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Dentist-administered cognitive behavioural therapy versus four habits/midazolam: An RCT study of dental anxiety treatment in primary dental care

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Abstract

The study aimed to test the effectiveness of cognitive behavioural therapy (CBT) administered by a general dental practitioner (GDP) in a general dental practice. In a two-arm parallel randomised controlled trial, the experimental group received a short dentist-administered CBT-intervention (D-CBT). A best-practice control group (FHM) received dental treatment during sedation with midazolam combined with an evidence-based communication model (The Four Habits Model). Ninety-six patients with self-reported dental anxiety were allocated to the treatment arms at a 1:1 ratio. Modified Dental Anxiety Scale (MDAS) scores spanned from 12 to 25, and 82 patients (85%) had a score of 19 or more, indicating severe dental anxiety. In both treatment arms, scores on MDAS and Index of Dental Anxiety and Fear (IDAF-4C) decreased significantly, but no differences were found between treatment arms. Mean reductions were: MDAS scores: −6.6 (SD = 0.5); IDAF-4C scores: −1.0 (SD = 1.1). In conclusion, local GDPs in general dental practices with proper competence have the ability for early detection of dental anxiety and, with the use of a manual-based D-CBT or FHM treatment, GDPs could offer efficient first-line treatment suitable for dental anxiety of varying severities.

KEYWORDS
post-traumatic, quality of life, stress disorders

INTRODUCTION

Dental anxiety is regarded as a public health problem [1], being reported by one in every six adults [2–6]. It can be estimated that, globally, 1%–6% of the adult population exhibits extreme dental fear [2,6,7]. Postponement or avoidance of dental treatment is often seen in patients with dental anxiety [8], and this is a major risk factor for poor oral health [9]

and reduced oral health-related quality of life [10]. Effective dental anxiety treatment has been associated with increased quality of life [11].

Berggren and Carlsson [12] described a vicious circle in which dental anxiety leads to the avoidance of dental treatment, resulting in deterioration of oral health. Visibly decayed teeth and the reduced ability to cope with dental treatment may lead to feelings of shame, guilt, and embarrassment, all

of which (again) increase anxiety [13–16]. Early detection and treatment of dental anxiety can facilitate early escape from this cycle. The resulting decrease in dental anxiety may improve both oral health and oral health-related quality of life [9,10].

Patients with dental anxiety are often treated with medications, commonly benzodiazepines, to help them calm down during treatment [17–19]. In European up-to-date dental education and practice, sedation is implemented as a combination treatment that integrates proper patient-centred communication [20]. The Four Habits model is an evidence-based communication model developed by the US Health Maintenance Organization Kaiser Permanente [21,22]. The model has produced favourable outcomes in Norwegian hospitals [23]. It has been adapted to dentistry and is today an essential part of the dental curriculum at the University of Oslo [24,25]. This model comprises four main elements, for didactic reasons called habits, which involve the communication skills and behaviours of the health professional. First habit: *Invest in the beginning* of the encounter to create a rapport and set an agenda acceptable to the patient. Second habit: *Elicit the patient's perspective* to attain a better understanding of the individual patient's concerns and treatment needs. Third habit: *Demonstrate empathy* to acknowledge and legitimize the patient's feelings and reactions to the treatment situation, as well as offering emotional support. Fourth habit: *Invest in the end* to provide sufficient information and adequate closure to ensure that the patient has an updated understanding, no unanswered questions, and is prepared for the next step in the treatment plan (e.g., treatment plan for the next session).

Psychological interventions represent a well-documented treatment approach when the aim is to achieve lasting reduction of dental anxiety. In a meta-analysis from 2004 conducted by Kvale et al. [26] and including 38 randomized controlled clinical trials, behavioural interventions proved effective in the treatment of dental anxiety. Wide Boman et al. [27] concluded the same in their review from 2013 based on 7 randomized controlled clinical trials (RCTs). CBT is the best documented psychological treatment method for anxiety disorders, and studies have also shown its usefulness in relation to dental anxiety. In 2002, Kvale et al. [28] documented the effect of a CBT intervention on dental anxiety in 70 patients, and in an RCT from 2008 comparing one-session ($n = 20$) and five-session ($n = 20$) CBT-treatment, Haukebø et al. [29] found that both CBT approaches were effective in reducing dental anxiety.

In a Norwegian publicly financed programme, specialist teams comprised of psychologists and dentists provide CBT treatment for dental anxiety followed by necessary dental treatment to individuals exposed to torture, abuse, or diagnosed odontophobia. The treatments are free of charge for the patient. Unfortunately, for many patients, travel distances to the nearest team are substantial and waiting lists are longer than the eight weeks indicated in national guidelines. Moreover, patients with strong dental anxiety who do not qualify for the diagnosis of odontophobia are not included in this programme.

