# EFFECT OF AN INFORMATIVE VIDEO UPON ANXIETY AND HEMODYNAMIC PARAMETERS IN PATIENTS REQUIRING MANDIBULAR THIRD MOLAR EXTRACTION: A RANDOMIZED CLINICAL TRIAL

## Short title: Video, anxiety and third molar surgery

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**ABSTRACT**

**Purpose:** To determine the effect of watching an informative video about mandibular third molar (M3M) removal upon patient anxiety and hemodynamic parameters.

**Patients and Methods:** A randomized controlled clinical trial was carried out in healthy patients (between 18-40 years of age) requiring M3M extraction under local anesthesia. Patients with previous tooth extractions, psychiatric disorders, cardiac problems or under anxiolytic or antidepressant drug treatment were excluded. Participants were randomized to two groups according to whether they watched an informative video about the surgical procedure (video group) or not (control group). The primary outcome variable was the difference between groups regarding patient anxiety assessed with the State–Trait Anxiety Inventory (STAI) and the Modified Dental Anxiety Scale (MDAS). Secondary outcome variables were hemodynamic parameters recorded in different moments of the surgical procedure. Descriptive, bivariate and multivariate analyses were made, and a repeated measure mixed model was generated. Statistical significance was considered for $p<0.05$.

**Results:** Fifty patients referred for M3M extraction met the inclusion criteria. Final data analysis was based on 47 patients: 25 from the video group and 22 controls. The bivariate analysis showed the video group to have a significant decrease in anxiety as measured by MDAS (p=0.006; 95%CI: –4.1 to –0.7) and STAI–State (p=0.003; 95%CI: –13.7 to –0.7). A significantly lower heart rate was likewise found in the video group (Chi-squared=4.30; df=1; p=0.038). The linear regression analysis adjusting for STAI-T also showed lower dental anxiety measured by the MDAS in the video group (p=0.023, 95%CI: 0.32 to 4.14).

**Conclusions:** Providing preoperative information through an informative video about M3M removal significantly reduces patient anxiety and heart rate during the surgical procedure.

**Type of article:** Randomized controlled clinical trial.

**Key words**: Dental anxiety, dental extraction, third molar, hemodynamic parameters, heart rate.

## INTRODUCTION

Mandibular third molar (M3M) removal is associated with pain, swelling and trismus, among other complications (1). Patient anticipation of these problems, together with dental fear, may be the reason why patients undergoing M3M extraction show high levels of anxiety (2,3).

Indeed, dental anxiety (DA) is a common phenomenon (4,5) that has been defined as "an emotional reaction characterized by feelings of tension, apprehension, nervousness and concerns provoked by an intangible and diffuse advancing threat or approaching danger, accompanied by activation of the autonomic nervous system" (6,7). In order to identify anxious patients, dentists can use a visual analog scale (VAS) or other specific scales such as the State–Trait Anxiety Inventory (STAI), the Modified Dental Anxiety Scale (MDAS), the Interval Scale of Anxiety Response (ISAR), among others (7–9).

High levels of DA may trigger unpleasant situations for patients and dentists. Also, such high stress levels may lead to longer operation times and more difficult procedures (10). Choi et al. (11) demonstrated that preoperative informative videos showing the surgical procedure decrease self-reported anxiety while increasing patient comprehension. However, other studies have shown that these results might not be significant (12) or may even create the opposite effect (13,14). The video content might make patients aware of the tissue damage they are going to experience, thereby increasing DA. On the other hand, many patients have already watched online videos about the surgical procedure, some of which have a misleading content (15). Therefore, informative videos explaining what the patient might feel and showing relaxation methods could help reduce DA.

The primary objective of the present trial was to determine the effect of an informative video about M3M removal upon patient anxiety. The secondary aim was to determine whether the video influences the hemodynamic parameters - specifically systolic blood

pressure (SBP), the diastolic blood pressure (DBP) and the heart rate (HR), during the surgical procedure.

## MATERIAL AND METHODS

*Study design*

A randomized controlled clinical trial with two parallel groups was carried out in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (16). The study abided with the Declaration of Helsinki on medical protocols and ethics, and the local Institutional Review Board of the Dental Hospital of the University of Barcelona (Barcelona, Spain) approved the trial (protocol number 37/2017).

