Protocol

Effects of App-Based Mindfulness Training on Dental Patients' Anxiety Symptoms Prior to Undergoing Dental Surgery: Protocol for a Mixed Methods Randomized Controlled Trial

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Abstract

Background: Dental anxiety is associated with treatment avoidance, poor oral health–related quality of life, increased procedural complications, and poor postoperative recovery. Negative appraisals may exacerbate anxiety and increase emotional and physiological arousal. Mindfulness may improve attentional and emotional regulation, and reduce dental anxiety through improved self-regulation.

Objective: The present study aims to investigate the effects of an app-based mindfulness intervention among patients experiencing dental anxiety prior to undergoing surgery.

Methods: Using a mixed methods design consisting of a randomized controlled trial and semistructured interviews, 100 participants will be randomized to an app-based mindfulness training or a control condition. Data will be collected prior to the start of the intervention (T0), postintervention, but presurgery (T1), and postsurgery (T2). Our primary outcome is dental anxiety; secondary outcomes include general anxiety, perceived stress, positive and negative affect, mindfulness, and postoperative pain. Analyses of covariance, mixed analyses of variance, and independent-samples 1-tailed *t* tests will be used to investigate within-group and between-group differences across 3 time points. Semistructured interviews will be conducted with 15 to 20 participants from the intervention group to explore patients' experiences; qualitative analyses will be conducted by 2 independent coders.

Results: Recruitment began in April 2026, and the first screening was completed on April 6, 2026. To date, 19 participants have completed the study, and 4 interviews have been completed. Study completion is projected for August 2027, with publication of the findings anticipated in December 2027. The study has not received any funding. Relative to T0, we expect significantly greater improvements across our primary and secondary outcomes among intervention group participants compared with control group participants at postbaseline time points.

Conclusions: Our findings may inform future efforts to implement cost-effective interventions in dental care settings to manage dental anxiety in order to reduce both stress- and anxiety-related burdens for patients and dentists.

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Introduction

Anxiety is an adaptive affective state elicited by a perceived threat and is modulated by activity within the sympathetic nervous system [1]. When such responses are triggered by an anticipated dental treatment or one that is currently ongoing, the anxiety response is referred to as dental anxiety [2]. Findings from a recent systematic review suggest that dental anxiety constitutes a prevalent issue, with 15.3% of individuals worldwide experiencing dental anxiety [3]. Symptoms of dental anxiety include, but are not limited to, feelings of substantial emotional distress, neurophysiological changes in vital signs, including increased blood pressure, heart rate, and respiratory rate [4], as well as increased sweating and sleeping difficulties [5]. Dental anxiety constitutes a multifaceted condition with a complex etiology comprising biological, environmental, and psychological factors [6], initially arising as early as childhood or developing later in life as a result of external or internal factors [7]. Factors contributing to the onset and persistence of dental anxiety include, but are not limited to, unpleasant personal experiences during dental treatments, exposure to reports of negative experiences made by others [8], fear associated with the sight, smell, and sound of dental instruments and products, and concerns regarding the behavior of dentists and their office staff [6]. Additional factors contributing to dental anxiety include mental health variables, such as general anxiety, personal oral health practices, and personality traits [6,9].

Dental anxiety can result in avoidance behavior, which, in turn, can lead to a lack of preventive dental care [10]. Avoiding preventive care can exacerbate dental conditions, subsequently leading to more invasive and often more painful treatments that further exacerbate dental anxiety, thus completing a vicious cycle [10]. Dental anxiety may also influence dental treatment choices, with anxious patients being more likely to opt for noncurative options, such as tooth extraction, rather than tooth-preserving treatments [11]. Unsurprisingly, increased levels of dental anxiety are also linked to decreased oral health-related quality of life, as indexed by uncomfortable oral health conditions, difficulties in social situations, concerns about perceived judgment from others, and low self-esteem [12-14]. Dental anxiety has also been linked to greater pain expectations prior to treatment [15], greater perceived pain during and after treatment [15,16], and more serious complications after surgery [17].