In a systematic review, Halonen et al. [30] found an increased risk for other psychiatric disorders in patients with dental anxiety. In torture survivors, symptoms of post-traumatic stress disorder (PTSD) have been found to be associated with the presence of dental anxiety [31]. Still, it remains unclear whether the presence of psychiatric illnesses, such as PTSD, should have implications for the treatment offered to dental anxiety patients. Kvale et al. [28] found no differences in the treatment effect between patients with a simple dental phobia and patients with multiple diagnoses.

It has been suggested by Hare et al. [32] that severe cases of dental anxiety should be referred for CBT treatment, while milder cases should be managed in general dental practice. However, most studies on dental anxiety treatment are based on interdisciplinary treatment performed in special clinics [27]. In 2000, Willumsen and Vassend [33] tested a 10-session CBT intervention administered by a dentist alone in a university clinic and saw clinically significant favourable effects that persisted over a five-year period. Despite these promising findings on dentist-administered dental anxiety treatment, few, if any, systematic studies have examined the effect of dental anxiety treatment within a general dental practice. The need for such scientific assessments has been pointed out in reviews by both Armfield and Heaton [34] and De Jongh et al. [35]

In Norway, like in many other countries, dental treatment is most frequently performed by general dental practitioners (GDPs) in general dental practices. Establishing a reliable method to reduce dental anxiety in this setting would improve access to treatment both in terms of distances and waiting time. This could be an efficient first-line treatment suitable for dental anxiety of varying severities. Early treatment may allow for early escape of the vicious circle described by Berggren and Carlsson [12], thereby evading negative health impacts. This creates the potential for economic savings both at a societal and individual level, and it provides an opportunity to prevent individual suffering due to untreated oral diseases. Accordingly, the present study aimed to develop a psychological treatment method for dental anxiety to be administered by a GDP in a general dental practice: a dentist-administered cognitive therapy (D-CBT). The study aimed to test the treatment effect of D-CBT by comparing it with a best-practice control condition. Dental treatment in accordance with 'The Four Habits' model combined with premedication with midazolam ('Four Habits'/

midazolam [FHM]) was chosen as an adequate and suitable best-practice control.

The study tested the three hypotheses that: (i) D-CBT treatment is associated with a greater reduction in dental anxiety than FHM treatment; (ii) both D-CBT and FHM treatments will produce a reduction in dental anxiety; and (iii) treatment of dental anxiety is associated with a lower score of oral impacts on daily performances and improved life satisfaction.

MATERIAL AND METHODS

Design and participants

This two-arm, parallel-group RCT was carried out in a general dental practice in Mandal, a typical small town in a rural area of Norway located about 40 km away from the district capital. The trial was approved by the Norwegian Regional Committee for Medical and Health Research Ethics (REC) with ID number 2017/97, and it is registered in www.clinicaltrials.gov with identifier: NCT03293342.

A total of 96 patients were admitted between September 2017 and March 2020. Information about the trial was spread through advertisements in local newspapers and via social media. Inclusion criteria were: (i) self-reported dental anxiety at a level of severity that affected the patient's self-perceived ability to go through with dental treatment (no lower limit of measured dental anxiety), and (ii) ability to communicate fluently in Norwegian.

Recruitment was conducted by a research assistant. In a baseline session, the research assistant provided more detailed information about the trial and the public treatment alternative in interdisciplinary teams. Thereafter, the patients signed an informed consent form, completed the questionnaires, and were randomly allocated to either the D-CBT ($n = 48$) or FHM ($n = 48$) group with a 1:1 ratio. Figure 1 presents a flow chart of the study procedure.

All patients were treated by the same dentist (MSH) in accordance with predefined manuals. Patients were offered four to five treatment sessions free of cost, with a duration ranging from 45–105 min. The total treatment duration was the same in both groups: approximately 300 min. Dental treatment was included for all patients in the FHM-group that were able to go through with it; the treatment would commonly include professional tooth cleaning, local anaesthesia, and 1–4 composite fillings. In the D-CBT group, the amount of dental treatment depended on the progression of therapy and was less extensive, seldom exceeding 1 composite filling. Dental treatment offered as part of the anxiety treatment was free of charge, while the following dental treatment was (partly or in full) privately financed by the patient.

All sessions were videotaped. The second author and last author evaluated a random selection of videotapes together and assessed whether the treatments adhered to the manual. The manual was condensed into a checklist, and it was verified that all the themes on the list were included in the treatment in a relevant manner.

Treatment methods

The development of the manual for Dentist-administered Cognitive Behavioural Therapy (D-CBT) was based on literature reviews and clinical experience. The 3 main researchers produced a first manual draft describing the intervention in detail. The manual was then evaluated by two professors of psychology and by an expert group consisting of three clinical psychologists and three dentists with a high level of clinical experience. Based on the corresponding feedback, the final D-CBT manual was developed. A pilot study including 10 patients with dental anxiety was conducted. Each patient received 5 manualized 60-min D-CBT consultations.

