

Effect of Musical Therapy on Salivary Cortisol Levels and Oral Health Related Quality of Life in Patients with Fixed Prosthesis- A Research Protocol of Randomised Controlled Trial

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ABSTRACT

Introduction: Tooth loss exerts a significant psychological impact on adult patients. Also, it affects the psychological aspect of patient's behaviour, which can have a dynamic effect on an individual's mind. Many patients feel anxious while facing dental clinics or while getting treated. These stressful situations can cause alterations in neuro hormonal mechanism and can induce cardiovascular events. If the patient's mind is distracted to listen to music during treatment processes, his or her anxiety levels can be lowered, resulting in maximum compliance.

Need of the study: The need of the research is to determine impact of musical therapy on salivary cortisol level. As different therapy such as musical therapy, has achieved significant among alternative therapies as it is not invasive and very helpful to decrease the unfavourable effect of strength on patients mind.

Aim: To determine the effect of musical therapy on salivary cortisol levels and Oral Health Related Quality of Life (OHRQoL) in patients under prosthetic rehabilitation with fixed prosthesis.

Materials and Methods: This randomised controlled trial will be conducted at Sharad Pawar Dental College and Hospital, Sawangi(M), Wardha on 30 patients undergoing fixed prosthetic rehabilitation. Salivary cortisol levels will be checked in both experimental group and control group, undergoing prosthetic rehabilitation with fixed partial denture. To analyse OHRQoL before and after treatment in both groups. Oral Health Impact Profile (OHIP) will be used, which includes a questionnaire. Following the assessment, correlation of OHRQoL of both groups and their salivary cortisol levels before and after treatment will be done.

Keywords: Cortisol, Dental anxiety, Fixed rehabilitation, Psychological impact

INTRODUCTION

Patients are quite anxious about all forms of dental treatments [1]. Many patients feel anxious while facing dental clinics or while getting treated. These stressful situations can cause alterations in neurohormonal mechanism and can induce cardiovascular events [2]. It mainly results in inflated Heart Rate (HR), increase in Blood Pressure (BP), and high activity of the hypothalamic axis coupled with the stimulation of immune cells resulting in the secretion of several hormones, particularly salivary cortisol, which is well thought as the stress hormone. Saliva is secreted by an active process regulated by the Autonomic Nervous System (ANS) and the anxiety increases the secretion of epinephrine and norepinephrine, which act on the adrenergic receptors in the salivary glands and vascular tissue associated with the glandular tissue [2,3]. Thus, the decrease in salivary flow rate may be understood as the classical fight or flight response to stress [3]. Also, an association between stimulated salivary flow rate and stress is been reported. Accordingly to these, in the various studies a significant negative correlation between the levels of cortisol and stimulated salivary flow was found [3-8].

Salivary cortisol is a useful biomarker in the field of stress investigation. It is an expression of free plasma cortisol concentrations more than total plasma cortisol. Free cortisol plasma freely expands in the saliva and remains steady in that environment [2,3,5,8].

The OHRQoL is a convenient tool for gaining a better understanding of treatment and patient's satisfaction. It has been recognised as capable of modifying emotional wellbeing, physical health, social functioning, and communication activities among the tools available [4,9].

The literature reports dental anxiety and dental phobia in surgical extractions and implant procedures and in young patient populations

[2]. As reported in a previous study, listening to music during prosthetic treatment could significantly reduce the level of anxiety at the end of the treatment but not necessarily because of cardiovascular parameters [10].

The use of music as a therapeutic intervention is largely a development of the middle of the 20th century. The rise in the use of music as an intervention in recent years may, be credited to the increasing mass appeal of complementary therapies [11]. Potential benefits of musical interventions include reducing treatment related exposure to frightful noises. Physiological patient functions like blood pressure and HR are influenced by musical interventions, but also controls emotions like perioperative anxiety levels and pain thresholds [10].

Pitch, rhythm, dynamics, and common elements like dynamics, tone, and resonance are all incorporated in a structured manner in the art of arranging sounds in time to produce a constant blend of melody and harmony. The use of music to reduce or eliminate anxiety is referred to as audio-analgesia or audio-anxiolysis [12]. Music therapy is the controlled use of music and its components to influence a person's physiological, psychological, and emotional status while they are receiving treatment for a disease or illness. There are two types of music therapy: active and passive [13]. Active music therapy is the application of music by qualified musicians or music therapists to promote health, wellbeing and welfare. On the other hand, passive music therapy, also referred to as receptive music therapy, is the passive listening to prerecorded music offered by medical professionals, such as doctors and dentists, without the involvement of a music therapist. According to research, active music therapy is significantly more effective than passive music listening for treating medical conditions [14].