However, the effects of dental anxiety extend beyond dental patients. Past research findings highlight that patients' dental anxiety affects dentists as well [18], with dentists ranking the treatment of anxious patients as one of their most prevalent stressors [19], and over 90% of dentists reporting stress when treating patients with anxiety [20]. Treating anxious patients can lead to longer treatments, an increased risk of misdiagnosis, and an increased risk of incorrect treatment [19,21]. To decrease anxiety among patients and, subsequently, reduce the well-documented burden experienced by dentists [22-24], effective interventions are needed. Several approaches to managing dental anxiety have previously been investigated. A recent systematic review and meta-analyses revealed that, depending on the severity of a dental patient's condition, dental anxiety may be effectively alleviated by interventions such as cognitive behavioral therapy, pharmacotherapy, and hypnosis [25]. Although promising, the aforementioned approaches may not always be feasible due to time constraints, limited resources, or a lack of patient accessibility [26,27]. Mindfulness-based intervention may present a feasible option for reducing dental anxiety in clinical settings. Mindfulness entails sustained present-centered awareness of bodily, emotional, and cognitive experiences, as well as the surrounding environment, accompanied by an attitude of openness and equanimity [28]. The effects of mindfulness on anxiety have been well documented, with recent literature reviews revealing that mindfulness can reduce the severity of anxiety symptoms in clinical and nonclinical populations [29,30]. An emerging body of literature has revealed the beneficial effects of mindfulness on dental anxiety [31], with findings highlighting mindfulness meditation as a potentially effective tool for managing anxiety during dental surgery [32]. Although mindfulness may reduce dental anxiety, face-to-face interventions may be limited by time constraints and the need for trained facilitators. App-based mindfulness interventions may offer a feasible and flexible alternative, allowing individuals to access mindfulness exercises independently [32]. Additionally, implementing mindfulness-based interventions could aid with stress management, as some research highlights the role of stress in the development and maintenance of dental anxiety; for example, children who report greater perceived stress also suffer from greater anticipatory pain prior to dental treatments [33]. Negative appraisal of a future event, such as the belief that one will experience pain during an upcoming dental treatment, can create stress, which, in turn, can increase physiological and psychological arousal [34]. Stress has been described as the processes involved in allowing individuals to adapt to internal and external challenges via endogenous self-regulatory mechanisms [35] and can contribute to poor mental health outcomes [36,37]. Acting as a buffer, mindfulness may strengthen self-regulatory resources by improving attentional and emotional regulation, thus facilitating more adaptive responses to internal and external stressors [35]. As a result, mindfulness interventions may, via the pathway of improved self-regulation, prompt an innate "relaxation response," that is, a counterpart to the stress response [38], by setting in motion several neurobiological mechanisms resulting in anxiolytic effects (for more information [39]). The present mixed methods study aims to examine whether the hypothesized self-regulatory and anxiolytic effects of mindfulness may decrease dental anxiety among patients scheduled to undergo dental surgery. Specifically, we will conduct a randomized controlled trial (RCT) to assess whether, and to what degree, an app-based mindfulness training program can reduce dental anxiety, general anxiety, perceived stress, postoperative pain, and negative affect, as well as improve mindfulness and positive affect. Additionally, we will conduct semistructured interviews with participants randomized to the intervention group to gain insight into participants' experiences, perceived benefits,

barriers to engagement, and potential mechanisms underlying the observed quantitative effects.

We hypothesize that participants in the intervention group who use the app-based mindfulness training will exhibit significantly lower postintervention levels of dental anxiety compared to their preintervention levels and compared to participants in the control group. We also hypothesize that general anxiety, preoperative anxiety, and perceived stress will decrease, while subjective well-being and mindfulness will increase from baseline among participants randomized to the intervention group and compared to the control group. Additionally, we hypothesize that postoperative pain will be greater in the control group than in the intervention group. Lastly, we hypothesize that, among participants randomized to the intervention group, more frequent app use will be significantly related to lower ratings of postoperative pain and greater improvements over time across the outcomes assessed at several time points. Our quantitative investigation will be followed by semistructured interviews with individuals who were randomized to the intervention group in order to explore participants' experiences with the app-based mindfulness training, as well as their perceptions of its usability, engagement, and perceived effectiveness in helping them cope with anxiety and stress. We will assess whether being randomized to the intervention group is associated with any adverse experiences and will document and report any adverse events reported by participants.

Methods

Ethical Considerations

Research Ethics Approval and Trial Registration

Ethics approval was obtained from the Institutional Review Board (IRB) at Witten/Herdecke University in September 2025 (120/2025). Informed consent will be collected from all participants prior to the start of data collection. Any amendments will be submitted to the IRB as well as to the German Clinical Trial Registry (DRKS). Reporting will follow the CONSORT (Consolidated Standards of Reporting Trials) reporting guideline.

Patient and Public Involvement

Patients and members of the public were not involved in the design of this study and will not be involved in the conduct of the study or in the planned reporting of this trial.

Informed Consent

If they are deemed eligible according to the inclusion criteria, eligible participants receive an email containing study-related information, data protection information, and an informed consent form pertaining to the study. Additionally, the email contains a link to the baseline (T0) survey.

Incentives

No incentives will be provided. Individuals randomized to the intervention group will receive access to the app at no cost. Individuals randomized to the control group will also receive access to the app at no cost once the study has been completed. However, the premium version of the app is also covered by statutory health care providers in Germany; i.e., individuals with statutory health insurance who do not participate in the present study can also be able to download and use the app for free.

Confidentiality and Data Access

Personal information from potential and enrolled participants will be collected exclusively by members of the research team and will remain inaccessible to any unauthorized individuals. Both personal information and survey responses will be pseudonymized using unique identification numbers. When the qualitative data analysis has been completed, audio recordings of the interviews will be deleted from the secure institutional network drive, where the data will be stored until that point. Access to all study data will be restricted to authorized study personnel. Participant records will be stored in an anonymized format for a period of 10 years following study completion.