*Sample description*

Inclusion criteria were healthy patients (ASA score < III) between 18-40 years of age that were visited in the context of the Master Degree Program in Oral Surgery and Implantology of the University of Barcelona, and who required M3M removal. Patients who had undergone permanent tooth extraction in the past, who needed more than one M3M extraction, took anxiolytic or antidepressant drugs, or had any heart condition or severe disease were excluded. Patients who were unable to understand the study or to complete the questionnaires were also excluded. Patients were recruited at their first appointment in the Dental Hospital of the University of Barcelona (Hospital Odontològic, Universitat de Barcelona), and were asked to complete the STAI-T questionnaire. The surgical procedure and the study intervention (video) were performed in another appointment, at least one week later.

A four-minute video was filmed and edited with the help of a psychologist. It consisted of a three-minute speech by an experienced surgeon (EVC) in a room with the hospital logo and wearing casual clothes. The surgeon explained that the staff was experienced in the scheduled procedure and described the sensations which the patients would experience (numbness, vibration and pressure). Also, the video explained that patients could request a pause in the surgical procedure, especially if pain was present. The rest of the video included images of natural surroundings and relaxing music.

On the day of surgery, the patients were randomly assigned to one of the two study groups (video group or control group) using a randomization list generated with Stata14 (StataCorp., College Station, USA) and in 1:1 proportion. An independent investigator (AST) concealed the sequence using sealed opaque envelopes. Another investigator (JTS) opened the envelope after the patient had entered the waiting room. Only patients assigned to the video group watched the preoperative video in a tablet with earphones while still in the waiting room. The surgeon was blinded, since he did not know whether the patient had seen the video or not. Dental anxiety was assessed before and after surgery based on the STAI (Trait-T and State-S) and MDAS questionnaires. In the video group, the questionnaires were answered after the participants watched the video.

Before surgery, students of the Master degree program in Oral Surgery and Implantology explained to the participants of both groups the surgical procedure and its possible risks and complications, such as swelling, pain or nerve injury. Also, the patients were reassured that they should not feel any pain during the extraction. Finally, the patients signed the informed consent before the surgical procedure. All these steps are a standard procedure in our center.

All extractions were made by Master degree program students with a similar level of experience and under direct supervision of experienced staff members. The patient was covered with sterile drapes, leaving only the nose and mouth exposed. The surgical procedures were performed under local anesthesia employing a 4% articaine solution with epinephrine 1:100.000 (Artinibsa; Inibsa; Lliçà de Vall, Spain) using an inferior alveolar nerve block (Halstead technique) supplemented with a buccal infiltration. A buccal full-thickness flap was raised and, if necessary, the clinician performed bone removal and tooth sectioning with a slow-speed handpiece under abundant irrigation with sterile distilled water. The M3M was extracted using elevators, and the wound was closed with simple 3/0 silk sutures (Silkam, Braun; Tuttlingen, Germany). Patient SBP, DBP and HR were recorded at different timepoints: at the beginning of the extraction (before the local anesthetic was delivered), after incision, at the beginning of bone removal, at the beginning of tooth sectioning, and just after the last suture knot. Patients were discharged after receiving printed postoperative instructions and prescriptions: a nonsteroidal antiinflammatory drug (usually ibuprofen during 4 days), a chlorhexidine mouthrinse and, if considered necessary, an antibiotic (usually amoxicillin 750 mg during 4 days). Figure 1 shows the main interventions and the most relevant variables recorded in each appointment.

*Study variables*

The primary outcome variable was the difference in anxiety score. The patient characteristics (age, gender, marital status, body mass index (BMI) and smoking habit) and surgical variables (operated side, previous symptoms, M3M impaction, Pell & Gregory classification, Winter classification, bone removal and tooth sectioning) were

also recorded. The secondary outcome variables were HR, SBP and DBP. An independent blinded investigator (JTS) that performed none of the extractions recorded all the study variables.

*Sample size*

A previous analysis by our group obtained a mean STAI-S score of 22 ± 5.5. The sample size was calculated using the G * Power 3.0 statistical program (Heinrich-Heine-Universität, Düsseldorf, Germany), with an alpha value of 0.05, a statistical power of 80%, and the capacity to detect a difference of 5 points in the STAI-S scores. The power analysis determined the need for a minimum of 21 patients per group. The final sample was increased to 50 patients (25 in each group) in order to compensate possible dropouts.