The final D-CBT manual is comprised of four main components:

A Building a good relationship with the patient
B Psychoeducation in anxiety symptoms
C Exploration of individual symptoms of anxiety
D Exposure to the frightening stimuli

The D-CBT is shorter but otherwise comparable to the CBT treatment offered in the study by Willumsen and Vassend [33]. The D-CBT manual can be found as an Appendix in the Supporting Information section of this article and the treatment method is further described in Table 1.

The best-practice control condition was dental treatment with midazolam sedation while following the principles of the Four Habits model (FHM). Approximately 300 min were spent with the patient over four different appointments, one to plan treatment, two more for dental treatment while premedicated, and a last one for finalizing and planning further treatment. The Four Habits Model is outlined in Table 2.

The methods utilize contrasting principles. These principles and the implications of the two treatments are presented in Table 3.

Background measures

Information on patients' age, sex, number of years since last dental treatment, and experience of a traumatic incident was collected at baseline.
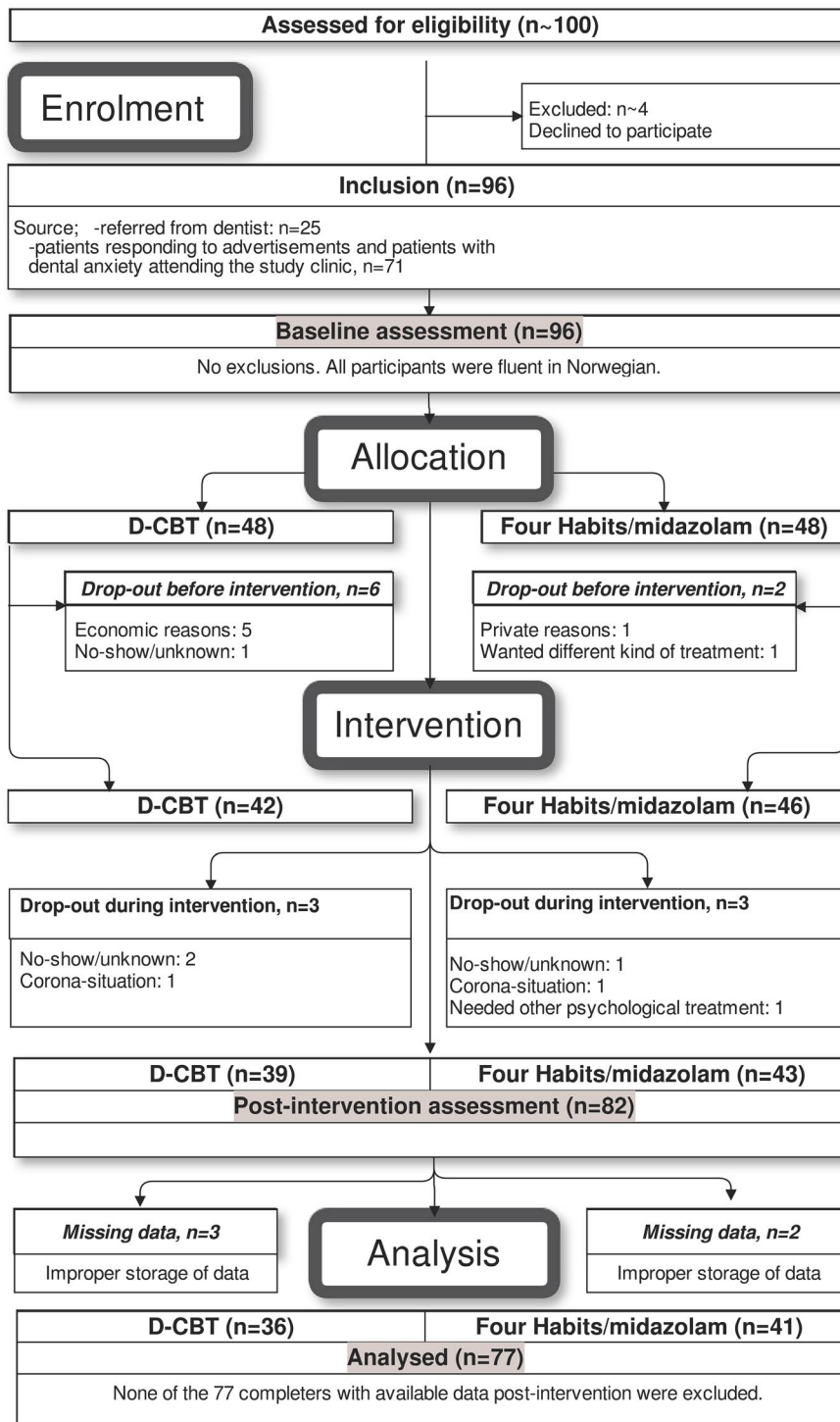
Assessed for eligibility (n~100)

Enrolment

Excluded: n~4
Declined to participate

Inclusion (n=96)

Source; -referred from dentist: n=25
-patients responding to advertisements and patients with
dental anxiety attending the study clinic, n=71

Baseline assessment (n=96)

No exclusions. All participants were fluent in Norwegian.