White noise effect is the practice of playing music before a procedure in order to reduce anxiety. However, music acts as a stimulus and influences pain elimination, it masks the unpleasant sounds and encourages relaxation [15].

Many patients are afraid of winding up in dental chair, with drills going off in their mouth; they refrain from addressing dental problems. In literature, music is used as alternative therapy to reduce dental anxiety [1,3,6,7,10-15]. Novelty of this study is that this study mainly focuses on the correlation of salivary cortisol levels and effects of musical therapy in patients undergoing prosthetic rehabilitation with fixed prosthesis.

Hence the aim of the present study is to determine the effect of musical therapy on salivary cortisol levels and OHRQoL in patients under prosthetic rehabilitation with fixed prosthesis.

Study Objectives

- To evaluate OHRQoL before prosthetic rehabilitation.
- To evaluate OHRQoL using OHIP after prosthetic rehabilitation
- To evaluate salivary cortisol levels in patients undergoing treatment for FPD with musical therapy. (experimental group)
- To evaluate salivary cortisol levels in patients undergoing treatment for FPD without musical therapy. (control group)
- To compare salivary cortisol levels of intervention group with control group.
- To correlate OHRQoL of both groups with their salivary cortisol levels before and after treatment.

REVIEW OF THE LITERATURE

Mustafa NW et al., in 2021 conducted a study with music therapy on gagging patient. Music was given to the patient according to their will and the impact of music on physiological parameters was investigated. 25 patients were chosen at random to undertake the impression procedure. The severity of gagging was subsequently determined using a self-reported gagging problem evaluation questionnaire. The identical patient's maxillary impression was obtained twice in two different intervals, the first without any musical therapy and the second with musical therapy. The HR and oxygen saturation were measured during both procedures, and the psychometric assessment was examined using the (OHIP-14) [1].

The effects of music therapy on physiological markers during dental procedures in patients suffering from dental stress were compared by Mejia-Rubalcava C et al., In this investigation, physiological parameters were measured in 34 patients at random. The Dental Fear Scale (DFS) and a modified version of the MDAS were used to assess dental anxiety [3]. When saliva secreted during active process, it is regulated by ANS. Stress hormones such as epinephrine and nor epinephrine fluctuates in flight and fright responses. Hence, correlation of salivary cortisol with musical therapy was assessed here [3].

A prospective pilot study was done by Mijiritsky E et al., in which development and validation of a questionnaire was done for evaluating the impact of prosthetic dental treatments on patients OHRQoL. A total of 24 adult volunteers were recruited and asked to fill a questionnaire twice before treatment and after treatment to measure the influence of prosthetic treatment on OHRQoL. By using OHIP they calculated significant difference [4].

In Turkey, Gulnihar Y and Kupeli I, studied the effect of different kinds of music on anxiety during implant surgery in 2020. Researchers compared the effects of various types of music and its effect on anxiety levels while doing dental implant procedures. The study included 80 dental implant surgery patients. Four groups of patients were formed. Group 1 consists of traditional Turkish music, group 2 of classical music, group 3 of slow rock music, and group 4 of the control group. The patient's physiological parameters such as oxygen saturation measured by oximeter, BP, pulse rate were

measured, as well as Corah's dental anxiety assessment. Turkish music and classical music were effective introducing dental anxiety compared to soft rock music [6].

A study was done in 2016 by Di Nasso L et al., to determine impact of music as a non pharmacological stimulant on symbolic changes in physiologic parameters such as before, during, after treatment, as well as anxiety levels as measured by the Corah dental anxiety scale. In this study, patients were given 432 Hz music to listen while endodontic treatment, and their SBP, DBP, and HR all fell dramatically [10].

MATERIALS AND METHODS

A randomised controlled trial (CTRI/2022/09/045795) will be conducted in Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (M), Wardha from May 2023 to May 2025. Ethical Clearance: Ethical approval for the study was obtained from the Institutional ethics committee of Datta Meghe Institute of Medical Sciences (Deemed to be University) (ref no: DMIMSU(DU)/IEC/2022/782).

Inclusion criteria:

- Patients aged 18-60 years with partial edentulism were randomly selected.
- Patients undergoing treatment for 3 unit, 4 unit FPD or a single crown.
- All patients will be given consent form, also instructions will be given by both verbally and in written in both Marathi and English languages.

Exclusion criteria:

- Patients with medical history of systemic diseases such as physical and mental disabilities, respiratory, pregnancy, neuromuscular, cardiovascular, disorder.
- Patients who needs full mouth rehabilitation.
- Patients undergoing treatment for implant supported overdenture.
- Patients with profound hearing disabilities.