*Statistical analysis*

The data was processed using the Stata 14 statistical package (StataCorp., College Station, USA) by an independent and blinded investigator (OCF). Categorical outcomes were presented as absolute and relative frequencies. Normality of scale variables was explored through the Shapiro-Wilk test and visual analysis of the P-P and box plots. Where normality was rejected, the interquartile range (IQR) and median were calculated. In the presence of normal data distribution, the mean and standard deviation (SD) were used. In some variables 95% confidence intervals (95%CI) were also reported. The association between categorical variables was assessed with either Pearson's chi-squared test or the Fisher exact test, whereas the unpaired Student t-test or Mann-Whitney U-test was used for scale variables. If a statistically significant ($p<0.05$) difference in preoperative variables between groups was recorded, the randomization process was considered jeopardized. Accordingly, a multivariate analysis was contemplated

performed through a linear regression model for explanatory purposes. A repeated measure mixed model was used to analyze the effects upon SBP, DBP and HR of the operation, time and interaction between each pair of variables. Fulfillment of the assumptions was ensured through graphical distribution of the residuals. For each follow-up timepoint, pairwise comparisons between groups were made. The p-value was set at 0.05, using Bonferroni correction for multiplicity of contrasts.

## RESULTS

*Participants and recruitment*

Of the 460 patients scheduled for third molar removal between January 2018 and November 2019, a total of 50 met the inclusion criteria and were enrolled in the study. Three patients in the control group were excluded from the analysis because they received anxiolytic medication during M3M removal. The recruitment process is summarized in the CONSORT flow chart (Figure 2).

*Baseline data*

Data analysis was based on 25 patients belonging to the video group and 22 to the control group. Table 1 shows the main patient features and surgical data. No significant differences were found regarding age (video group: mean age of 22.8 years; 95%CI: 21.3 to 24.4; control group: mean age of 24.6 years; 95%CI: 21.7 to 27.5). Female patients had a significantly higher presurgical anxiety evaluated by means of MDAS (p=0.026), STAI-T (p=0.010) and STAI-S (p=0.031). On the other hand, these anxiety variables were not correlated with either marital status or age (p>0.05).

*Anxiety scores*

The video group varied significantly from the control group in the STAI-T (p=0.002; 95%CI: 3.1 to 12.4) and preoperative STAI-S scores (p=0.036; 95%CI: 0.5 to 13.5). No other anxiety scale differences were observed between the groups (Table 2).

The video group also showed a greater decrease in both the STAI-S (p=0.031; 95%CI: –13.7 to –0.7) and MDAS scores (p=0.006; 95%CI: –4.1 to –0.7) versus the control group (Table 3). Linear regression analysis adjusted for STAI-T also showed lower levels of DA measured with the MDAS, though no differences were found regarding STAI-S (p=0.130, 95%CI: -1.7 to 12.8).

*Hemodynamic parameters*

Table 4 shows the SBP, DBP and HR at the different timepoints. Heart rate at the beginning of bone removal was significantly lower in the video group versus the control group (p=0.037; 95%CI: -22.5 to -0.7). All other parameters showed no relevant differences between groups.

The mixed model showed the SBP (chi-squared=18.43; df=4; p=0.001), DBP (chi-squared=13.38; df=4; p=0.01) and HR values (chi-squared=42.05; df=4; p<0.01) to differ significantly over time. Heart rate (beats per minute, bpm) was significantly lower in the video group (chi-squared=4.30; df=1; p=0.038), especially at the beginning of bone removal (contrast=10.9 bpm; 95%CI: 1.7 to 20.1; p=0.020) and tooth sectioning (contrast=11.5 bpm; 95%CI: 1.6 to 21.5; p=0.023). Lastly, both groups showed the same pattern over time regarding SBP (chi-squared=1.41; df=4; p=0.842) and DBP (chi-squared=5.22; df=4; p=0.266) but not HR (chi-squared= 9.69; df=4; p=0.046).

