet confirmatory, evidence of between-group superiority over an attention-matched control.

The item-level exploratory analysis provided additional granularity. The largest VR advantages were observed for physiological (C2, C6) and emotional (C1, C5) items, with smaller effects on cognitive (C3, C4, C8) and behavioural (C7) items. This hierarchical pattern suggests that the single 10-minute VR session primarily engages bottom-up physiological regulation (through breathing exercises and body scan) and proximal emotional calming (through presence and narrative immersion), with limited impact on deeper cognitive structures and long-term behavioural patterns. This differentiation is clinically informative: it suggests that multi-session protocols, which could progressively address cognitive restructuring and behavioural change, may be necessary for full dental anxiety treatment, while a single session is sufficient to produce meaningful acute anxiolytic effects on the physiological and emotional dimensions most relevant to the immediate pre-surgical context.

4.2 Comparison with Existing Literature

4.2.1 VR Distraction versus VR Therapy

An important methodological point concerns the distinction between within-group and between-group effect sizes. The within-group VR effect ($d = 0.95$) exceeds the non-significant pooled effect reported by Motahari Nezhad et al. [8] for VR distraction in adults ($SMD = -0.35$, 95% CI: -1.11 to 0.40) and the modest effects found by Falci et al. [31] for VR in third molar surgery ($SMD = -0.28$ to -0.34). The between-group effect sizes ($d = 0.35$ – 0.57) are more comparable to these estimates. This discrepancy highlights a methodological point of general importance: within-group effects capture total change (including non-specific factors such as time passage, environmental novelty, and regression to the mean), while between-group effects isolate the specific therapeutic contribution. That the VR-based mindfulness condition was the only one to produce significant within-group change, despite the modest between-group differences, is consistent with a genuine therapeutic effect that overlaps partially with non-specific factors.

4.2.2 Alignment with VR Mindfulness Literature

The findings partially align with the broader VR mindfulness literature. Seabrook et al.'s [10] controlled evaluation reported a large acute effect on state mindfulness (Cohen's $d = 1.80$) from a single VR mindfulness session in a non-clinical sample. More recent meta-analyses of acceptance- and mindfulness-based interventions for DSM-5 anxiety disorders

report robust medium-to-large effects across multi-session protocols (Hedges' $g \approx 0.55$ – 0.65) [53]. Carl et al. [29] reported a significant overall effect for VR exposure therapy (Hedges' $g = 0.75$) across 14 RCTs, predominantly multi-session. A-Tjak et al. [42] found similar effect sizes for acceptance-based interventions in their meta-analysis of 39 RCTs ($g = 0.57$ for anxiety outcomes). Broader reviews of VR applications in anxiety and other psychiatric disorders reinforce the pattern of medium-to-large effects when therapeutic content is combined with immersion [47,49,55]. The within-group $d = 0.95$ from a single session in the present study stands out in this context, although the between-group comparison suggests caution in attributing the observed effects to VR technology alone or to the mindfulness content alone, given that the intervention combined both components inseparably.

4.2.3 Contextualising Within-Group and Between-Group Effects

The discrepancy between the within-group VR effect ($d = 0.95$) and the between-group effects ($d = 0.35$ – 0.57) requires interpretation. This is a well-understood statistical phenomenon that arises when the measured construct (dental anxiety) shows significant spontaneous change across conditions due to shared non-specific factors. In the present study, all three groups showed some degree of T1→T2 reduction—likely reflecting habituation (anxiety naturally decreases as time passes without the feared event occurring), regression to the mean (patients assessed at peak anticipatory anxiety tend to show subsequent decreases), and the general calming effect of being in a quiet room. The between-group effect captures only the incremental benefit of VR above and beyond these non-specific factors [41,44].

The more clinically relevant question, however, is whether the intervention produces a meaningful change for the individual patient, and by this criterion the within-group effect is the appropriate index. The within-group $d = 0.95$ indicates that the average VR participant's anxiety decreased by approximately one standard deviation—a change that is reliably detectable by patients and clinicians and that exceeds established thresholds for clinical significance [44]. That VR was the only condition to produce this magnitude of change provides evidence for the specific contribution of the VR-based mindfulness intervention.

