

Study Protocol On “Effect Of Playing An Audio Clip For Pain And Anxiety Control For Burn Patients While Dressing Burn Wounds: RandomizedControlled Trial.

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ARTICLE INFO ABSTRACT

Introduction: Burn injuries cause significant pain and anxiety, especially during procedures like dressing changes. Current treatments often involve opioid and antianxiety medications, which may not fully alleviate discomfort. Music therapy, including patient-preferred audio, has emerged as a non-pharmacological option to address these challenges. This study assesses tailored audio interventions for burn patients in Qatar, where cultural preferences, such as Quranic recitations, may enhance therapeutic outcomes.

Research Methodology: This open-label randomized controlled trial will assess the effectiveness of listening to an audio clip as an adjunct to treatment as usual (TAU) among hospitalized burn patients. Eligible patients, meeting specific inclusion criteria, will be randomly assigned to either the intervention or control group, and outcomes related to pain and anxiety will be analyzed without blinding.

Results: Descriptive statistics will summarize sample characteristics, with normally distributed data reported as mean (SD) and non-normally distributed data as median (IQR). Categorical data will be analyzed using Chi-square or Fisher's exact test, and continuous data using unpaired t-tests or Mann-Whitney U tests. Multivariate regression will assess predictors for pain and anxiety scores.

Discussion: The primary outcomes of this study are reduced pain and anxiety levels during dressing changes, with a 15-20% reduction anticipated in the experimental group compared to the control group receiving treatment as usual. The secondary outcome is improved control of hemodynamic parameters (heart rate, respiratory rate, and blood pressure)& analgesic use in the experimental group compared to the control group.

Key Words: Burn pain management, Anxiety reduction, Audio intervention

Introduction and Background

Burn injuries demand immediate care and often require long-term treatment, including multiple outpatient visits for rehabilitation, dressing changes, and reconstructive surgeries. These treatments frequently necessitate extended hospital stays, and the associated health outcomes are compounded by additional socio-economic burdens for burn victims and their families (Ghezeljeh et al., 2015). Burn patients endure various painful procedures, such as wound debridement, dressing removal, and wound washing. These procedures are known to increase anxiety and pain, significantly impacting the healing process. Managing this pain and anxiety typically involves the use of opioid analgesics and antianxiety medications as a primary approach (Ferguson & Voll, 2004), did not find significant reductions in pain or anxiety with audio-based interventions. The evidence regarding the efficacy of playing audio clips for burn patients is thus mixed, with some research supporting its effectiveness and other findings showing little to no benefit.

Given this inconsistent evidence, there is no compelling support to suggest that audio clips are universally

effective for reducing pain and anxiety in burn patients. This study aims to explore further and contribute to the evidence base by investigating the effects of patient-preferred audio clips as a non-pharmacological intervention for pain and anxiety management. Al Wakra Hospital, Qatar's National Burns Center, currently does not use adjuvant therapies alongside its analgesic protocols for pain and anxiety management. Based on consultations with burn doctors and the medical team, the researcher aims to evaluate the effectiveness of an audio clip intervention in this setting, which could lead to changes in practice at the hospital.

Cultural factors are also considered in the selection of the preferred audio clip, acknowledging the role of patient preference in therapeutic interventions. Audio clip interventions are simple, non-invasive, low-cost, and well-tolerated, making them a viable option for patients and healthcare staff in clinical settings. However, limited data is available on the combination of patient-preferred audio clips with standard treatment for reducing pain and anxiety among hospitalized burn patients.

Most clinical trials examining audio-based interventions for burn pain and anxiety have been conducted in Western countries, where the audio interventions are often predefined by the researcher. In contrast, this study focuses on patient-preferred audio clips, including self-selected music, sounds from nature, and religious recitations. The researcher identified a lack of clinical evidence regarding the use of patient-selected audio clips, particularly Quranic recitations, among burn patients in Qatar and the Middle East.

There is growing interest in the Middle East in using audio-based interventions in clinical research. For example, Weill Cornell Medicine-Qatar (WCM-Q) has introduced music therapy courses aimed at using audio interventions to treat various health conditions. Conducting this study in Qatar, with its culturally diverse population, provides an opportunity to evaluate the effectiveness of different audio preferences, which may vary according to individual backgrounds.