## DISCUSSION

The present trial confirmed that watching an informative video about patient perceptions during surgery and instructions for relaxation effectively reduces DA in patients undergoing M3M extraction. Furthermore, the video resulted in decreased HR, especially during bone removal and tooth sectioning, which might reflect better coping with stress.

One possible drawback of the present study is related with the limited experience of the surgeons (students of the Master Degree program in Oral Surgery and Implantology), since more experienced clinicians might be more skillful in reducing patient's anxiety. Although this issue might slightly compromise the external validity of this study, it is important to stress that both groups were equally affected by this factor. Likewise, it would have been interesting to include a third group of patients in which the informed consent and preoperative explanations were made by the same surgeon that appeared in the video. Another limitation was related to the fact that the presurgical hemodynamic parameters (secondary outcome variables) were measured in the surgical appointment, when the patient's procedure-associated anxiety was likely to be present. Future studies should consider gathering these variables in the first appointment, before performing any surgery. However, it must be pointed out that this option might also have downsides since SBP, DBP and HR might be influenced by other time-related factors like circadian rhythm, vigilance states or by environmental and behavioral factors as well (17–19). Finally, the groups were unbalanced in terms of some preoperative variables. However, the adjusted multivariate analysis still showed DA to be lower in the video group.

The video included information and reassurance / relaxation instructions, so the reduction of stress could be attributable to any of these factors. Indeed, most preoperative videos include real or simulated surgery images, which might prove detrimental for stress control. For example, a recent trial (13) concluded that visual information including details of the surgery evoked greater anxiety in the patient. To the best of our knowledge,

the present study is the first to evaluate patient responses to an informative and relaxing video without including any images related to the procedure.

Several studies have reported that scarce preoperative information can lead to an increased risk of anxiety during M3M extraction (20,21). Choi et al. (11), using a preoperative slideshow containing simple illustrations, found no reduction in STAI or MDAS, but observed a significant decrease in self-reported anxiety scores in the test group. Similar results were obtained by Tanidir et al. (22), who found no differences in anxiety scores when using a preoperative video. On the other hand, several studies have demonstrated that viewing a preoperative video increases the anxiety levels of patients (12–14,23). In contrast, the present study found the video to result in lower levels of anxiety as measured by the STAI and MDAS, probably because of the non-explicit contents, which were oriented towards information and relaxation.

Regarding the hemodynamic parameters, Hollander et al. (24) reported that HR was highest during incision and bone removal, in agreement with our own findings. Patients that watched the video had lower HR, which might indicate that relaxation was effective in controlling the neurovegetative response, as described by Yamashita et al. (25,26).

The prevalence of DA is very high, with dentoalveolar surgery being one of the most feared dental procedures (5,27–30). Dental anxiety and fear should be controlled in order to avoid unpleasant and uncomfortable situations for both patients and clinicians, which means less stress and greater productivity (31,32).

Age, gender, marital status and propensity to anxiety are considered important factors when assessing anxiety (20,33). In the present study, female patients were significantly more anxious, but no association was found with the marital status or age, probably because of the reduced range of these variables and the employed study design (randomized clinical trial). On the other hand, no significant differences were found

between both groups, indicating that these variables were unlikely to have any confounding effect. Still, if the results reported by Astramskaite et al. (33) are taken into consideration, the patients in the video group should have been more prone to anxiety since the proportion of females, single individuals and younger patients was slightly higher in the video group.

Dental anxiety can be measured using different scales (34). We selected two validated anxiety questionnaires: the STAI (a tool commonly used in psychology to assess trait-state anxiety) and MDAS (which is specific for DA). Tarazona et al. (35) reported that both scales are useful for detecting anxiety changes in patients undergoing M3M extraction.

The reduction of DA is important for patients and surgeons, because M3M removal under local anesthesia is more difficult in patients with high DA, thus increasing the operating time and patient discomfort (10,36). For this reason, several audiovisual strategies such as music, glasses or videos have been tested in oral surgery (11). These tools, which reassure and help patients to relax, are simple and effective, require minimum time and money investment, and can be of value in medical litigation cases.

Future research should focus on determining the effect of these videos in individuals with previous bad dental experiences or in highly anxious patients, since these subjects are more likely to benefit from such strategies.

In conclusion, providing preoperative information about M3M removal and enhancing relaxation by means of a video significantly reduce patient anxiety and heart rate during the procedure.