Allocation

D-CBT (n=48)

Drop-out before intervention, n=6

Economic reasons: 5
No-show/unknown: 1

Four Habits/midazolam (n=48)

Drop-out before intervention, n=2

Private reasons: 1
Wanted different kind of treatment: 1

Intervention

D-CBT (n=42)

Four Habits/midazolam (n=46)

Drop-out during intervention, n=3

No-show/unknown: 2
Corona-situation: 1

Drop-out during intervention, n=3

No-show/unknown: 1
Corona-situation: 1
Needed other psychological treatment: 1

D-CBT (n=39) | **Four Habits/midazolam (n=43)**

Post-intervention assessment (n=82)

Missing data, n=3

Improper storage of data

Analysis

Missing data, n=2

Improper storage of data

D-CBT (n=36) | **Four Habits/midazolam (n=41)**

Analysed (n=77)

None of the 77 completers with available data post-intervention were excluded.

FIGURE 1 The diagram shows the flow of the study, including the different stages and a description of dropout and missing data

Outcome measures

All the following measures were recorded at baseline and post intervention.

The Modified Dental Anxiety Scale (MDAS) [36] includes five questions that mention different potentially frightening stimuli in response to which participants report the level of anxiety they experience using a 5-point scale with the following options: 'not anxious', 'slightly anxious', 'fairly anxious', 'very anxious', and 'extremely anxious'. A sum score (range 5–25) of 19 or higher is indicative of extremely high dental anxiety [36–39]. The Cronbach's α of MDAS´s dimensions has been reported to be 0.89 [40], while in this study, it was 0.75. Several studies have findings that confirm its validity as a measure of dental anxiety [38,41].

The Index of Dental Anxiety and Fear (IDAF-4C+) was developed by Armfield in 2010 [42]. The Norwegian translation was done in 2012 by researchers at the University of

TABLE 1 The main elements of the interventions

D-CBT-intervention	FHM-intervention
Semi-structured interview on patient history focused on anxiety.	All consultations are organized according to the "Four Habits" model.
Education about anxiety symptoms and their purpose.	Unstructured interview about individual anxiety.
Exploration of catastrophic thoughts.	Psychoeducation about anxiety symptoms and purpose, when considered necessary.
Cognitive restructuring of catastrophic thoughts.	Stop-signal is introduced and practiced.
Building an individual anxiety hierarchy.	Midazolam is introduced as an excellent alternative to reduce the patient's anxiety symptoms and render him/her able to go through necessary dental treatment.
Explanation of the purpose of gradual exposure with the aid of the anxiety curve and the window of tolerance.	Patient decides which dental treatment needs to be addressed first, although they are encouraged to choose comparably small tasks (to drill a regular sized cavity) to increase chances of a "good start".
Discussing and planning a stepwise exposure to frightening stimuli using the patient´s individual anxiety hierarchy.	A coping plan for further dental treatment is made in collaboration with the patient.
Stepwise exposure while continuously monitoring anxiety level on a 10-point scale.	
Stop-signal is introduced and practiced.	
Rapport-building is explored in each appointment.	
Conclusion of treatment. Check for change in beliefs in catastrophic thoughts.	
A coping plan for further dental treatment is made in collaboration with the patient.	

Abbreviations: D-CBT, Dentist-administered Cognitive Behavioural therapy; FHM, The Four Habits Model combined with midazolam administration.

TABLE 2 The basic elements of the Four Habits Model

HABIT	SKILLS
Invest in the beginning	Create rapport quickly
	Elicit the patient's concerns
	Plan the visit with the patient
Elicit the patient's perspective	Ask for the patient's ideas
	Elicit specific requests
	Explore the impact on the patient's life
Demonstrate empathy	Be open to the patient's emotions
	Make an empathic statement
	Convey empathy nonverbally
Invest in the end	Deliver diagnostic information
	Provide education
	Involve the patient in making decisions
	Complete the visit