Study Design

The present study will use a mixed methods design. We will conduct a two-arm, parallel-group RCT to determine the effects of an app-based mindfulness training on dental anxiety (primary outcome), as well as general anxiety, preoperative anxiety, perceived stress, positive and negative affect, mindfulness, and postoperative pain among patients scheduled to undergo dental surgery at a university-based dental clinic or 2 other private dental practices in Germany. Using semistructured interviews, we will also investigate participants' experiences with the app-based mindfulness training and their perceptions of its usability, engagement, and perceived effectiveness in coping with anxiety and stress. This study protocol was developed in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines. The completed SPIRIT checklist is provided in Checklist 1.

Participants

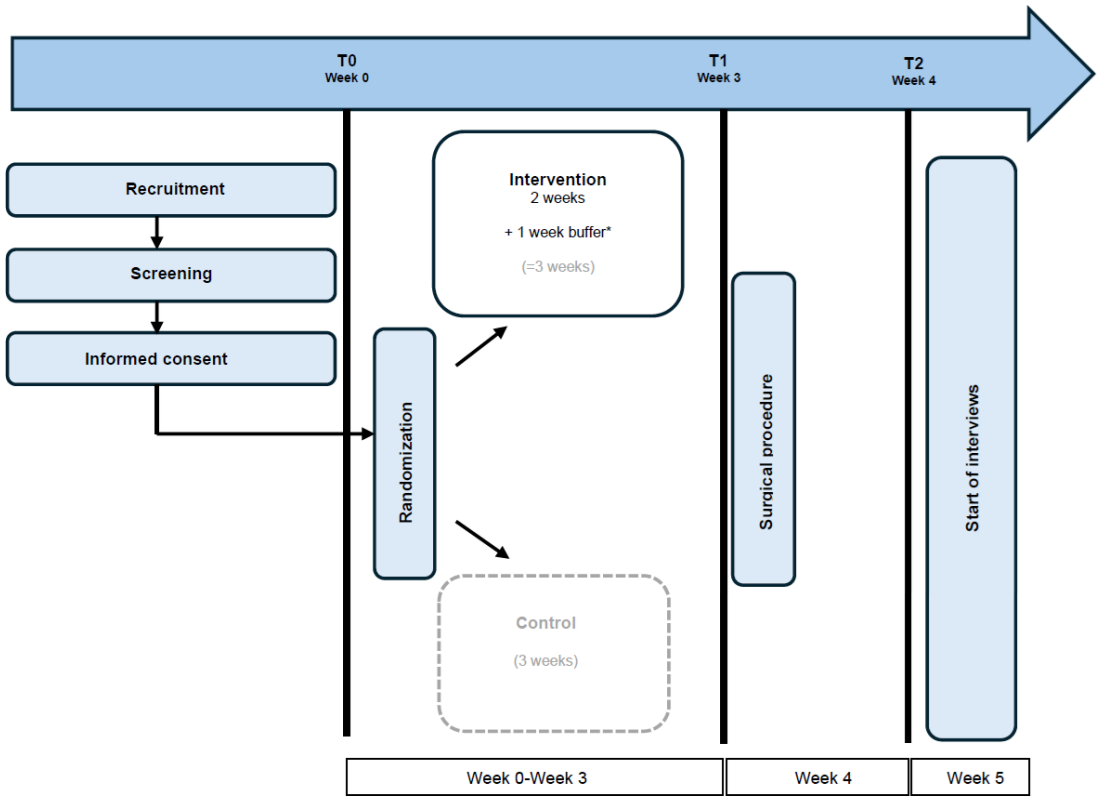
Interested individuals undergo a screening process to determine eligibility. Eligible participants are aged 18 to 65 years, have already been scheduled to undergo a dental operation at the participating dental clinic or the 2 private dental practices at least 4 weeks away from the point of screening, and are willing to participate in the study. Additionally, eligible participants own a smartphone, are willing to use the app, and are willing to complete a survey at 3 different time points. Lastly, eligible participants are able to provide informed consent and can read and write fluently in German. Exclusion criteria include self-reported psychiatric illnesses, alcohol and/or other substance use disorders, cognitive limitations, insufficient ability to read and write in German, engagement in meditation and/or relaxation

practices within the past 8 weeks, and inability to access the App Store or Google Play to download the app. Lastly, individuals in need of an emergency dental operation are excluded. Additional inclusion criteria apply when selecting participants for the semistructured interviews. To participate in an interview, participants must have been randomized to the intervention group, must have completed the intervention, must have completed both surveys up to this point (T0 and T1), must have expressed interest at T1 in being contacted about participating in an interview, and must have consented to participate in the interview. Exclusion criteria include being randomized to the control group, not completing the intervention or both surveys up to that point (T0 and T1), declining to be contacted for an interview, and not signing the informed consent form.