## CONFLICTS OF INTEREST

None of the authors have any relevant financial relationship(s) related to this study.

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**FIGURE LEGENDS:**

**Figure 1.** Infographic showing the main interventions and variables recorded in each study appointment. STAI-T: Spielberger State Anxiety Inventory- Trait, STAI-S: Spielberger State Anxiety Inventory- State, MDAS: Modified Dental Anxiety Scale, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate.

**Figure 2.** CONSORT flow-chart of the patients included in the study.

**TABLES**:

| | | Video group | Control group | p value |
|---|---|---|---|---|
| **Patients' characteristics** | | | | |
| Mean age (95% CI) | | 22.8 (21.3 to 24.4) | 24.6 (21.7 to 27.5) | 0.273 |
| Mean BMI (95%CI) | | 24.4 (22.0 to 26.8) | 24.4 (22.6 to 26.1) | 0.965 |
| Marital status | Single | 24 (96%) | 18 (82%) | 0.116 |
| | Married | 1 (4%) | 4 (18%) | |
| Gender | Male | 9 (36%) | 9 (41%) | 0.730 |
| | Female | 16 (64%) | 13 (59%) | |
| Smoking habit | Yes | 5 (20%) | 5 (23%) | 0.820 |
| | No | 20 (80%) | 17 (77%) | |
| **Surgical variables** | | | | |
| Operated side | 3.8 | 13 (52%) | 10 (45%) | 0.654 |
| | 4.8 | 12 (48%) | 12 (55%) | |
| Previous symptoms | Yes | 17 (68%) | 15 (68%) | 0.989 |
| | No | 8 (32%) | 7 (32%) | |
| Mucosa retention | No retention | 2 (8%) | 4 (18%) | 0.559 |
| | Partial | 15 (60%) | 11 (50%) | |
| | Complete | 8 (32%) | 7 (32%) | |
| Bone retention | No retention | 5 (20%) | 3 (14%) | 0.685 |
| | Partial | 19 (76%) | 17 (77%) | |
| | Complete | 1 (4%) | 2 (9%) | |
| Pell&Gregory | A-I | 3 (12%) | 2 (9%) | 0.498 |
| | A-II | 14 (56%) | 10 (45%) | |
| | A-III | 1 (4%) | 2 (9%) | |
| | B-I | 0 (0%) | 1 (5%) | |
| | B-II | 3 (12%) | 6 (27%) | |
| | B-III | 2 (8%) | 0 (0%) | |
| | C-I | 0 (0%) | 0 (0%) | |
| | C-II | 2 (8%) | 1 (5%) | |
| | C-III | 0 (0%) | 0 (0%) | |
| Winter position | Vertical | 9 (36%) | 8 (36%) | 0.911 |
| | Mesioangular | 9 (36%) | 9 (41%) | |
| | Horizontal | 3 (12%) | 3 (14%) | |
| | Distoangular | 4 (16%) | 2 (9%) | |
| Bone removal | Yes | 21 (84%) | 16 (73%) | 0.346 |
| | No | 4 (16%) | 6 (27%) | |
| Tooth sectioning | Yes | 19 (76%) | 10 (45%) | 0.032 |
| | No | 6 (24%) | 12 (55%) | |

**Table 1.** Main clinical features of the participants included in the trial. BMI: body mass index expressed in $kg/m^2$, 95% IC: 95% confidence interval.

| | | Video group | Control group | *p* (95%CI) |
|---|---|---|---|---|
| | | Mean (SD) | | |
| *STAI–T* | | 20.9 (9.2) | 13.1 (6.1) | 0.002 (3.1 to 12.4) |
| *Baseline* | *STAI–S* | 25.8 (11.3) | 18.8 (10.8) | 0.036 (0.5 to 13.5) |
| | *MDAS* | 13.7 (3.5) | 12.1 (4.6) | 0.179 (-0.8 to 4.0) |
| *After surgery* | *STAI–S* | 14.5 (7.1) | 14.7 (6.8) | 0.922 (-4.3 to 3.9) |
| | *MDAS* | 11.0 (3.5) | 11.8 (4.7) | 0.526 (-3.2 to 1.7) |