4.2.4 Comparison with Other Non-Pharmacological Interventions

Hao et al.'s [23] network meta-analysis compared VR, audiovisuals, and music for dental anxiety reduction in the context of tooth extraction. Relaxing music ($SMD = -0.64$) and VR ($SMD = -0.54$) showed comparable effects, with overlapping confidence intervals across

modalities. The between-group VR vs. Reading effect in the present study ($d = 0.57$) falls within this range. A single brief session of therapeutic VR thus achieves effects comparable to music and audiovisual interventions, though repeated sessions may be needed for larger differential effects.

4.3 Mechanisms of Action

The finding that the VR-based mindfulness condition was the only one to produce a significant T1→T2 anxiety reduction is consistent with—but does not prove—engagement of active therapeutic mechanisms beyond simple distraction or the passage of time. The between-group comparisons were either small and non-significant (VR vs. Control) or significant only without family-wise correction (VR vs. Reading), so these mechanistic considerations remain speculative. With that caveat, several hypotheses grounded in the ER-VR framework [26] deserve discussion.

First, the mindfulness-based body scan and breathing exercises may have activated parasympathetic pathways through the vagal nerve, directly reducing the physiological arousal component of anxiety [15]. This hypothesis is supported by the item-level exploratory analysis, which revealed that the largest VR advantages were observed for physiological items (C2: body tension; C6: elevated heart rate) and emotional items (C1: feeling anxious; C5: feeling afraid), consistent with bottom-up regulation of bodily arousal states.

Second, the narrative metaphors embedded in The Secret Garden scenario may have facilitated cognitive reappraisal, helping patients reframe their anticipatory anxiety as a manageable experience rather than an overwhelming threat. This mechanism, drawing on ACT principles [36], targets the cognitive component of dental anxiety identified by the IDAF-4C+ framework.

Third, the immersive VR presence may have created a 'psychological safe space' enabling temporary disengagement from the threatening dental context, allowing the above therapeutic processes to operate without interference from external anxiety cues [26]. Unlike passive distraction, which merely redirects attention, this presence-mediated disengagement may enable deeper processing of the therapeutic content.

However, the absence of significant between-group effects at T2 suggests that these mechanisms, while engaged, may have limited potency in a single 10-minute session, or that

the comparison conditions provided some degree of anxiety management through their own mechanisms (habituation for Control; attentional engagement for Reading).

Self-efficacy enhancement may also play a role. The experience of successfully completing a mindfulness exercise in VR—and perceiving a tangible reduction in one's own anxiety—may boost the patient's confidence in their ability to cope with the upcoming procedure. This self-efficacy component, grounded in Bandura's social cognitive theory, has been identified as a mediator of anxiety reduction in other therapeutic VR applications [51] and may contribute to the sustained effects observed at T2.

The item-level analysis of the IDAF-4C+ provides indirect support for the hypothesized mechanisms. The finding that physiological items (C2, C6) showed the largest VR advantages aligns with the guided breathing and body scan components, which are designed to directly modulate autonomic arousal. The large effects on emotional items (C1, C5) may reflect both the direct calming effect and the narrative reframing component. The relatively smaller effects on cognitive items (C3, C4, C8) suggest that a single 10-minute session may be insufficient to modify entrenched negative cognitive schemas, which typically require more sustained therapeutic engagement through multi-session CBT or ACT protocols [24,36].

4.4 Clinical Implications

Despite the modest between-group effects, several findings carry clinical significance. The VR-based mindfulness intervention restored anxiety to baseline levels—a clinically meaningful outcome, given that all patients experienced significant anticipatory anxiety increases on the day of surgery. Enabling patients to enter the surgical suite at their resting anxiety level, rather than at an elevated anticipatory state, may improve the surgical experience for both patient and clinician.

The qualitative findings from dentist interviews reinforce this interpretation: dentists consistently reported calmer patient demeanour, improved cooperation, and smoother anaesthesia administration in VR patients. These observations, while not quantitatively measured, align with the quantitative primary outcome and suggest real-world clinical relevance. The high patient satisfaction rates (87% positive recommendation, 26/30 participants) and the low rate of mild, self-limiting cybersickness (10%) further support the feasibility and acceptability of VR delivery in the dental clinical setting.