Study Procedure

Please see Figure 1 for a depiction of the study timeline.

Figure 1. Study timeline. *One additional week serves as a buffer, giving participants time to download the app after receiving the code and allowing time for a T1 survey reminder email to be sent and read, in case the initial survey invitation is missed.



Recruitment

Recruitment for the RCT started in April 2026 and will continue until we reach a sample size of 100. Recruitment takes place at a participating dental clinic and 2 participating private dental practices. Dentists and clinic staff inform patients who are scheduled to undergo an operative dental procedure about the study and provide them with a flyer containing a study description and relevant contact information.

Screening

Interested individuals are asked to contact the researchers via email. Individuals who email the study staff to indicate their interest receive an email containing an explanation of the purpose of the screening survey, data protection information, and an informed consent form for the screening survey only. Individuals who complete the screening survey can check a box labeled “I consent,” indicating that they wish to submit their responses to the researchers.

Randomization

Participants who have been deemed eligible after screening and who have completed the T0 survey are randomized to either the intervention group or the control group. To avoid unequal group sizes, permuted block randomization is used. Participants are randomly allocated to either the intervention or the control group using a 1:1 ratio. The randomization sequence was generated by a research team member not involved in recruitment, data collection, or data analysis. The randomization sequence was conducted using the online randomization website Sealed Envelope [40], with a block size of 4. Allocation will occur only after T0 has been completed; thus, group assignment will remain concealed until a participant has been enrolled.

Blinding

Due to the nature of this trial, neither the investigators nor the participants have been blinded. Outcomes will be assessed using self-reported measures, and no separate

blinded researcher will be involved in assessing the outcomes. Statistical analyses will also be conducted unblinded.

Sample Size

Our sample size was calculated a priori using G*Power (version 3.1.9.7; Heinrich Heine University Düsseldorf) for a planned analysis of covariance to detect between-group differences in Modified Dental Anxiety Scale (MDAS) at T1, controlling for T0 MDAS scores. We assumed a moderate effect size (Cohen f=0.30). Accounting for one covariate (MDAS scores at T0) and 2 groups, the α level was set at .05; power was set at 0.80, resulting in a required sample size of 90 participants. Accounting for attrition, 50 participants per group (total n=100) will be recruited.

Intervention

Once randomized, participants are sent an email containing information on how to install the app on their smartphone and how to enter the code to access the app-based content. The app features over 2000 content items in the form of courses and individual units related to mindfulness and meditation [41], and has been previously investigated, with findings highlighting improvements across several health-related outcomes [42]. When receiving the access code by email, participants are informed that the modules titled "Basics" and "Dealing with Anxiety" are recommended, but that they are welcome to explore all additional content as well. Additionally, participants are informed that they should use the app daily and complete all recommended modules. The app-based content is informed by established mindfulness training programs [43]. Throughout the duration of the present RCT, the app developers do not anticipate any revisions except for routine fixes of minor bugs.

When opening the app, participants can access an introductory meditation course that includes 7 modules addressing mindfulness and stress management. Another 7-module meditation course focuses on anxiety management. Available meditation exercises consist of recordings lasting between 9 and 15 minutes. The intervention group is advised to practice meditation daily by completing at least one meditation practice per day for the 2-week duration of the study. Importantly, although the app includes additional relaxation exercises, including progressive muscle relaxation, breathing exercises, and visualization exercises, and also features cognitive behavioral therapy–based stress management techniques, the recommendations made to participants as part of the present study include only meditation exercises. The app features some gaming elements, allowing individuals to track their progress, reach milestones, and earn medals. When activated by the user, push notifications and motivational messages remind users to use the app. The number of modules completed and the number of minutes spent using the app are automatically tracked via the app and recorded in each user's profile. Researchers are not able to access users' app use data.

For participants who only participate in the RCT but opt not to partake in the interviews or are not invited to the interview (ie, participants randomized to the control group), the study timeline spans 4 weeks. Throughout the duration of the RCT, participants are asked to respond to a total of 3 online surveys, administered at T0 (baseline survey), T1 (3 weeks postbaseline), and T2 (4 weeks postbaseline). The link to each survey is sent to the email addresses provided by the participants; 2 additional reminders will be emailed to participants who do not complete the survey. Personalized links are created via LimeSurvey to ensure that participant data can be matched across the 3 time points.