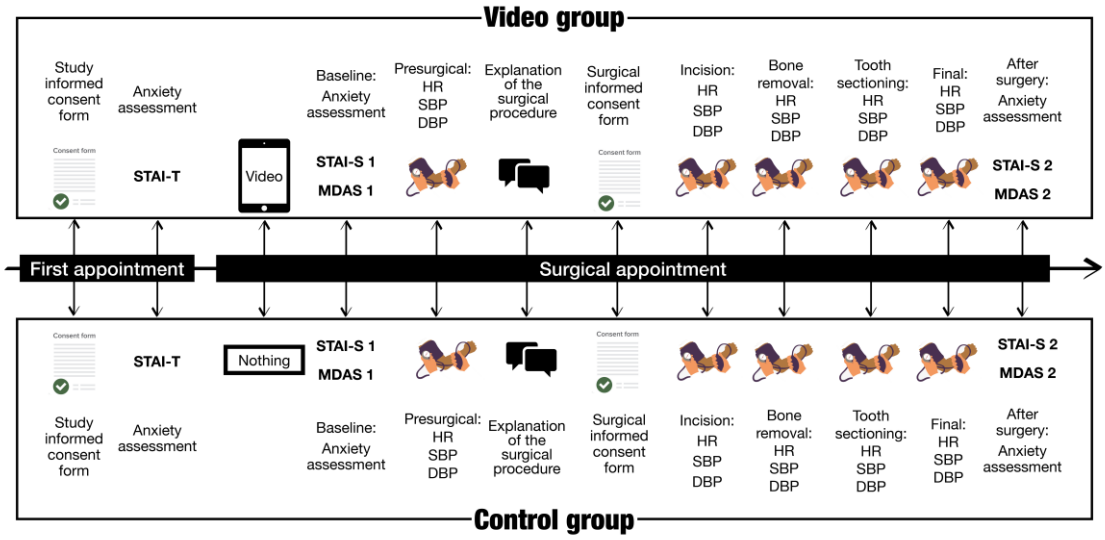
**Table 2.** Results regarding patient's anxiety in both groups. STAI-T: Spielberger State Anxiety Inventory- Trait, STAI-S: Spielberger State Anxiety Inventory- State, MDAS: Modified Dental Anxiety Scale, SD: standard deviation, 95%CI: 95% confidence interval. Differences between groups was determined with t test.

| | *p* | CI 95% | |
|---|---|---|---|
| | | Lower limit | Upper limit |
| Diff. *STAI*–S | 0.031 | -13.7 | -0.7 |
| Diff. *MDAS* | 0.006 | -4.1 | -0.7 |

**Table 3.** Main outcome variable results: Anxiety reduction in the video group reported by STAI-S and MDAS surveys. Bivariable analysis with t test showed a lower anxiety levels in the video group. 95%CI: 95% confidence interval; Diff: differences.

| *Secondary outcome variables* | | Video | Control | *p* |
|---|---|---|---|---|
| | | Mean (SD) | | |
| Presurgical | SBP | 124.0 (12.0) | 122.4 (8.9) | 0.603 |
| | DBP | 71.9 (9.8) | 75.3 (8.5) | 0.212 |
| | HR | 80.6 (13.9) | 82.2 (14.6) | 0.706 |
| Incision | SBP | 126.0 (15.0) | 125.6 (10.5) | 0.910 |
| | DBP | 69.8 (9.5) | 70.0 (8.6) | 0.939 |
| | HR | 86.1 (15.0) | 92.9 (19.4) | 0.189 |
| Bone removal | SBP | 127.0 (18.0) | 125.5 (14.6) | 0.796 |
| | DBP | 70.3 (10.5) | 69.6 (10.4) | 0.835 |
| | HR | 82.7 (11.7) | 94.3 (20.1) | 0.037 |
| Tooth sectioning | SBP | 128.9 (15.6) | 128.1 (15.6) | 0.898 |
| | DBP | 70.6 (10.2) | 69.7 (8.6) | 0.819 |
| | HR | 80.6 (15.3) | 88.2 (17.8) | 0.252 |
| Post - intervention | SBP | 123.4 (12.6) | 121.1 (9.2) | 0.498 |
| | DBP | 70.8 (9.7) | 72.1 (10.4) | 0.640 |
| | HR | 77.8 (13.6) | 84.0 (14.0) | 0.135 |

**Table 4.** Hemodynamic parameters registered during different moments of the mandibular third molar extraction. SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate, SD: standard deviation. The level of significance was determined with t tests.