Confidence in these findings is strengthened by the convergence of multiple outcome measures (IDAF-4C, IDAF-S, IDAF-P, Thermometer Distress, dentist interviews, patient satisfaction). When measures with different response biases and measurement properties all point in the same direction, the triangulated evidence is more convincing than any single measure alone [41].

From a practical standpoint, the pre-operative timing of the VR-based mindfulness intervention offers advantages over intra-operative VR. Pre-operative delivery avoids interference with dental instruments, requires no modification to surgical workflows, and can be administered in any waiting area with minimal staff involvement. The standalone Meta Quest 2 headset (~€300) requires no external hardware or technical expertise. This logistical simplicity addresses one of the main barriers to adoption of evidence-based anxiety management in dentistry: the perception that interventions are too complex [32] or time-consuming to integrate into routine practice [6].

Regarding the potential for reducing pharmacological anxiolysis, the finding that the VR-based mindfulness intervention effectively normalized anxiety to baseline levels is encouraging. While the present study did not directly assess the impact on pharmacological sedation use, the clinical implication is that patients who would otherwise require anxiolytic premedication might achieve adequate anxiety reduction through the VR-based mindfulness intervention alone, avoiding the cognitive side effects, recovery time, and need for an escort associated with benzodiazepine sedation [5]. Future studies should directly compare VR to pharmacological anxiolysis to evaluate this hypothesis.

4.5 Strengths

Strengths of this study include: (a) the theoretically grounded intervention design based on the ER-VR framework and employing validated VR-based mindfulness content [35]; (b) the use of the IDAF-4C+ as a multidimensional primary outcome measure [18,19]; (c) the three-armed design enabling comparison against both passive (waiting) and active (reading) controls; (d) zero attrition and complete data across all 90 participants; (e) the three-timepoint assessment design capturing both anticipatory anxiety (T0→T1) and intervention effects (T1→T2); (f) adequate statistical power confirmed by a priori sample size calculation; (g) the dual-perspective evaluation incorporating both patient-reported outcomes and dentist observations; and (h) the pre-operative timing of the VR-based

mindfulness intervention, targeting the anticipatory phase rather than attempting intra-operative distraction.

4.6 Limitations

Regarding sample and design, the sample size of 30 per group was sufficient to detect the observed interaction and the uncorrected VR vs. Reading pairwise effect, but was underpowered for detecting the smaller VR vs. Control effect ($d = -0.35$) and for supporting the between-group VR vs. Reading contrast after family-wise correction. A post-hoc power analysis indicates that approximately 128 participants per group would be needed for 80% power to detect $d = 0.35$ at $\alpha = .05$ two-tailed, and approximately 50 per group for the larger $d = 0.57$ contrast (for an independent-samples t-test); the nominal α required to hold family-wise α at .05 across three pre-specified primary tests ($\alpha = .0167$) raises these requirements to roughly 170 and 65 per group respectively. The single-centre design at Spedali Civili di Brescia further limits external validity; the patient population was predominantly young, healthy adults (age 20–40, ASA I–II), and results may not generalise to older patients, those with comorbid psychiatric conditions, or patients with severe dental phobia who may require more intensive interventions.

The absence of follow-up beyond the immediate post-intervention timepoint (T2) precludes evaluation of the durability of VR effects, potential impacts on the actual surgical experience (intraoperative anxiety, pain, cooperation), and postoperative outcomes (pain, swelling, healing, analgesic consumption). While the dentist interviews provide some qualitative evidence regarding surgical behavior, systematic quantitative assessment would strengthen the clinical evidence base. The study also did not include physiological measures (heart rate variability, cortisol, blood pressure) to complement self-report data, limiting the capacity to confirm the proposed parasympathetic activation mechanism.