Data collection will occur at the same 3 time points for participants in the intervention group and participants in the control group. T0 will mark the beginning of week 1. After completing T0, participants in the intervention group will receive access to the app, whereas participants in the control group will not receive access to the app at this time. Upon receiving the access code, participants in the intervention group are asked to use the app for a total duration of 2 weeks. However, 2 reasons have led to the addition of a third week between T0 and T1. First, participants receive the download code via email and may not be able to access their email account, retrieve the code, and download and activate the app within the same day. Second, not all participants may complete T1 immediately upon receiving the email but may instead need a reminder email. In order to account for delays resulting from the aforementioned circumstances and still allow sufficient time to use the app for 14 consecutive days, we have added one additional week as a buffer, resulting in a 3-week period between T0 and T1. Therefore, T1 takes place 3 weeks after T0, after the 14-day intervention period has been completed but prior to the scheduled dental operation. T2 will take place 1 week after the operation. The control group will receive treatment as usual in order to compare the effects of the intervention to routine care received by patients awaiting dental surgery. At the end of the 4-week study period, participants randomized to the control group will be granted access to the app as well.

Interviews

During T1, participants who were randomized to the intervention group will be asked whether they would like to be contacted to schedule an interview. If participants agree to be contacted, they will receive an invitation via email. Interview appointments will be scheduled starting 1 week postoperation. Prior to the start of each interview, informed consent will be obtained electronically. A total of 15 to 20 semistructured interviews will be conducted. We will use convenience sampling within our participant sample to recruit interviewees by inviting all individuals who meet the previously described inclusion criteria. Interviews will continue until thematic saturation is reached. Prior to conducting the first interview, the interviewer will receive training. The training will focus on covering the interview guide, the use of open-ended interview questions, and nondirective prompts. Additionally, procedures for recording, documentation, and taking of field notes will be discussed as part of the training. By the time of the interview, participants will have completed the intervention and undergone a dental operation at least 1 week prior. After an interview appointment has been scheduled, participants who have provided

informed consent to participate in the interview will meet with the trained interviewer via Zoom. The semistructured interviews will be conducted and recorded via Zoom. Each interview will take approximately 45 minutes. Using an interview guide, we will ask open-ended questions, supplemented by nondirective prompts when applicable, to allow participants to describe their perceptions and experiences with the intervention.

Outcomes

For information on which measures were used at T0, T1, and T2, please see Table 1. All outcomes will be assessed using online surveys.

Table 1. Measures used at T0 (baseline week), T1 (3 weeks postbaseline), and T2 (4 weeks postbaseline).

Questionnaire	Group					
	Intervention group			Control group		
	T0	T1	T2	T0	T1	T2
Demographics	✓			✓		
GAD-7[a]	✓	✓	✓	✓	✓	✓
MDAS[b]	✓	✓	✓	✓	✓	✓
PANAS[c]	✓	✓	✓	✓	✓	✓
APAIS[d]	✓	✓		✓	✓	
PSS[e]	✓	✓	✓	✓	✓	✓
FMI[f]	✓	✓	✓	✓	✓	✓
App usage		✓				
Subjective evaluation and side effects		✓				
Pain intensity			✓			✓

[a]GAD-7: Generalized Anxiety Disorder Scale-7.
[b]MDAS: Modified Dental Anxiety Scale.
[c]PANAS: Positive and Negative Affect Schedule.
[d]APAIS: Amsterdam Preoperative Anxiety and Information Scale.
[e]PSS: Perceived Stress Scale.
[f]FMI: Freiburg Mindfulness Inventory.

Sociodemographic Items

Sociodemographic variables include age, gender (man, woman, or diverse), education, relationship status, hours of paid work per week, children living at home (no or yes), current enrollment in another health promotion course (no or yes), and previous meditation experience (no or yes).

Primary Outcome

The primary outcome of the present study is postintervention dental anxiety at T1, assessed using the validated German version of the MDAS [44]. The MDAS consists of 5 items, with response categories ranging from 1 (not anxious) to 5 (extremely anxious), with higher scores indicating greater dental anxiety.

Secondary Outcomes

Secondary outcomes include changes in scores relative to baseline at T1 and T2. General anxiety is assessed using the validated German version of the Generalized Anxiety Disorder Scale-7 (GAD-7) [45]. The GAD-7 consists of 7 items, with response options ranging from 0 (not at all) to 3 (nearly every day), with higher scores reflecting greater symptom severity. Perceived stress is assessed using the validated German version of the 10-item Perceived Stress Scale (PSS) [46], with response options ranging from 0 (never) to 4 (very often). Greater scores reflect greater perceived stress. Preoperative anxiety and information requirements will be measured using the validated German version of the Amsterdam Preoperative Anxiety and Information Scale (APAIS) [42], with 4 of the 6 items assessing preoperative anxiety and the remaining 2 items assessing patients' need for information about the surgical procedure, and greater scores reflecting greater preoperative anxiety or greater need for information. Postoperative pain will be assessed using a rating scale ranging from 0 to 10. Mindfulness is measured using the 14-item Freiburg Mindfulness Inventory (FMI) [47], with response options ranging from 1 (rarely) to 4 (almost always) and higher scores reflecting greater levels of mindfulness. Additionally, positive and negative affect will be measured using the validated German version of the 20-item Positive and Negative Affect Schedule (PANAS) [48], with answer options ranging from 1 (not at all) to 5 (very much), with higher scores reflecting greater positive or negative affect.