Video group
Study informed consent form
Anxiety assessment
STAI-T
Video
Baseline: Anxiety assessment
STAI-S 1
MDAS 1
Presurgical: HR SBP DBP
Explanation of the surgical procedure
Surgical informed consent form
Incision: HR SBP DBP
Bone removal: HR SBP DBP
Tooth sectioning: HR SBP DBP
Final: HR SBP DBP
After surgery: Anxiety assessment
STAI-S 2
MDAS 2
First appointment
Surgical appointment
STAI-T
Nothing
STAI-S 1
MDAS 1
STAI-S 2
MDAS 2
Study informed consent form
Anxiety assessment
Baseline: Anxiety assessment
Presurgical: HR SBP DBP
Explanation of the surgical procedure
Surgical informed consent form
Incision: HR SBP DBP
Bone removal: HR SBP DBP
Tooth sectioning: HR SBP DBP
Final: HR SBP DBP
After surgery: Anxiety assessment
Control group

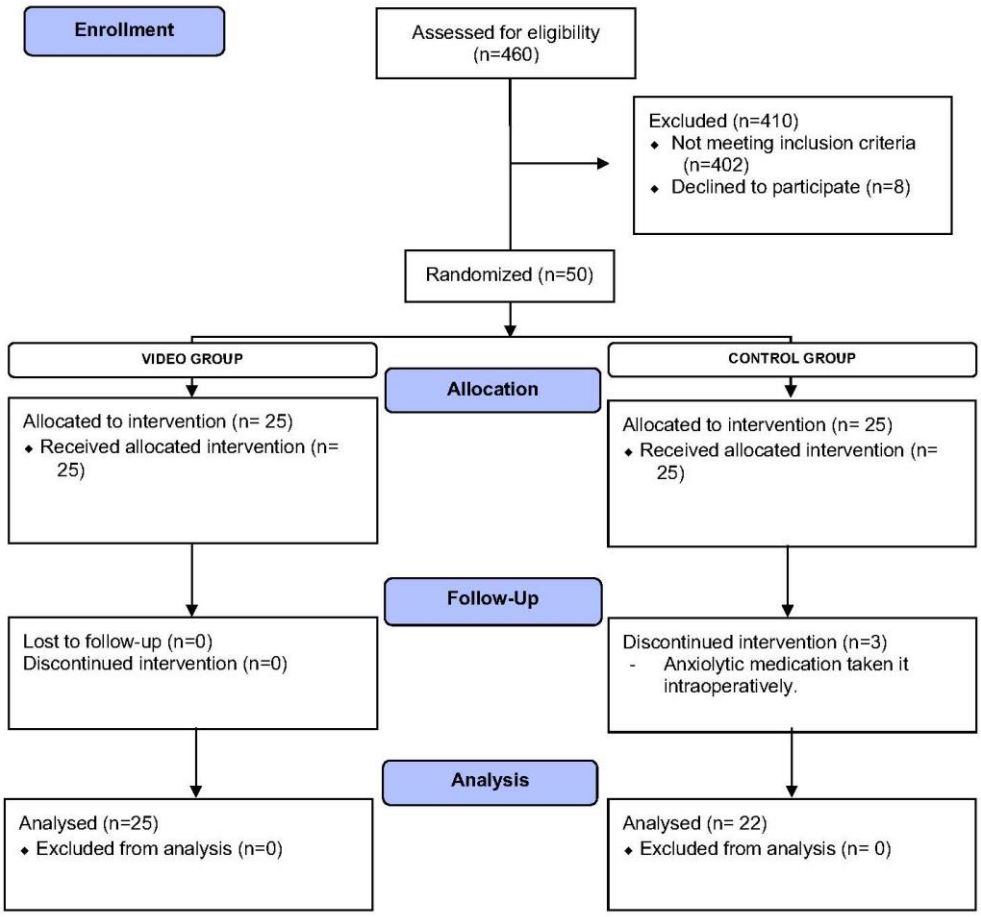



**Figure 1.** Flow-diagram CONSORT.