The diversity in patient-selected audio clips will allow for a broader understanding of the intervention's effectiveness and enable generalization of the results. Should the audio clip intervention prove successful in reducing pain and anxiety, it could also lead to reduced consumption of analgesics and anxiolytics, ultimately improving patient outcomes and reducing hospitalization times.

Currently, there is no strong evidence to suggest that playing audio clips, particularly Quranic recitations, is highly effective for reducing pain and anxiety in burn patients. While some studies, such as those by (Mohammadpoor et al., 2020) and Masoomah et al. (2020), have explored the impact of Quranic recitations on anxiety in chemotherapy and acute coronary syndrome patients, they did not focus on burn patients or include pain as an outcome measure. This study seeks to fill this gap by exploring the effect of patient-preferred audio clips, including Quranic recitations, on burn patients in Qatar.

To date, no studies in Qatar have explored the impact of audio clips as an adjunctive therapy for burn patients. This research aims to introduce audio clips as a potential intervention to reduce pain and anxiety, improve the quality of life, and increase patient satisfaction during hospitalization. The findings may inform future practice and lead to the incorporation of non-pharmacological interventions like audio clips in burn care protocols at Al Wakra Hospital and other healthcare settings in the region.

Objectives

The objectives of the study were:

Primary Objective - To investigate the effectiveness of listening to an audio clip intervention in reducing burn's patient pain and anxiety during burns dressing compared to treatment as usual (TAU).

Secondary Objective- To investigate whether the experimental and control group differ in terms of a) Hemodynamic parameters like heart rate, respiration rate and blood pressure. b) quantity and type of pain medications used during burn dressing.

Hypothesis:

The following hypothesis is formulated

H1: The use of an audio clip intervention will significantly reduce the pain levels experienced by burn patients during dressing Changes in comparison to the standard treatment as usual (TAU).

H2: The use of an audio clip intervention will significantly reduce the anxiety levels experienced by burn patients during dressing Changes in comparison to the standard treatment as usual (TAU).

H3: There will be a significant difference in hemodynamic parameters (heart rate, respiration rate, and blood pressure) between the experimental group (audio clip intervention) and the control group (TAU) during burn dressing changes.

H4: The quantity and type of pain medications used during burn dressing will differ significantly between the experimental group (audio clip intervention) and the control group (TAU).

Study Methodology

Study Design: This open-label, randomized controlled trial will assess the effectiveness of listening to an audio clip as an adjunct to treatment as usual (TAU) for hospitalized burn patients. The study will follow a prospective, parallel-group design, with participants randomly assigned to either the intervention or control group. No blinding will be performed, but the outcome analysis will be blinded. Patients meeting the inclusion criteria of 10-30% total body surface area burns and a pain score of ≥ 4 will be recruited, while those

with cognitive impairments or critical conditions will be excluded.

Pilot Study: A pilot study will be conducted with four burn patients three months before the main study. The purpose is to test the proficiency of the data collection tools and to assess the feasibility of the study procedures. This preliminary phase will help refine the study design and ensure that the chosen methods are effective and practical for the larger trial.

Setting: This open-label randomized controlled trial will be conducted in a selected Government Hospital Qatar.

Tools/Instruments: Demographic data, including age, sex, occupation, education, degree, nature, location, and body surface area of burns, along with analgesic use and audio clip selection, will be collected.

Numerical Rating Scale (NRS): A segmented 0-10 scale will be used to assess pain intensity, categorized as none (0), mild (1-3), moderate (4-6), and severe (7-10). Pain scores will be measured before and after the burn dressing procedure.

Beck Anxiety Inventory (BAI): This 21-item tool will assess anxiety levels, categorized as low (0-21), moderate (22-35), and potentially concerning (36+). Anxiety scores will be collected 30 minutes before and after the procedure.

Inclusion criteria: Adult patients aged 18 years and above, with severe burn injuries covering 10%-30% of total body surface area (TBSA) as per clinical guidelines, and an expected hospital stay of at least 10 days. Patients must be literate to understand instructions and the audio clip, and capable of providing questionnaire responses. Additionally, participants must have a pre-intervention pain score of ≥ 4 on the Numerical Rating Scale (NRS), indicating moderate pain.

Exclusion Criteria: Burn patients who are critically ill and on ventilator support, patients with respiratory problems or hearing impairments, those with cognitive impairments, and burn patients with diabetic neuropathy.