As part of the T1 online survey, participants randomized to the intervention group will also be asked about their app use. To determine which modules have been completed, participants are prompted to access their user profile within the app and list the number and the names of the completed modules listed there. We will assess the number of days on which the app was used during the intervention period by asking participants how often they used the app, with response options ranging from never to daily. The number

of days per week on which the app was used can range from 0 to 7. Participants will be categorized as adherent if they report having used the app daily and self-report having completed all of the recommended modules. Participants who met these requirements and report having engaged with additional app content beyond the recommended modules will also be considered adherent. Individuals who report using the app daily but have not completed the recommended modules will not be considered adherent. Also, individuals who report having completed all recommended modules but do not report daily use of the app will not be considered adherent.

The dose of intervention exposure will be assessed by prompting participants taking the T1 survey to access their user profile within the app and report the total number of minutes of app usage listed there.

Participants who indicate that they have never used the app will be asked to select a reason for never using it. Response options include, but are not limited to, a lack of time, interest, relevance, perceived helpfulness, and interest in app-based mindfulness practice in general. A text option is also included. Participants are also asked to report the time of day during which they typically used the app (in the morning, midday, in the afternoon, in the evening, or before bed).

Acceptability will be measured by asking participants whether and to what degree they agree with a series of statements by selecting one of the answer options ranging from "not at all" to "completely agree." Participants are asked to rate how satisfied they are with the app; whether and to what degree the app has met their expectations; whether and to what degree they perceive changes in mindfulness to have occurred; how effective they perceive the app contents to be in managing anxiety and stress; and whether they plan to continue using the app after the study has ended. Lastly, participants are asked whether they have experienced any adverse events while engaging in app-based mindfulness training and, if so, which adverse effects occurred.

Semistructured Interviews

The interview guide covers 4 domains. First, participants will be asked about their previous experiences with dental procedures, including dental operations, if applicable. Questions will address the extent to which patients had previously experienced dental anxiety prior to dental procedures, whether their experiences of stress and anxiety prior to past dental operations and/or nonoperative dental procedures had differed from those before their most recent dental operation, and how they had previously coped with perceived stress and anxiety. Second, we will inquire about participants' previous experiences with meditation and stress management and ask about their beliefs and perceptions regarding the use of meditation to cope with stressful life events (eg, perceived helpfulness of meditation when experiencing anxiety and stress). Third, we will inquire about preoperation patterns of app use, including whether participants used the app regularly throughout the entire intervention period or predominantly used the app at a specific time during the intervention (eg, only at the beginning of the intervention, mostly right before the operation, etc). Fourth, we will inquire about whether participants believed this specific intervention was helpful in preparing for their most recent dental operation and, if so, how they perceived their preoperation experience to have differed due to the intervention. We will also inquire about which content and modules participants found especially helpful and whether participants would recommend this intervention to other dental patients preparing for dental surgery.

Analyses

Overview

Statistical analyses will be conducted using SPSS Statistics (version 31; IBM Corp). Data cleaning and testing for outliers will be completed prior to conducting any analyses. For all tests, the significance level will be set at α=.05. Patterns of missing data will be investigated using Little's test of missing completely at random. If applicable, multiple imputation will be used to preserve statistical power. Prior to conducting analyses, the assumptions of normality, homogeneity of variances, and sphericity will be assessed. In cases of sphericity violation, as indicated by Mauchly's test results, the Huynh-Feldt corrections will be applied for epsilon >0.75, whereas Greenhouse-Geisser corrections will be applied for epsilon <0.75 [49]. Effect sizes will be calculated using Cohen *d* for independent-group *t* tests, and using Cohen *f* for ANOVA results.

For continuous variables, descriptive statistics will be used to calculate means, SDs, minimums, and maximums. For categorical variables, frequencies will be analyzed. Bivariate analyses, including chi-square tests for categorical variables and independent-samples 1-tailed *t* tests, will be conducted to determine whether any variables vary across groups. We will control for any variables that are determined to vary at T0. If applicable, nonparametric tests will be used.

Primary Analysis

Our primary outcome, dental anxiety at T1, will be assessed using an analysis of covariance. MDAS scores at T1 will be entered into the model as the dependent variable, treatment group as the independent variable, and MDAS scores at T0 as the covariate.

Secondary Analyses

The secondary analyses will be conducted using a 2 × 3 mixed ANOVA, with group (intervention vs control) as the between-subjects factor and time of data collection (T0, T1, and T2) as the within-subjects factor. For our secondary analysis, we will investigate the main effect of time, including changes over time in general anxiety, dental anxiety, preoperative anxiety, mindfulness, and positive and negative affect regardless of randomization status. Additionally, secondary analyses will involve the main effects of group, including the differences between the intervention and control groups regardless of time points. Lastly, the interaction effect of time and group across all secondary outcomes will be assessed to investigate whether changes over time differ by group.

