

Study Protocol and Statistical Analysis Plan

Musical Grammatological and Neurocognitive Parameterization of Analgesic and Anxiolytic
Effects of Culturally and Personally Contextualized Music Listening During Painful Dental
Procedures

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Musical Grammatological and Neurocognitive Parameterization of Analgesic and Anxiolytic Effects of Culturally and Personally Contextualized Music Listening During Painful Dental Procedures

I-Objective

This study aims to verify, with a significant sample of 30 Lebanese adults, the hypothesis that listening to a personally and culturally contextualized musical sequence during a painful dental procedure induces a significant decrease in perceived pain and patient anxiety. The music is chosen by the patient from a pre-established selection of tracks based on grammatological criteria recognized for their analgesic potential. The study also seeks to observe favorable modulation of physiological parameters related to stress.

II- Research Questions

- Can listening to a musical statement chosen from a pre-selected palette based on soothing musical grammatological criteria induce an analgesic effect in patients undergoing painful dental care?
- Would this musical statement have a modulating effect on the activity of the autonomic nervous system, particularly by inhibiting physiological responses associated with stress?
- Do the analgesic and anxiolytic effects of the musical sequence vary according to implicit cultural preferences (e.g., Mashriq musical tradition vs. Western music) expressed in the patient's choice?
- Are the musical sequences chosen freely by patients from a pre-established palette perceived as effective in mitigating pain and anxiety, and to what extent is this perception correlated with physiological data and self-assessments?

III- Musical Material

The patient is invited to choose a musical sequence from a palette of tracks from various musical genres, pre-selected for their relaxing and soothing musical grammatological criteria:

- Samā'ī in Rāst mode – Ghassan Sahhab
- Taḥmīlat Rāst – Album *Waṣalāt* – Nidaa Abou Mrad and the Antonine University Classical Arabic Music Ensemble
- Bašraf Rāst – Album *Waṣalāt* – Nidaa Abou Mrad and the Antonine University Classical Arabic Music Ensemble
- Bašraf Rāst – Album *Mikha'il Mashâqa* – Nidaa Abou Mrad and the Antonine University Classical Arabic Music Ensemble
- Taqṣīm in Rāst mode – Ghassan Sahhab
- "In a Sentimental Mood" in D Major – Duke Ellington
- Nocturne Op.9 No.2 in Eb Major – Chopin
- Cello Suite No. 1 in G Major, BWV 1007: I. Prélude in C Major – Bach

- Sonata for Two Pianos K.448: II. Andante in D Major – Mozart
- Clair de Lune in Db Major – Debussy

IV- Type of Dental Procedure Studied

The experimental situation selected for this study is dental drilling during cavity treatment, performed without local anesthesia or in conditions where pharmacological analgesia is partially or totally ineffective.

- **Stimulus:** Dental drilling constitutes a continuous painful stimulus associated with the activation of pain responses and the autonomic nervous system.
- **Scientific Model:** It represents a relevant model for studying central mechanisms of pain modulation (Melzack & Wall, 1965b; Tracey & Mantyh, 2007).
- **Clinical Relevance:** While local anesthesia is standard, it can be ineffective during acute pulp inflammation, in patients with hypersensitivity/intolerance to anesthetics, or due to complex nerve anatomy (Hargreaves & Keiser, 2002; Meechan, 2005).
- **Patient Preference:** Some patients prefer to tolerate the pain of drilling rather than experience the prolonged jaw numbness associated with local injections.
- **Alternative:** In these situations, functional music therapy serves as a pertinent non-drug analgesic alternative. Music is a non-invasive intervention that can modulate perceived pain, anxiety, and autonomic activation through attentional, emotional, and autonomous mechanisms (Bradt et al., 2013; Roy et al., 2008).

V- Methodology

The study was conducted from October 1, 2025, to December 23, 2025, in a private dental clinic in Aley, Mount Lebanon, following ethical approval from Antonine University on July 16, 2025.

V-1- Population

- **Inclusion Criteria:** Adult patients (ages 18–60) visiting the clinic for cavity treatment who provide informed consent.
- **Exclusion Criteria:** Non-consenting patients, children, patients with mental or physical disorders, pregnant women, and patients taking analgesics, anxiolytics, or antidepressants.

V-2- Study Procedure

1. **Welcome:** The patient is welcomed in a calm atmosphere and the procedure is explained.
2. **Assessment:** The patient completes a general information questionnaire and the Corah Dental Anxiety Scale (DAS).

3. **Consent & Selection:** The patient signs the informed consent form, chooses their musical sequence, and adjusts the volume.

On the dental chair :

4. **Baseline (Phase 0):** Heart rate (HR) and blood pressure (BP) are measured at rest (T0).
5. **Control 1 (Phase 1):** 30 seconds of drilling without music. Measurements: HR, BP, and Pain Intensity (PI) via Visual Analog Scale (T1).
6. **Pause/rest (120s) + beginning of the music listening**
7. **Test (Phase 2):** 30 seconds of drilling *during* music playback. Measurements: HR, BP, and PI (T2).
8. **End of the music listening - Pause/rest (120s)**
9. **Control 2 (Phase 3):** 30 seconds of drilling. Measurements: HR, BP, and PI (T3).
10. **Completion:** The patient completes a post-treatment evaluation questionnaire. Note: The study takes place at the start of the clinical visit; dental treatment continues normally after the final study measurements are taken.

VI- Statistical Analysis Plan (SAP)

VI-1 Study Design

- **Type:** Single-arm, within-subject experimental study.
- **Participants:** 30 adults undergoing dental treatment for caries.
- **Phases:** Baseline (T0), Phase 1 (pre-music silence), Phase 2 (music), Phase 3 (post-music silence).
- Each participant serves as their own control.

VI-2- Data Collection: Pain measured via Visual Analog Scale (VAS); heart rate (HR) and systolic/diastolic blood pressure (BP) recorded at all phases.

VI-3- Statistical Methods

Primary Outcome – Pain (VAS)

- **Analysis:**
 - Compare pain levels across phases using repeated measures ANOVA (or Friedman test if data violate normality).
 - Post-hoc pairwise comparisons between phases (Phase 1 vs Phase 2, Phase 2 vs Phase 3) using Bonferroni adjustment to correct for multiple testing.
- **Assumptions:**
 - Normality of residuals checked with Shapiro-Wilk test.
 - Sphericity checked with Mauchly's test; Greenhouse-Geisser correction applied if violated.

Secondary Outcomes

- **Physiological Parameters (HR, BP)**
- **Analysis:**
 - Repeated measures ANOVA for HR, systolic BP, and diastolic BP across the four phases.
 - Pairwise comparisons with Bonferroni correction.
- **Assumptions:** Same as primary outcome; log transformation applied if data are skewed.
- **Post-Treatment Perception of Music Effectiveness**
- **Analysis:**
 - Frequency distributions and descriptive statistics.
 - Association with pain reduction and physiological changes assessed using Spearman correlation.

VI-4- Software

- Statistical analyses will be performed using Python.

Bibliography

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