Study Population and Study Setting/ Location Target Population: The target population includes patients undergoing painful burn dressings, such as skin grafting, escharotomy, debridement, and dressing changes. These patients are of particular interest because they typically experience significant pain and anxiety due to repeated burn dressing procedures.

Sample Size: The sample size for this study is calculated to achieve a 30% reduction in pain. The control group is expected to have a mean pain score of 6 on the NRS, while the experimental group should achieve a score of 3. With 80% power, a 5% significance level, and a 1:1 treatment allocation, 50 subjects per group (100 total) are required. Additionally, a 15% loss to follow-up is accounted for. The formula for sample size calculation is:

$$n = f(\alpha/2, \beta) \times [p_1 \times (100 - p_1) + p_2 \times (100 - p_2)] / (p_2 - p_1)^2$$

where p_1 and p_2 are the percent 'success' in the control and experimental group respectively, and

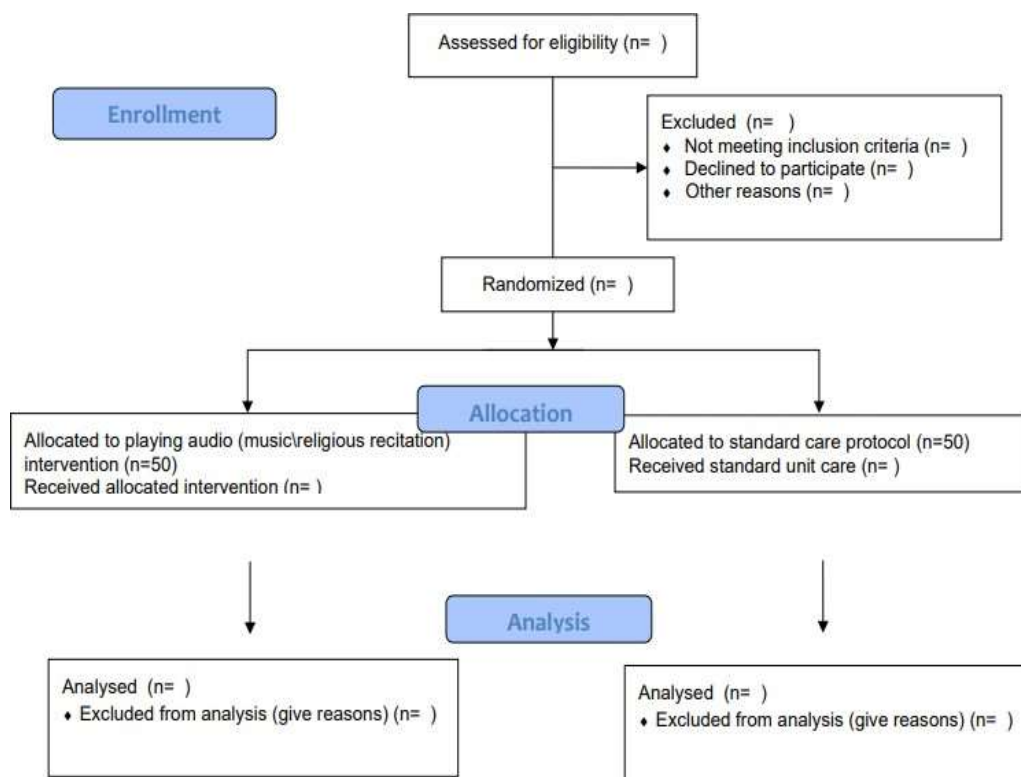
$$f(\alpha, \beta) = [\Phi^{-1}(\alpha) + \Phi^{-1}(\beta)]^2$$

Φ^{-1} is the cumulative distribution function of a standardized normal deviate.