Oslo. Two copies were translated from English to Norwegian. Two different people translated the texts back to English. The two resulting documents were thereafter evaluated by the creator of the original version of the index (Jason Armfield), resulting in the version that was used in the present study. It has three modules (IDAF-4C, IDAF-S, and IDAF-P) that can be used separately or in combination [43–45]. In a Scandinavian sample, the fear and stimulus modules show good validity, but there are uncertainties regarding the validity of the phobia module (IDAF-P) [46]. The IDAF-4C—dental anxiety and fear module—is comprised of eight items, with two items each measuring the emotional, behavioural, cognitive, and physiological components of anxiety. The items are scored on a scale from 'disagree' (scored as 1) to 'strongly agree' (scored as 5). It is recommended that a mean of all items be calculated to obtain an overall score (range: 1–5). A cut-off score of >2.50 has been used to indicate potentially moderate to extreme dental fear [2]. The Cronbach's α in a Swedish clinical sample was 0.94 [47]. while in our study, it was 0.71. The stimulus module of the IDAF (IDAF-S) contains 10 items covering a range of stimuli that are reported to cause anxiety in the dental setting. Items are rated on a response scale from 'not at all' [1] to 'very much' [5]. All items are to be analysed individually, and sum scores are not used.

The Oral Impact on Daily Performances (OIDP) instrument measures oral impairment and how it affects physical, social, and physiological performances [48–50]. Through eight questions, it explores how often oral health issues have a negative impact on daily tasks and performances (e.g., brushing teeth, sleeping, smiling). Each question is answered on a 5-point scale assessing the frequency of influence on

TABLE 3 The contrasting principles underpinning the two interventions

	D-CBT	FHM
Focus	Stimuli-Thoughts-Anxiety	Effect of midazolam, relaxation, indifference
Anxiety arousal	Necessary	Unwanted
Level of learning	"Schema shift"	Positive experiences from similar situations
Indication of change	Reduction of catastrophic beliefs	Reduction of fear response
Medium of change	Dialogue and behaviour	Behaviour
Therapist role	Socratic Dialogue Partner	Administering midazolam
Start of regular dental treatment	After three to seven sessions	After one session
Practical implications	None	Fasting, need of companion, reduced functioning for the remaining part of the day
Post graduate training of dentist	Specific courses and supervision	None: undergraduate communication and pharmacological skills are sufficient

Abbreviations: D-CBT, Dentist-administered Cognitive Behavioural therapy; FHM; The Four Habits Model combined with midazolam administration.

daily tasks in each area; the answers range from 'every day' to 'never', which are reverse-scored with 1 for never and 5 for every day. The total score ranges from 5–40, with higher scores indicating a higher negative impact of oral issues on daily life. Good validity and internal consistency have been demonstrated [49,51]. Cronbach´s α in our sample was 0.91.

The Satisfaction with Life Scale (SWLS) is a self-report tool developed by Diener and Diener [52] in 1985. It assesses global life satisfaction and comprises five questions that are scored from 1 to 7. Based on their sum score, respondents are categorised as very highly satisfied, highly satisfied, averagely satisfied, dissatisfied, or extremely dissatisfied. Normative data for SWLS are available for diverse populations [53,54] and, in a representative Norwegian sample, the mean score was found to be 26.2 [55]. Validity is good and a score of the Cronbach's α of the original scale was 0.87 [56], while in our sample, it was 0.91.

To assess possible symptoms of post-traumatic stress, patients were asked if they had ever experienced a traumatic incidence. If their answer was affirmative, the PTSD checklist for DSM-IV (PCL), version PCL-S [57], was used. This is a measure that consists of 17 questions with five possible answers. The total symptom severity score is between 17 to 85. Cut off is suggested to be 30–35 in population screening [57]. Validity and reliability of this test has proven to be acceptable, and it has been supported as a brief screening instrument for PTSD [58].

At the end of the study period, it was registered if the patient wanted to continue treatment with a local general dentist or if they preferred further anxiety and dental treatment in the public system.

Sample size estimation

Sample size was estimated from the DAS values among patients with dental anxiety but without diagnosed odontophobia reported in a Norwegian study conducted by Kvale et al. [28] The mean baseline DAS score was 15.0 (SD = 3.6) and the relevant between-group difference in outcome was considered 20%. Statistical power was set at 80%, with a significance level of 5%. Based on these criteria, the desired sample size was calculated as 24 in each group. Considering a possible 50% rate of drop out/referrals to public teams and adequate power to test the effect of treatment in general practice from a longer time perspective, the study included 96 patients.

Data analysis

Statistical analysis was conducted using the STATA/SE 16.0 statistical software (StataCorp). Visual inspection of variable histograms indicated non-normality for most of the outcomes assessed (Figures S1–S4). Tables of skewness and kurtosis affirmed this (Table S1). Therefore, treatment effects were analysed through non-parametric analyses using the Wilcoxon matched-pairs signed-ranks tests and the Wilcoxon rank-sum test. For binomial data, Pearson's chi-squared test was applied. A significance level of 0.05 was adopted. The data were stored and analysed in anonymised form, only identifiable by project number, at the Services for Sensitive Data at the University of Oslo.

The findings have been reported according to the updated CONSORT 2010 guidelines [59,60].