Sample size calculation: The sample size calculation is done using the sample size formula for absolute difference between two means. Thirty samples will be included in the study, randomly divided into two groups.

Sample size formula for difference between two mean:

$$N = \frac{(z\alpha + z\beta)^2 (\delta_1^2 + \delta_2^2 / k)}{\Delta^2}$$

where,

$Z\alpha$ is the level of significance at 5% i.e., 95%

Confidence interval=1.96

$Z\beta$ is the power of test=80%=0.84

δ_1 =SD of salivary cortisol in control group=0.1 [3]

δ_2 =SD of salivary cortisol in experimental group=0.9 [3]

$k=1$

Δ =Difference between two means [3]

=1.3-0.5=0.8

$$n = \frac{(1.96+0.84)^2 (0.12+0.92/1)}{0.82}$$

=10.04

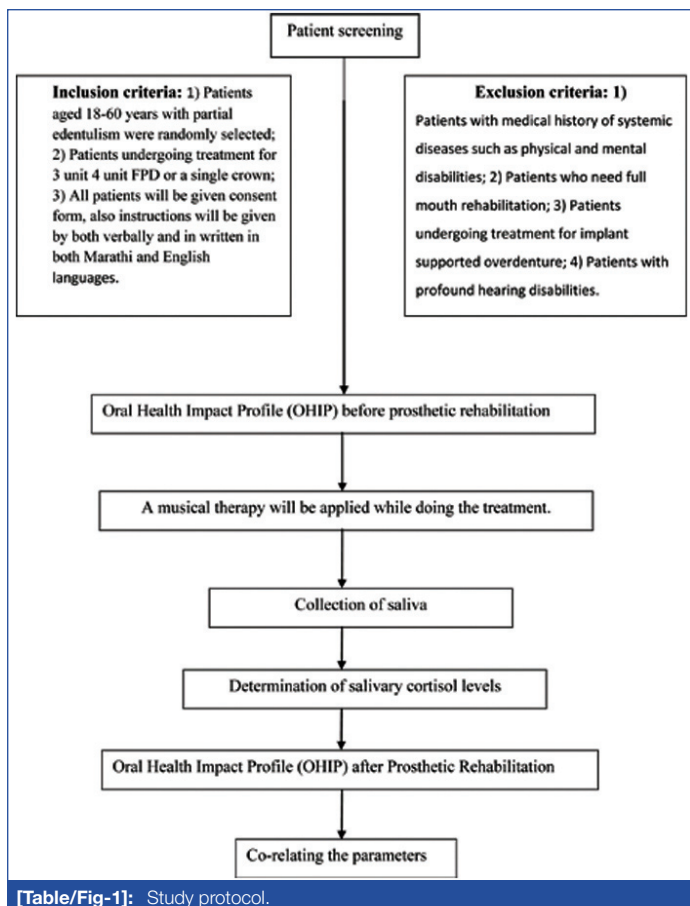
$n=15$ patients needed in each group

Subjects will be selected using simple random sampling method. A protocol to perform study is summarised in [Table/Fig-1].

Parameters to be compared:

1. Determination of Oral Health Impact Profile (OHIP):

- It gives idea about patient's opinion and satisfaction and it will be assessed by OHIP questionnaire. There are seven domains that are included in this questionnaire [4].



[Table/Fig-1]: Study protocol.

- Question will be asked and responses will be categorised in a likert format scale which is five point scale, ranging from 0-4 (0=never, 1=hardly, 2=occasionally, 3=fairly often, 4=very often)
- Their relationship between pretreatment and post-treatment results will be assessed.

2. Collection of saliva and determination of salivary cortisol levels:

- Each patient will be directed not to drink, eat or perform oral hygiene before and during the procedure.
- Collection of whole saliva will be done by allowing the saliva to accumulate in the floor of mouth and then spitting into a graduated plastic container: 1st sample-before start of treatment, 2nd sample-after 45 min, (45 min time required to complete treatment).
- Saliva will be collected and stored at -20°C until it is processed using the commercial available Salivary Cortisol ELISA Test Kit.

3. Musical therapy:

- A musical therapy will be given to the patients while doing the treatment.

- According to patient's comfort and preference music and the volume will be selected and adjusted.

3. Headphones will be used for patients to listen the music.

Primary outcome- Reduction in stress and anxiety levels will be assessed using cortisol levels in saliva before and after musical therapy.

Secondary outcome- The OHRQoL will be assessed using OHIP in patients rehabilitated with fixed dental prosthesis before and after musical therapy.

STATISTICAL ANALYSIS

Analytical tests like Chi-square test, student's t-test and Pearson correlation test will be performed. All the statistical analysis will be performed using SPSS software, version 27.0. $p < 0.05$ will be considered as the level of significance.

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