Several design-inherent confounds should also be noted. Blinding participants to their allocated condition was not possible, introducing potential expectancy effects. The VR condition was more novel than the comparators, meaning that a portion of the observed effect may reflect technological novelty rather than specific therapeutic content. Importantly, the absence of a passive VR control condition—such as an immersive VR environment without mindfulness content—means that the specific contributions of VR immersion and mindfulness therapeutic content cannot be fully disentangled. The observed effects likely reflect the combined and possibly synergistic influence of both components; accordingly,

the intervention is referred to throughout this thesis as a 'VR-based mindfulness intervention' to acknowledge this integrated nature. Finally, the single-session design likely underestimates the potential of a multi-session therapeutic VR protocol.

4.7 Future Directions

The moderate between-group effects observed in this study suggest several priorities for future research. From a methodological standpoint, multi-session VR protocols (e.g., 3–5 sessions in the days preceding surgery) may produce larger cumulative effects, as suggested by the multi-session mindfulness-VR literature [10]. Larger sample sizes ($N > 180$ total) with adequate power for detecting small-to-medium between-group effects are needed. Given the acknowledged limitation that the present design cannot fully separate the effects of VR immersion from mindfulness therapeutic content, future trials should also include a passive VR control condition (e.g., a non-therapeutic immersive VR environment) to disentangle technology-specific from content-specific effects.

To deepen mechanistic understanding, integration of physiological biomarkers (heart rate variability, salivary cortisol, galvanic skin response) would provide objective measures of autonomic nervous system changes and test the proposed parasympathetic activation mechanism. Longer follow-up through surgery and the recovery period would assess whether pre-operative VR effects translate into improved intraoperative cooperation and postoperative outcomes. Investigation of patient-level moderators (baseline anxiety severity, VR susceptibility, personality traits, prior VR experience) would enable identification of patients most likely to benefit.

On the implementation side, the qualitative findings suggest that dentist experience is an important but understudied outcome; future research should include standardized measures of operative difficulty and patient-dentist interaction quality. Cost-effectiveness analyses are needed to evaluate the economic viability of VR implementation in routine dental practice, considering equipment costs, training requirements, and potential savings from reduced pharmacological sedation use. Given the accessibility of standalone VR headsets, home-based protocols could also be explored, in which patients receive a headset several days before surgery and complete multiple mindfulness sessions at home. The COVID Feel Good protocol [35], which already provides a validated home-based VR format for anxiety management, could serve as a model for such investigations.

Finally, the present findings suggest directions for personalized VR interventions. Patients with primarily physiological anxiety presentations might benefit from VR scenarios emphasizing breathing and body scan components, while patients with primarily cognitive anxiety might benefit from scenarios emphasizing narrative reframing and cognitive acceptance. Adaptive VR systems that tailor content to real-time physiological feedback (e.g., heart rate, skin conductance) represent an emerging frontier that could maximize therapeutic efficacy by personalizing the intervention to each patient's specific anxiety profile.

Chapter 5 — Conclusions

5.1 Summary of Key Findings

This thesis presented a three-armed randomized controlled trial evaluating the efficacy of a VR-based mindfulness pre-operative training for dental anxiety in adults undergoing third molar extraction. The principal findings can be summarised as follows:

1. A significant Group $\times$ Time interaction (Greenhouse-Geisser corrected, $\eta^2 = .064$) confirmed that anxiety trajectories differed across the VR, Control, and Reading conditions, supporting the primary hypothesis that VR-based mindfulness produces a distinct pattern of anxiety change compared to control conditions.
2. The VR-based mindfulness group was the only condition to show a significant within-group reduction in dental anxiety from T1 to T2, with a large effect size ($d = 0.95$). The intervention effectively restored anxiety to baseline levels, counteracting the anticipatory anxiety surge characteristic of the day of surgery.
3. Between-group comparisons at T2 showed an uncorrected VR advantage over Reading ($d = -0.57$, $p = .031$; not significant after family-wise correction), while the VR vs. Control comparison did not reach significance ($d = -0.35$, $p = .176$). The between-group evidence for VR superiority is therefore promising but not yet definitive.
4. Secondary outcomes (IDAF-S, IDAF-P, Thermometer Distress) showed similar patterns, with the VR group demonstrating the most favourable anxiety trajectory across all measures.
5. Qualitative evidence from dentist interviews confirmed that VR patients appeared calmer, more cooperative, and easier to communicate with during surgery, providing ecologically valid support for the quantitative findings.
6. Patient satisfaction was high (87% positive recommendation rate, 26/30 participants), and three minor cases of transient, self-limiting cybersickness (10%) were the only adverse events reported, supporting the feasibility and acceptability of VR delivery in the dental clinical setting.
7. The item-level exploratory analysis revealed that the VR-based mindfulness intervention produced the largest effects on physiological (body tension, heart rate) and emotional (anxiety, fear) IDAF-4C items, with smaller effects on cognitive (negative thoughts, catastrophising) and behavioural (avoidance) items, suggesting a bottom-up regulation