RESULTS

Out of the one hundred patients that were offered participation, four patients declined, citing one of two reasons: the patient considered the anxiety level to be too low to require treatment, or he/she preferred more economically favourable

treatment in the public system (Figure 1). In total, 96 patients were recruited into the trial, and 82 patients completed treatment. No participants were excluded but five records were lost from the storage facility due to technical difficulties, leaving 77 records available for the completers' analysis (Figure 1).

After examination of a random selection of videotapes from treatment sessions, it was concluded that the items on the checklist for each treatment manual were included in the treatment in a relevant manner in all examined sessions.

As shown in Table 4, there were no statistically significant between-group differences in the distribution of background variables or in the baseline scores of the outcomes considered. Participants' age ranged from 19 to 65 years, while MDAS scores spanned from 12 to 25, and 82 patients (85%) had a score of 19 or more. Among patients with traumatic experiences, 38 (70%) had a PCL-S score of 35 or higher. The number of years since last dental treatment varied substantially: from 0 to 40 years.

The anxiety reduction did not differ between the D-CBT and FHM groups when measured by the MDAS or IDAF (Table 5). Both treatments caused significant and comparable reductions in dental anxiety scores. Following treatment, the proportion of patients with extreme dental anxiety (MDAS score >19) decreased from 86.1% (31/36) to 16.7% (6/36) in the D-CBT group and from 82.9% (34/41) to 19.5% (8/41) in the FHM group.

Scores on all items in IDAF-S decreased significantly during treatment (Table S2). Fear of experiencing pain, being treated by an uncompassionate dentist, and losing control were reported to be the most anxiety-provoking stimuli. No significant between-group differences were seen.

In total, 14 patients dropped out from the study. No significant differences in terms of their baseline data were found between those who completed the study and those who dropped out (Table 6). When possible, patients were requested to provide reasons for dropping out (see Figure 1).

To determine whether the present findings were influenced by dropout, an intention-to-treat-analysis was performed on the primary treatment outcomes of all randomised subjects (Table 7). Imputation of missing data was conducted using the last-observation-carried-forward (LOCF) method, which, in this case, means that pre-treatment values were used as substitutes for the post-treatment values when these were missing. This approach means that the treatment effect was assumed to be zero for all dropouts. The overall treatment effect remained statistically significant.

At the end of the study period, all patients were offered referrals either to a local general dentist for further dental treatment at full cost, or to further anxiety and dental treatment free of charge in public teams. In total, 23 (29.9%) patients preferred the public treatment option. The main reasons reported were economy (16 patients; 9 and 7 in the D-CBT and FHM groups, respectively) and persistent high dental anxiety (7 patients; 3 and 4 in the D-CBT and FHM groups, respectively).

DISCUSSION

In this study, D-CBT and FHM both effectively reduced dental anxiety when delivered by a GDP in a general dental practice. D-CBT treatment was not associated with a greater reduction in dental anxiety than the best-practice control condition.

The study has several strengths, as well as some limitations. Specifically, the RCT design and the use of validated

TABLE 4 Key characteristics of the demographic variables and the baseline scores for the outcome measures given for each intervention group

	Intervention group		
	D-CBT (*n* = 48)	FHM (*n* = 48)	Between-group difference
Variables			
Age (years), mean (95% CI)	38.0 (34.5, 41.9)	39.0 (35.4, 42.2)	1.0 (−4.4, 5.6)
Sex, % female	69%	63%	6% (−12.7, 25.2)
Years since treatment, mean (95% CI)	11.0 (7.2, 13.8)	9.0 (6.4, 11.9)	1.0 (−2.8, 5.6)
MDAS, mean score (95% CI)	21 (20.2, 21.8)	21 (20.2, 21.9)	0 (−1.9, 2.5)
IDAF−4C, mean score (95% CI)	4.2 (4.0, 4.3)	4.1 (3.9, 4.3)	0 (−0.4, 0.6)
Traumatic incidents, %	54%	58%	−4% (−23.8, 15.8)
PCL-S score >35%	40%	38%	2% (−17.5, 21.5)
PCL-S, mean score (95% CI)	43 (36.6, 48.8)	39 (34.4, 42.7)	−4 (−11.2, 2.9)

Abbreviations: D-CBT, Dentist-administered Cognitive Behavioural therapy; FHM, The Four Habits Model combined with midazolam administration; IDAF-4C, Index of Dental Anxiety and Fear anxiety and fear module; MDAS, Modified Dental Anxiety Scale; OIDP, Oral Impact on Daily Performances; PCL-S, PTSD checklist for DSM-IV (PCL), version PCL-S; SWLS, Satisfaction with Life Scale.