Among individuals randomized to the intervention group, linear regression analysis will be used to investigate whether total app use time (in minutes) is associated with postintervention outcome scores after controlling for baseline scores.

Intention-to-Treat

All randomized participants will be included in the primary analysis regardless of adherence; that is, regardless of the number of days on which they report having used the app or which modules they report having completed. Missing data will be addressed using multiple imputation to preserve statistical power.

Per-Protocol Analysis

Additionally, per-protocol (PP) analyses will be performed, including only participants who completed the intervention in accordance with the protocol. Participants who report having used the app daily and completed all recommended modules will be included in the PP analyses. Individuals who report having used the app daily and having completed all recommended modules may also report having used additional app content and still be considered adherent; that is, data derived from individuals who have been deemed adherent per the aforementioned criteria will still be used in our PP analyses even if additional modules and/or exercises have been completed.

Qualitative Data Analysis

Recordings will be transcribed verbatim. Our qualitative analyses will be performed according to Kuckartz [50]. Coders will be trained in qualitative data analysis according to Kuckartz [50]. Prior to coding the first interview, coders will be familiar with the interview guide, inductive coding, and the use of MAXQDA (Verbi GmbH), the software that will be used to conduct qualitative data analysis.

Despite using an interview guide, we will use an inductive approach to category development, with overarching themes derived from the interview transcripts using systematic coding; no categories will be developed prior to the start of transcript review begins [50]. Coding will begin once the first interviews have been transcribed. AS and CH will code the transcripts independently and compare their findings. Discrepancies will be discussed and resolved. If AS and CH are unable to agree, a third coder will be included to resolve differences.

Once coding of the initial transcripts has been completed, the emergence of new codes in subsequent interviews to determine when data saturation has been achieved. Data saturation will be considered achieved when subsequent interviews no longer yield novel codes or when existing categories have been developed to the point that the range of participants' experiences is sufficiently reflected [51].

Trial Monitoring

No formal trial monitoring protocol has been established for this trial. Given the low-risk nature of the intervention and the short intervention period, trial procedures and data quality will be overseen by the study investigators.

Results

For this study, we selected a mixed methods approach to derive complementary methodological perspectives regarding the effects of the intervention on the outcomes of interest. Methodological independence of the 2 approaches will be maintained while conducting the study [52]. The quantitative and qualitative findings will be integrated following their separate analyses to allow for triangulation and identify potential areas of convergence and divergence [52]; we also anticipate that our interview data will expand on our quantitative findings by providing contextual information about participants' experiences, for example, by improving our understanding of their expectations prior to starting the intervention and allowing comparisons between their past experiences of dental anxiety and their most recent experiences while using the intervention. The first screening was completed on April 6, 2026. To date, 19 participants have completed the study, and 4 interviews have been completed. Study completion is projected for August 2027, with publication of the findings anticipated in December 2027. The study has not received any funding.

Discussion

Expected Results

Patients receiving the app-based mindfulness training are expected to show significantly greater reductions in dental anxiety relative to baseline when compared to the control group. Meditation practice has been linked to reduced rumination and worry, both of which play an active role in the facilitation and maintenance of anxiety symptoms [53,54]. Individuals undergoing dental surgery have been found to experience states of preoccupation with the upcoming procedure prior to the operation [55,56]; however, mindfulness meditation has been suggested to improve emotional regulation and attentional control [35,56], which could help patients avoid ruminative thoughts, interrupting the cycle of unhelpful cognitive patterns, and subsequently alleviate anxiety. Previous findings have highlighted mindfulness meditation as a helpful tool for reducing preoperative anxiety among individuals undergoing dental surgery [32]. Additionally, perceived stress is likely to decrease among participants receiving the intervention, as mindfulness meditation has been linked to reduced stress [35]. Previous literature suggests that one's susceptibility to experiencing anxiety as well as the intensity of one's anxiety symptoms is influenced by perceived stress [36]; thus, an anticipated reduction in perceived stress may contribute to the hypothesized effects of the intervention on anxiety. As mindfulness has been linked to positive emotional states [57,58], we also expect positive affect to increase as a result of the intervention. Previous literature suggests that increases in positive affect can, in turn, predict positive cognition and vice versa [58]; additionally, positive affect may serve as a protective factor against stress

responses and stress-related effects [59]. Although research has investigated the effects of meditation on pain [60], its effectiveness has not yet been established [61]. However, despite not being developed specifically to address pain [61], mindfulness may exert beneficial effects on pain perception, perhaps via pathways of attention regulation [35], which has been suggested to modulate individuals' pain responses [62]. Importantly, our intervention consists of a general rather than an indication-specific mindfulness-based training program. Although no dental anxiety-specific content is featured in the app, the approach of choosing a readily available, general mindfulness training is consistent with established approaches in the mindfulness literature; for example, Mindfulness-Based Stress Reduction (MBSR), a standardized mindfulness program, can still produce condition-specific improvements when no condition-specific content is included, for example, in patients with lower back pain [63].