Adjustment for crossovers based on formula: $n_{adj} = n \times 10,000 / (100 - c_1 - c_2)^2$

where c_1 and c_2 are the percent cross-over in the control and experimental group respectively

Figure: 1 Flow Chart of The Clinical Trial Design based on the Standard Protocol



Study Procedure: This intervention is designed based on a review of literature and suggestions from medical experts. Prior notification will be given to unit nurse leaders to inform the research team about potential subjects. The principal investigator will consult the Scheduling and Tracking Office (STO) for elective admissions, while emergency admissions will be notified by the unit in charge. The principal investigator will assess patient eligibility, and if deemed eligible according to the checklist, the investigator will conduct a formal interview to explain the study. The potential subject will receive a research information sheet, and those not interested may opt-out. The research nurse will assess eligibility according to the pre- defined checklist based on inclusion criteria, and patients will be assigned a PIN/identification number. The principal investigator will assign a study code for each participant and randomly assign them to either the experimental or control group. Randomization will be unstratified, with patients allocated to randomly distributed blocks of four and six. Once four patients are completed in the random block, samples will be assigned equally to control and experimental groups in a 1:1 ratio. Randomization, assessment, and education will occur in the inpatient units.

Patients, their clinical team, and the research team will be aware of patient allocation. Information will be given to the team, and the audio clip will start from Day 1 for the experimental group, while the control group will not receive the intervention. Blinding is not possible since subjects will select and listen to their preferred audio clips. The analysis plan will be pre-specified and conducted in a blinded manner to minimize potential bias. Data related to religion will be collected, and during the initial interview, patients' preferred audio clips (e.g., music, nature sounds, religious recitations) will be recorded on a USB under each patient's health card number. Music players, selected by patients, will be used to play the audio clips during the intervention. The Numerical Rating Scale (NRS) and Beck Anxiety Inventory (BAI) will be used to assess pain and anxiety, both of which are reliable and valid tools. A clinical assessment form will collect data on rescue analgesia (dosage, drug, route) and hemodynamic parameters (blood pressure, pulse, and respirations) using a Dynamap.

The intervention, including audio clips and music player software, will be tailored to the patient's preferences. Patients in the intervention group will be introduced to the music player before the procedure. On the same day or the next, prior to the dressing change, NRS and BAI will be administered to assess pain and anxiety, and vital signs will be recorded. Audio clips selected by the patients will be played continuously during the dressing change. Headphones/earphones will be provided to help patients focus on the audio clip and minimize distracting sounds in the burn unit (e.g., monitors, talking).

Nurses will play the audio clips during the dressing, which will last for at least 90% of the dressing time over

the intervention days. If the patient does not listen to the audio clip, they will be considered a dropout. The intervention will last 10 days, during which the audio clip will play throughout the dressing procedure, typically lasting 60-90 minutes. A researcher will be present to oversee the treatment process. If a patient voluntarily decides not to continue or experiences intolerable pain, they will be considered a dropout. After completing the intervention, pain, anxiety, and hemodynamic parameters will be collected.

Control group patients will receive treatment as usual, with no additional intervention. Pain, anxiety, and hemodynamic parameters will be measured before the dressing (0 minutes) and after the dressing (60 minutes) in both the intervention and control groups.

Burn Unit Care Protocol: According to the routine standard care in the burn unit, dressings are changed daily for patients with burn injuries. Upon admission, patients are bathed with water and a chlorhexidine scrub. The burn dressing is performed by the attending burn unit nursing team. After cleaning, the burn wounds are dried using sterile dressing pads.

An antibiotic ointment, silver sulfadiazine, is applied to the burn wounds. The wounds are then covered with a double layer of sterile dressing pads, which are secured with a setonet. Pharmacological interventions, including pain management and antibiotics as prescribed by the attending physician, are administered as part of the routine care. These standard procedures will continue throughout the study period for all patients, ensuring consistent care between the control and experimental groups.

Data Collection:

Baseline Data Collection& confidentiality: The research team members will collect data related to demographic variables using a researcher-made questionnaire. Standardized tools, the Numerical Rating Scale (NRS) and Beck Anxiety Inventory (BAI), will be used to collect data on pain and anxiety levels.

Protected personally identifiable information (PII) will be replaced with research identification codes (ID codes). Data will be collected with de-identified codes, which will be used to replace patient identifiers such as name, health care (HC) number, and date of birth. The link between the code and the identifier will be destroyed upon completion of the study. Identified data will be stored for a minimum of five years.

All collected data will be entered into a database. Only research team members will have access to the database, which will be protected by a passcode. Access to the master code lists/key codes will be limited to the research team. Files containing electronic data will be password-protected, and computers containing these files will be locked when left unattended. Research information sheets and other authorization forms will be stored securely in locked cabinets/rooms, separate from the research data.