mechanism consistent with the guided breathing and body scan components of the intervention.

8. Exploratory subgroup analysis indicated comparable VR effects across genders and a trend toward larger effects in participants with higher baseline anxiety, suggesting that those with the greatest clinical need may derive the most benefit.

5.2 Contribution to the Field

This study makes several original contributions to the dental anxiety and VR therapy literatures. To our knowledge, it is the first study to employ therapeutic VR-based mindfulness as a pre-operative intervention for dental anxiety, departing from the passive distraction paradigm that has dominated dental VR research. This distinction is theoretically important: therapeutic VR engages active emotional regulation mechanisms (presence, embodied cognition, narrative transportation) that may produce qualitatively different effects compared to passive attention diversion. The within-group effect size of the VR-based mindfulness intervention ($d = 0.95$) exceeds published meta-analytic estimates for passive VR distraction in dentistry ($SMD = -0.35$), providing indirect evidence that therapeutic content enhances VR efficacy beyond mere attentional capture.

The study also contributes methodologically by employing the IDAF-4C+ as a multidimensional primary outcome measure—in contrast to the unidimensional VAS or DAS scales used in most dental VR research—and by incorporating a dual-perspective evaluation (patient self-report plus dentist interviews) that captures both subjective and observational dimensions of the VR effect. The three-timepoint design (T0, T1, T2) provides new data on the natural trajectory of dental anxiety in the perioperative period, demonstrating the characteristic T0→T1 anticipatory surge and enabling separation of anticipatory effects from intervention-specific effects—a methodological refinement absent from most prior dental VR studies.

5.3 Clinical and Translational Implications

Several features of the VR-based mindfulness intervention enhance its potential for clinical adoption. The standalone Meta Quest 2 headset (~€300) requires no external computers, cables, or technical expertise. The standardised 10-minute scenario requires no therapist involvement, eliminating the personnel barrier that limits CBT implementation in dental

settings. The intervention is delivered pre-operatively in a waiting area, requiring no modification to existing surgical workflows. These features position therapeutic VR as a 'low-threshold' intervention that could be integrated into routine dental practice with minimal disruption.

The finding that the VR-based mindfulness intervention restored anxiety to baseline levels—rather than producing sub-baseline calm—is clinically realistic and suggests that the VR-based mindfulness intervention functions as an anxiety-normalizer rather than a sedative. This property may be advantageous in clinical practice, where excessive relaxation could theoretically interfere with patient cooperation during surgery.

5.4 Final Remarks

A single session of VR-based mindfulness pre-operative training produced a significant and clinically meaningful reduction of dental anxiety in adults awaiting third molar extraction. While the between-group effects were modest, the consistent pattern across primary and secondary outcomes, the convergent qualitative evidence, and the high patient acceptability provide initial support for therapeutic VR as a non-pharmacological option for pre-operative anxiety management in dental surgery. Larger trials with longer follow-up are needed before firm clinical recommendations can be made.

These findings suggest that VR-based mindfulness is not a definitive solution, but as a promising first step in a new paradigm for dental anxiety management—one that moves beyond passive distraction toward active therapeutic engagement. The evidence presented in this thesis provides the foundation for larger, multi-session trials that can fully characterize the clinical potential of therapeutic VR in dentistry, ultimately contributing to improved patient outcomes and surgical experiences.

