

# INPLASY PROTOCOL

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**Review Stage at time of this submission:** Piloting of the study selection process.

**Conflicts of interest:**  
None declared.

## Audio Intervention for Acute Pain Management - Protocol of Systematic Review and Meta-Analysis

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**Review question / Objective:** This study aims to investigate, review, and assess existing literature concerning audio intervention to reduce acute pain.

**Condition being studied:** The study will focus on acute pain experienced by adults in any diseases or surgical procedures.

**Eligibility criteria:** This study will exclude papers published older than ten years ago to collect updated data, non RCTs, non-English literature, paper with combined interventions, and papers with an incomplete essential statistical value of pain for meta-analysis.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 January 2023 and was last updated on 01 January 2023 (registration number INPLASY202310002).

### INTRODUCTION

**Review question / Objective:** This study aims to investigate, review, and assess existing literature concerning audio intervention to reduce acute pain.

**Rationale:** Undermanaged acute pain has potential consequences in the development of chronic pain. Up to one-half of surgical patients experienced prolonged pain after lower limb surgery, coronary bypass, and

breast and thoracic surgery (Kehlet et al., 2006). In research of 95 patients undergoing breast surgery, acute pain is more prevalent in those developing chronic pain (45%) than those without chronic pain (27%) with  $p=0.05$  (Poleshuck et al., 2006). Similarly, a post-operative follow-up of 30 lateral thoracotomy patients revealed that intense postsurgical pain is a risk factor for developing chronic pain (Katz et al., 1996). Plums et al. (2006) supported that chronic pain was associated with constant and

severe postsurgical pain ( $p=0.0004$  and  $p=0.0001$ ) accordingly.

Untreated patient pain can also lead to complications such as reduced quality of life (QoL). A study by Strassels et al. (2004) revealed the reduced sexual function and physical activities associated with pain after surgery, assessed with a Short Form (SF) of 36 QoL questionnaire and treatment of outcomes of pain survey. A prospective cohort carried out by Wu et al. (2003) supported the deteriorating physical and mental functions correlated with SF 12 QoL Questionnaires ( $P < 0.01$  for both). Some studies specifically found that acute pain influences impaired sleep (Pavlin et al., 2004; Dihle et al., 2006) and physical function (Foss et al., 2009).

Inadequate management is an influencing factor. These factors compromise the lack of patient education from health professionals about opioid use (Apfelbaum et al., 2003), physiological side effects of analgesic therapy, concern about cost, and fear of drug addiction prescribed by doctors (Eberhart et al., 2002). Those elements contribute to the patient's compliance and, thus, the effectiveness of pharmacological acute pain management.

Nowadays, in addition to pharmacological management for pain, complementary therapies have been performed as an integral part of health care (Snyder & Wieland, 2003). In a study conducted on 31,044 adults in the US, the usage rate of alternative therapies was 36% in 2003, mainly covering back pain and lumbago and neck pain. While prescribed drugs were performed to address physiological issues, alternative therapies were applied to manage affective, cognitive, and behavioral aspects associated with pain (Yavuz, 2006). The complementary is applied for moderate and severe pain intensity (Delaune & Ladner, 2002). These therapies can be divided into non-invasive such as music therapy, meditation, biofeedback, and progressive relaxation, and invasive such as acupuncture (Menefee & Monti, 2005).

In the era of technology, digital-integrated complementary intervention has been used to reduce chronic pain, such as audio intervention. For example, a randomized

controlled trial/RCT of Audio recording was conducted by Eaton et al. (2022) on 109 cancer survivors with chronic pain. Through the pre-recorded hypnosis and relaxation audio, pain reduction can be achieved. Supporting this, a Meta-Analysis carried out by Lee (2016) found that music intervention had a statically significant effect in reducing pain on the 0-10 scale (MD = -1.33) and another scale (SMD - 0.39). Despite the beforementioned concerns, a small number of studies investigating: 1. the effect of audio greater degree, such as type of content (informative, suggestive, relaxing, or with music, and 2. The implication is specified in acute pain.

**Condition being studied:** The study will focus on acute pain experienced by adults in any diseases or surgical procedures.

## METHODS

**Search strategy:** The search will be performed by an independent reviewer (KT) and two pre-trained research assistants (AK & MT) under the supervision of a supervisor (CC). The search will be conducted from January 15th to February 28th, 2023. The following terms will be employed for the literature search: "Acute Pain," "Audio Intervention," "Suggestive Audio," "Music Therapy," "Pain Management," "Pain Remedy," and "Pain level." The search will be filtered based on the Boolean operator (And, Or, and Not).