Strengths and Limitations

The present study uses a randomized controlled design and validated instruments to assess primary and secondary outcomes and investigate the effect of app-based mindfulness training on dental anxiety.

Given the global prevalence of dental anxiety [3] and its detrimental effects on oral health-related quality of life and personal dental care [64], resources are needed to alleviate the burden on patients and dentists [20]. Additionally, by incorporating both intention-to-treat (ITT) and PP analyses, findings derived from the present RCT will reflect both real-life scenarios, in which noncompliance and deviations from the treatment protocol occur, as well as the effects of adherence to treatment [65]. By conducting both ITT and PP analyses and contrasting the findings, we will allow for a complete investigation of potential treatment effects across different scenarios [66]. Findings on whether recommended app-based mindfulness training can decrease dental anxiety among patients scheduled to undergo surgery, and/or whether improvements can only be expected among adherent participants, may help inform future recommendations for patients experiencing dental anxiety prior to surgical procedures. Therefore, obtaining findings on both practical effectiveness and the potential maximum benefits associated with app-based mindfulness training allows for interpretations regarding clinical relevance.

Limitations include our choice of data collection time points. T1 takes place after the intervention but prior to the surgery. An individual who completes the T1 survey 4 days prior to their surgery may perceive the scheduled appointment as less of an immediate threat relative to someone who responds to the survey while sitting in the waiting room prior to being called on by the dentist just minutes before undergoing their operation. Even though we are able to assess the number of days left until each participant's operation relative to the date they complete the survey, we cannot account for any changes in anxiety or stress occurring immediately prior to the operation. Another limitation is that we cannot control the extent to which individuals use the app, if at all, and that the app is assessed only via self-report. Previous research suggests that self-reported adherence to digital interventions differs from objectively measured adherence, with participants overreporting adherence [67]. Therefore, PP analyses may not accurately distinguish among levels of intervention use, requiring caution when interpreting findings on dose-response relationships, adherence, and treatment effects. Future research should include objective app usage data to allow for a more accurate assessment of intervention use.

Moreover, although mindfulness exercises are included in the 7mind app, we cannot control whether individuals indeed use the recommended mindfulness practice modules or whether they prefer to use other app-based content, including categories titled "Knowledge," which feature educational content on topics such as sleep, or "Impulses," which include brief self-reflections. Also, dental anxiety is likely a complex construct, influenced by additional factors not assessed by our study; for example, previous research findings suggest that dental anxiety may be linked to patients' personality traits, with patients high in neuroticism experiencing greater dental anxiety [68], while other findings suggest that even patients' perceptions of their dentist's personality traits can influence dental anxiety [8]. By not including (perceived) personality traits or other relevant constructs, findings will not shed light on factors potentially driving anticipated effects of app use on dental anxiety. Lastly, we acknowledge that selecting a general, rather than a condition-specific mindfulness training differs from interventions specifically targeting individuals living with dental anxiety and may not directly address dental-specific fears, dental treatment-related cognitions, or situational triggers commonly experienced in dental settings. Incorporating dental anxiety-specific elements into our intervention could possibly lead to additional benefits for individuals with dental anxiety.

Conclusions

Dental anxiety can lead to avoidance behavior, which in turn results in the worsening of dental conditions that may subsequently need to be addressed using more invasive and more painful treatment approaches [10,11]. Although mindfulness-based approaches have previously been highlighted as potentially effective tools for managing anxiety [29,30], evidence regarding their application in dental practice remains sparse. The RCT aims to evaluate the effect of an app-based mindfulness training on dental anxiety levels among adult dental patients scheduled for dental surgery. Assessing changes in dental anxiety and other relevant outcomes over time may inform future research focused on scalable approaches to improving patient experience and anxiety management in routine dental practice. Using both ITT and PP analyses, we anticipate identifying treatment effects under real-world conditions as well as under optimal patient adherence, thus providing insight into its applicability and feasibility when implemented into dental care.

Generative AI Use

No generative AI tools were used at any stage in the preparation of this manuscript.

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Data Availability

Deidentified data and syntax will be made available upon reasonable request.
The findings of the trial will be published in peer-reviewed journals.

Conflicts of Interest

None declared.

Checklist 1

SPIRIT checklist.
[PDF File (Adobe File), 278 KB-Checklist 1]

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Abbreviations

APAIS: Amsterdam Preoperative Anxiety and Information Scale
CONSORT: Consolidated Standards of Reporting Trials
DRKS: German Clinical Trial Registry
FMI: Freiburg Mindfulness Inventory
GAD-7: Generalized Anxiety Disorder Scale-7
IRB: Institutional Review Board
ITT: intention-to-treat
MBSR: Mindfulness-Based Stress Reduction
MDAS: Modified Dental Anxiety Scale
PANAS: Positive and Negative Affect Schedule
PP: per-protocol
PSS: Perceived Stress Scale
RCT: randomized controlled trial
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

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