TABLE 5 The mean scores for the four psychometric instruments applied as observed at baseline (Pre) and after (Post) treatment, and their changes (Pre minus Post) in each of the treatment groups

Instrument	D-CBT ($n = 36$)		FHM ($n = 41$)		Group effect
	Pre Mean (95% CI)	Post Mean (95% CI)	Pre Mean (95% CI)	Post Mean (95% CI)	Difference (95% CI)
MDAS	20.9 (19.8, 21.9)	14.2 (12.6, 15.8)	21.0 (20.0, 21.9)	14.5 (12.9,16.0)	0.3 (−1.8, 2.5)
IDAF−4C	4.1 (4.0, 4.3)	3.1 (2.7, 3.5)	4.2 (3.9, 4.4)	3.2 (2.8, 3.5)	0.1 (−0.4, 0.6)
SWLS	23.7 (20.9, 26.4)	23.9 (21.3, 26.5)	23.2 (20.7, 25.8)	24.2 (22.1, 26.3)	0.3 (−3.0, 3.6)
OIDP	18.3 (15.2, 21.3)	16.5 (13.7, 19.4)	21.2 (18.4, 23.9)	20.2 (17.7, 22.8)	3.8 (−0.1, 7.5)

Note: Also calculated is the mean difference (95% CI) between groups (D-CBT minus FHM) in the changes in scores for each instrument.

Abbreviations: D-CBT, Dentist-administered Cognitive Behavioural therapy; FHM, The Four Habits Model combined with midazolam administration; IDAF-4C, Index of Dental Anxiety and Fear anxiety and fear module; MDAS, Modified Dental Anxiety Scale; OIDP, Oral Impact on Daily Performances; SWLS, Satisfaction with Life Scale.

TABLE 6 Background characteristics of those who completed the trial and those who dropped out

	Completed trial ($n = 82$)	Dropped out ($n = 14$)	Between-group difference
Variables			
Age (years), mean (95% CI)	39.0 (36.3, 41.7)	36.0 (29.0, 42.0)	3.5 (−3.5, 10.5)
Sex, % female	63	79	−16 (−39.8, 7.8)
Years since treatment, mean (95% CI)	10.0 (7.4, 12.2)	10.0 (5.7, 14.0)	0 (−6.0, 6.0)
MDAS, mean score (95% CI)	21 (20.3-21.6)	21 (20.4, 22.3)	0 (−2.1, 1.3)
IDAF−4C, mean score (95% CI)	4.1 (4.0-4.3)	4.3 (4.0, 4.5)	0 (−0.4, 0.2)
Traumatic incidents, %	56	57	−1 (−29.1, 27.1)
PCL-S score>35, %	38	50	−12 (−40.2, 16.2)
PCL-S, mean score (95% CI)	43 (38.8-47.0)	47 (37.1, 56.2)	−4 (−14.1, 6.6)

Abbreviations: IDAF-4C, Index of Dental Anxiety and Fear anxiety and fear module; MDAS, Modified Dental Anxiety Scale; PCL-S, PTSD checklist for DSM-IV (PCL), version PCL-S.

TABLE 7 Results of the intention to treat-analysis

Instrument	D-CBT ($n = 36 + 12 = 48$)		FHM ($n = 41 + 7 = 48$)		Group Effect
	Pre Mean (CI)	Post Mean (CI)	Pre Mean (CI)	Post Mean (CI)	Difference (CI)
MDAS	21 (20.2, 21.8)	16.0 (14.5, 17.5)	21 (20.2, 21.9)	15.5 (14.0, 17.0)	0.5 (−1.5, 2.6)
IDAF−4C	4.2 (4.0, 4.3)	3.4 (3.0, 3.7)	4.1 (3.9, 4.3)	3.3 (3.0, 3.6)	0.1 (−0.4, 0.5)

Abbreviations: D-CBT, Dentist-administered Cognitive Behavioural therapy; FHM, The Four Habits Model combined with midazolam administration; IDAF-4C, Index of Dental Anxiety and Fear anxiety and fear module; MDAS, Modified Dental Anxiety Scale; Post, after treatment according to the LOCF-model; Pre, before treatment.

instruments and standardised treatment protocols (to ensure that treatment sessions differed in the predesignated way between the two methods) are methodological features that strengthen the generalizability of the findings from this study. It also adds to the quality of the study that adherence to manuals was evaluated through video recordings.

One dentist treated all patients, which is both a strength and a limitation of the study design. It is a strength in that it provides better control over the dependent variables. Variability can be assumed to be ascribed to the patients' responses to the treatment, and dentist variability did not influence the findings. The GDP in the present study is a practicing dentist who has undergone a standardized dentist education and, as

such, presumably represents dentists as a profession to a large degree. Even so, the main limitation to the present study design is that the assumption of generalizability of the findings to other GDPs could not be assessed.

Another limitation relates to the time frame of the study. In a study by Johren et al. [61] comparing the effect of a psychological intervention with midazolam sedation, the initial reduction in dental anxiety seen in the midazolam group dissipated after two months. Differing long-term effects may also be expected after treatment with the contrasting methods utilised in this study. The variability of the treatment effects over time could not be assessed in the present study.