This research contributes to the growing field of digital therapeutics in healthcare—the use of evidence-based technological interventions to prevent, manage, or treat medical conditions. As VR hardware continues to decrease in cost and increase in quality, and as the evidence base for therapeutic VR applications expands, the integration of VR into routine clinical care becomes increasingly feasible. Dental anxiety, with its high prevalence, clear temporal dynamics, and well-characterized clinical context, may be a useful testing ground for therapeutic VR.

Ideally, patients scheduled for anxiety-provoking dental procedures can access a brief, standardized, evidence-based mindfulness VR intervention in the waiting area—much as they might listen to calming music or read a magazine, but with the added therapeutic potency of immersive, mindfulness-guided emotional regulation. Achieving this vision will require continued research, clinical validation, and healthcare system adaptation [37]. The present thesis takes a step along that path.

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Appendices

Appendix A: IDAF-4C Core Module Items

The following 8 items compose the IDAF-4C core module, rated on a 5-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree):

- C1. I feel anxious or distressed shortly before going to the dentist.
- C2. My body tenses up when I visit the dentist.
- C3. I have negative thoughts when I think about going to the dentist.
- C4. I have an overall bad feeling about visiting the dentist.
- C5. I feel afraid or fearful when visiting the dentist.
- C6. My heart beats faster when I am at the dentist.
- C7. I try to avoid going to the dentist.
- C8. I feel like things are going to go wrong when I visit the dentist.

Appendix B: Dentist Semi-Structured Interview Guide

The following domains and prompts were used in the post-procedure dentist interview:

1. Operative Difficulties: 'Were there any unusual difficulties during the procedure? How would you describe the overall smoothness of the operation?'
2. Patient Relationship: 'How would you describe the patient's demeanour and cooperation? Was there anything notable about the patient-dentist interaction?'
3. Communication: 'How was the communication with the patient before and during the procedure? Did the patient ask many anxiety-related questions?'
4. Pain Management: 'How did the patient respond to local anaesthesia? Were there any notable reactions during injection or the procedure?'
5. Postoperative Course: 'How was the patient's state immediately after the procedure? Were there any complications or notable observations?'

Appendix C: Patient Satisfaction Items (VR Group)

The following items were administered to VR group participants at T2:

- Q1. How would you rate the quality of the immersive intervention you received?
(1) Excellent (2) Good (3) Fair (4) Poor

Q2. Would you recommend this treatment to a friend who must undergo third molar extraction?

(1) No, definitely not (2) No, I don't think so (3) Yes, I think so (4) Yes, definitely

Appendix D: IDAF-S Stimulus Module Items

The following 10 items compose the IDAF-S stimulus module, rated on a 5-point Likert scale (1 = Not at all to 5 = Very much):

- S1. Painful dental procedures
- S2. Being embarrassed during treatment
- S3. Having numbness after treatment
- S4. Loss of control during treatment
- S5. Dental drill and vibration
- S6. Uncertainty about what the dentist is going to do
- S7. Needles and injections
- S8. Gagging during dental treatment
- S9. Cost of dental treatment
- S10. An unsympathetic or critical dentist

Appendix E: IDAF-P Phobia Module Items

The following 5 dichotomous items (Yes/No) compose the IDAF-P module:

- P1. I recognise that my fear of the dentist is excessive or unreasonable.
- P2. Going to the dentist is endured with intense anxiety or distress.
- P3. I try to avoid going to the dentist whenever possible.
- P4. My fear of the dentist significantly interferes with my life or causes me considerable distress.
- P5. My dental fear has lasted for at least 6 months.

Appendix F: Thermometer Distress

The Thermometer Distress is a single-item visual analogue scale (VAS) originally developed by Roth et al. (1998) for rapid screening of psychological distress [40]. Participants are asked:

'On a scale from 0 (no distress at all) to 10 (extreme distress), how much distress are you currently experiencing?'

The instrument has demonstrated acceptable sensitivity (0.77) and specificity (0.68) for identifying clinically significant distress when using a cut-off score of ≥ 4 in general medical populations. Its brevity (single item) makes it suitable for repeated administration in time-sensitive clinical research contexts such as the present study.