The study is expected to start in September 2022 and will last for a total of 1 year and 6 months. This duration includes the submission and approval process, data collection, analysis, and the writing of the final report and manuscript.

Informed Consent: Prior notification will be given to unit nurse leaders to inform the principal investigator about the admission of potential subjects. Upon receiving notification, research team members will approach the patients and assess the percentage of burns and the inclusion criteria. After confirming that the patient is fit to participate in the study, a research team member will meet the patient in the inpatient ward to explain the study and its purpose.

The research team member will provide the patient with the research information sheet and ask for their consent to participate in the study. A time frame of 2 days will be given for the patient to make a decision. During this period, the patient will be provided with the contact information of the research team in case they have any questions or wish to communicate their decision.

Once consent is obtained, subjects will be randomly assigned to either the experimental or control group using a computer-generated randomization sequence. The sequence will be concealed in opaque envelopes and will only be opened after consent is given, as outlined in the research information sheet.

Subject Withdrawal/ Withdrawal of Consent: All participants will be informed of their right to refuse participation or to withdraw from the study at any time. Data from participants who withdraw will not be used in the analysis. Instead, the number of dropouts or the attrition rate will be reported in the results or discussion sections of the study upon completion. Any data collected from participants who withdraw will be managed in accordance with the Hospital Research policy.

Risk: There is no anticipated risk associated with the intervention.

Statistical Analysis: Descriptive statistics will be used to summarize the sample characteristics and participant data distribution. Normally distributed data will be reported with mean and standard deviation (SD), while non-normally distributed data will be presented as median and inter-quartile range (IQR). Pain and anxiety scores will be calculated as the sum of responses across various domains.

Categorical data will be summarized using frequencies and proportions. Associations between two or more qualitative variables will be assessed using the Chi-square (χ^2) test or Fisher's Exact test, depending on the appropriateness. For comparisons of quantitative data between two independent groups, either an unpaired

t-test or Mann-Whitney U test will be used, depending on the data distribution.

Univariate and multivariate linear regression analyses will be performed to assess the associations between predictors (such as group, age, gender, education, etc.) and the outcomes (pain and anxiety scores, and vital signs). The results of the linear regression analysis will be presented as coefficients with corresponding 95% confidence intervals (CI). All p-values will be two-tailed, with a p-value less than 0.05 considered statistically significant. All analyses will be performed using STATA version 15.1.

Discussion and Outcome:

The primary outcomes of this study are anticipated to show reduced pain levels during dressing changes in the experimental group by 15-20% compared to the control group, which receives treatment as usual. Similarly, it is expected that anxiety levels in the experimental group will decrease by 15-20% during dressing changes, compared to the control group. The results of these comparisons will be analyzed once data collection and analysis are complete.

The secondary outcomes are expected to demonstrate better control of hemodynamic parameters such as heart rate, respiratory rate, and blood pressure in the experimental group compared to the control group. Additionally, it is hypothesized that the use of analgesics will be lower in the experimental group due to the effectiveness of the intervention. These outcomes will be further explored and confirmed following the completion of the study.

Adverse Event Reporting: In the event that a participant develops any adverse or serious events related to the study, the intervention will be immediately stopped, and the event will be managed in accordance with the hospital's research policy. In the case of a cardio-respiratory arrest, a code blue will be activated, or a Rapid Response Team (RRT) code will be initiated as per the patient's clinical status.

Ethical consideration: This study will be conducted following approval from the Institutional Review Board (IRB) and the Medical Research Center (MRC) of Hamad Medical Corporation. The principal investigator affirms that the study will adhere to the principles outlined in the Declaration of Helsinki, Good Clinical Practice (GCP), and the laws and regulations set by the Ministry of Public Health (MoPH) in Qatar.

A research information sheet will be provided to patients who express willingness to participate, detailing the objectives and duration of the study. Participants will be informed of their right to refuse, participate, or withdraw from the study at any time, without any consequences.

Patient anonymity and confidentiality will be strictly maintained, with access to the data restricted to the core investigators. The routine treatment for patients in both the experimental and control groups will not be disrupted. Throughout the research process, care will be taken to ensure that no harm or discomfort is caused to the patients.

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Consent for Publication: Not applicable.

Competing Interests: The authors confirm that they have no competing interests.

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