The dropout rate was 20% in total, and it was larger in the D-CBT-group than in the FHM group. We believe this to be the result of a sudden change in the way treatment of dental anxiety patients was funded. Hence, by coincidence, more patients in the D-CBT group than the FHM group were about to start treatment when public support to treatment of odontophobia patients was discontinued in private dental practices. But even with a conservative approach (LOCF-method), the intention to treat analysis displayed a statistically significant dental anxiety reduction. This indicates that the missing data do not threaten the validity of the study's main findings.

The first hypothesis, 'D-CBT treatment is associated with a greater reduction in dental anxiety than FHM treatment' was not supported by the data. Comparable findings have been reported by Hakeberg et al. [62] Specifically, they found that both behavioural therapy delivered by a psychologist and dental treatment during premedication with diazepam resulted in significant and stable improvement (10-year follow-up) in dental anxiety scores [63]. They concluded that treatment elements shared by the two methods (rapport building, exposure, focus on control, detailed sensory and procedural information, and gradual progression) were probably responsible for a large part of the treatment effects seen. This may also be relevant in the present study.

Most studies on CBT treatment for dental anxiety have reported favourable findings [27]. For sedation treatment, outcomes are more variable. In a study by Thom et al. [64] comparing the use of benzodiazepine and a one-session CBT treatment, sedated patients had a poorer treatment outcome. The most obvious difference between the treatment manual followed by Thom et al. and the treatment manual used in the present study is the introduction of a communication model to support dental treatment during sedation. Another possible explanation for the lack of difference in effect between FHM- and D-CBT-treatment is that various therapy components (e.g., psychoeducation, conscious sedation) produce distinct but comparable effects in both research conditions.

Our second hypothesis, that 'D-CBT and FHM treatment are both associated with a significant reduction in dental anxiety', was confirmed. Interestingly, both treatment methods

were acceptable to the highly heterogenous group of patients. Only one patient did not accept the randomly selected treatment (FHM) and only four did not complete the full set of appointments due to no-show. At baseline, 85% of the participants had MDAS score above 19, approximately 50% had experienced a traumatic incident, and 35% had a high PCL-S score (indicating PTSD). This suggests that both treatment procedures tested benefitted patients with various backgrounds, resources, and vulnerabilities, including traumatic experiences indicating PTSD. To the best of the authors' knowledge, there are no previous studies that have explored whether patients with traumatic experiences benefit from dental CBT or FHM treatment of dental anxiety.

The third hypothesis, 'Treatment of dental anxiety is associated with a reduced score of oral impacts on daily performances and improved life satisfaction,' was partially supported by the findings. A significant decrease in OIDP scores was seen in the D-CBT group, while there were no significant changes in scores in SWLS for either group. It is possible that more positive changes in these two variables can be expected when dental treatment is completed and oral function is restored. Mehrstedt et al. [65] found that increased dental anxiety was associated with poorer oral health-related quality of life. The authors speculate that this might result from dental anxiety treatment (not only dental treatment) positively affecting oral health-related quality of life. This could explain the significant changes in OIDP seen in the D-CBT-group even before ordinary dental treatment, but it cannot explain why the findings differ between the two groups.

In dental care, as in medical care, the best available treatment should be used routinely [66]. Campbell et al. [67] argue that there are two principal dimensions of quality of care for individual patients: access and effectiveness. The major clinical implication from the present study is that dental anxiety can be treated effectively by a dentist within general dental care. The fact that the two contrasting treatment methods proved to be equally effective allows the dentist to choose treatment principles in accordance with the patient's preferences and within the dentist's resources and competencies. The findings in the present study support a model in which patients with dental anxiety receive treatment in primary dental care by GDPs, and when necessary, are further referred to secondary care/specialised interdisciplinary teams.

Future research should test the long-term effects and generalizability of D-CBT and FHM. In addition, it would be valuable to assess the degree to which different treatment elements contribute to the overall effect of treatment.

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the study continued undisturbed through administrative challenges.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization: Mariann Saanum Hauge, Tiril Willumsen; **Methodology:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora, Olav Vassend, Asle Hoffart; **Software:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora; **Validation:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora, Olav Vassend, Asle Hoffart; **Formal analysis:** Mariann Saanum Hauge, Tiril Willumsen; **Investigation:** Mariann Saanum Hauge; **Data Curation:** Mariann Saanum Hauge; **Writing - original draft:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora; **Writing - review & editing:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora, Olav Vassend, Asle Hoffart; **Visualization:** Mariann Saanum Hauge, Tiril Willumsen; **Supervision:** Tiril Willumsen, Bent Stora; **Project administration:** Mariann Saanum Hauge, Tiril Willumsen, Bent Stora.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.