**Participant or population:** The population of the study will be adults with acute pain.

**Intervention:** The study intervention in the study will include any audio-related intervention including but not limited to informative, suggestive, relaxing and music therapy. This intervention may or not be associated with other mobile-based or computer-based devices.

**Comparator:** None reported.

**Study designs to be included:** This study will use Systematic Review and Meta-Analysis by following the Preferred Reporting Items for Systematic Reviews

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and Meta-Analysis (PRISMA) 2020 guideline. This study will use systematic review and meta-analysis of RCTs.

**Eligibility criteria:** This study will exclude papers published older than ten years ago to collect updated data, non RCTs, non-English literature, paper with combined interventions, and papers with an incomplete essential statical value of pain for meta-analysis.

**Information sources:** Six electronic databases (PubMed, Web of Science, Cochrane library, Ovid Medline & Medline (EBSCOhost), and Embase) will be searched through the University of Pecs portal access.

**Main outcome(s):** The primary outcome of the study is "acute pain which is defined as a sudden onset of pain which is less than three months resulting from injury, surgery, illness, trauma or invasive medical procedure," by NANDA nursing diagnosis. Pain can be measured by categorical scales including verbal (verbal descriptor scale VDS), numerical (Verbal Numerical Rating Scale VNRS), and VAS (Visual Analog Scale), according to the world federation of societies of anaesthesiologists and other validated pain assessment tools such as the Faces Pain Scale-Revised (FPS-R) (Hicks et al., 2001; Ferreira-Valente et al., 2011).

**Additional outcome(s):** The Secondary outcome will include the use of analgesic and the length of recovery. While the analgesic will include opioid and nonopioid drugs, the length of recovery will be collected from length of stay (LoS) from arrival to hospital to discharge time.

**Data management:** The first author (KT) will screen all the studies with two research assistants who will be blinded by the research hypothesis (AK) and (MT). The data will be searched from the online databases. The found studies will be extracted in RIS format, saved in Mendeley, and uploaded to the Rayyan AI website. The search will be conducted asynchronously from January 7th to

February 7th, with weekly follow-up through Google Meetings.

The data will be filtered in several steps. The first step will compromise the selection of publication year via an automated database search engine and the removal of duplicates via web-based Zotero. Secondly, the abstract literature will be assessed based on population, intervention, outcome, and study design. Third, the first author will review the full paper with supervisors (KC) supervision shortlisted papers with a summary of intervention, pain assessment, and statistical pain result ( $p$ -value, standard deviation, and mean).

**Quality assessment / Risk of bias analysis:** The risk of bias in individual studies will be assessed based on the Cochrane Risk of Bias Assessment guideline. The Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) tool (version of August 22nd, 2019) will be used. The risk of bias assessment will comprise domains of randomization, deviations from intended intervention, missing data, outcome measurement, and selection of reported results. This risk of bias assessment will be performed by the first author (KT), (AK), and (KC). Robvis website tool will be deployed to create "traffic light" plots of domain-level judgment within each bias domain.

**Strategy of data synthesis:** The cumulative evidence will be analyzed using Grading of Recommendation, Assessment, Development, and Evaluations) GRADE approach. The GRADE analysis will be applied to construct a summary of findings (SoF) table. The Web-based GRADEpro will be used to manage the data. The detail of this summary will consist of author, publication year, country of origin, title, population, intervention, pain assessment tools, pain outcome, absolute effects, relative effects, and footnotes providing judgment. The intervention effectiveness will be synthesized in the narrative analysis.

**Subgroup analysis:** the subgroup analysis will be presented in a summary table of chracteristic of included studies. this

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characteristics will include article title, first author, country, year of publication, study sample (age, gender, number of arms and baseline acute condition), pain assessment points, pain assessment tools, statistical outcomes (p value, standard deviation, mean and interpretation) and conclusion.

**Sensitivity analysis:** The sensitivity analysis will be presented in a table format in which odds ratio, risk ratios and risk differences will be used for dichotomous variables while standardised means of all scales (variables) will be used for continuous outcome. This analysis will be performed using R.

**Language restriction:** This systematic review will only include studies published in English.

**Country(ies) involved:** This systematic review will involve University of Pécs, Hungary.

**Keywords:** acute pain, audio intervention, pain reduction.

**Contributions of each author:**

**Author 1 - Kevin Efrain Tololiu - Author 1** drafted manuscript including search strategy, data management, risk of bias assessment and data synthesis strategy.

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**Author 3 - Krisztina Csokasi - The author** contributed to the development of risk of bias assessment strategy and data synthesis.

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