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# The experience and effects of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: a randomised crossover and feasibility study protocol

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## Abstract

**Introduction:** Australian nurses have experienced higher levels of anxiety during the COVID-19 pandemic compared with the pre-pandemic. This may have affected their long-term mental health and intention to stay in the profession resulting in a workforce shortage which, further impacts the health of the public. Management is urgently required to improve nurses' wellbeing. However, there is limited evidence available. The proposed clinical trial aims to evaluate the feasibility and therapeutic effects of using light acupuncture and five-element music therapy to improve nurses' mental health and wellbeing during and post COVID-19.

**Methods and analysis:** This randomised, single blinding, two-arm crossover feasibility pilot study involves a 1-week run-in period, 2-week intervention and 1-week washout period in between interventions. Thirty-six eligible nurses will be recruited from the community and randomised into either a combination of light acupuncture treatment and five-element music therapy group or no treatment group for 2-week. After a 1-week washout period, they will be swapped to the different group. Participants will be asked to complete a set of online questionnaires throughout the trial period. Data will be analysed by Linear mixed modelling using R software.

**Ethics and dissemination:** Ethical approval was attained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). Research findings will be shared with hospitals and in various forms to engage broader audiences, including national and international conferences presentations, open-access peer-reviewed journal publications, and local community workshop dissemination with healthcare professionals.

**Trial registration:** Australian New Zealand Clinical Trials Registry (ANZCTR):

ACTRN12621000957897p https://www.anzctr.org.au/ACTRN12621000957897p.aspx

**Keywords**

Acupuncture; low-level laser acupuncture; photobiomodulation; nursing; mental health; depression.

## Strengths and limitations of this study

- ✓ A first study evaluating the light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19 in Western Australia hospitals.
- ✓ This study will examine the role of involving nurses in light acupuncture and five-element music therapy, which has remained under-explored in hospitals.
- ✓ Qualitative and quantitative approaches will be used to comprehensively assess the trial outcomes to inform a powered therapeutic effectiveness trial and whether it would be feasible.
- ✓ The outcomes to be assessed by this study have relevance to the healthcare workforce, patient outcome and policymakers.
- ✓ The findings need to be interpreted with consideration of the following limitation: the study uses a randomised crossover design, and this could potentially influence the findings of the therapeutic effect due to the carry-over effect—it is difficult to estimate the time required for the intervention to be fully washed-out.

## Introduction

The most affected professionals worldwide throughout the COVID-19 pandemic are healthcare workers, with at least one in five reporting mental health difficulties such as anxiety, depression, and stress-related symptoms including sleep disturbances and insomnia attributed to the pandemic (1-4). Nurses and midwives are reported to be the most affected of

all health professionals (1, 2, 5). Though Australia has not experienced the pandemic as severely as other countries, one study from a local area health service found Australian nurses experienced higher anxiety levels than their counterparts in other countries during the pandemic (6). This high level of anxiety can result in a lack of motivation and intention to leave the nursing and midwifery profession (7), leading to a workforce shortage and its associated impact on the health of the public. Furthermore, the stress and anxiety associated with the pandemic are expected to affect nurses' long-term mental wellbeing (8) and intention to stay in the profession.

Traditional Chinese Medicine (TCM) played a huge role and has been extensively used around the world to combat stress and promote mental health well-being (9). During COVID-19, TCM has also been used widely in China (10), and the World Health Organization has recognised its contribution. Recent systematic reviews have identified high-level evidence which supports the safe and effective application of acupuncture for treating depression and anxiety (11).

Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one of the more recent technological developments in acupuncture that integrates cutting-edge laser technology with a centuries old modality TCM (12) . Light acupuncture is non-invasive, painless, non-infectious, and safe to use (13) . This form of acupuncture has also become increasingly popular among patients with needle phobias, particularly older people, and children (14-16). Several studies have documented light acupuncture as a promising modality in managing mental wellbeing (17, 18).

The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of Medicine), the earliest and most influential medical text of TCM, states that different elements (tunes) of music can help treat different emotional disorders (19, 20). Based on its

theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi (*So*), and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal, wood, fire, water). According to TCM, the five elements in nature also represent five main human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry, anger, joy, and fear). For example, the Jiao note, corresponding to the wood element, influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a good combination of the notes can help balance the Yin and Yang and maintain the human body in a state of equilibrium and good health.

Acupuncture and five-element music therapy could be an effective regimen for mental wellbeing. However, research in this field is lacking and to date has proven inconclusive.

Following the Australian Medical Research Council framework for designing and evaluating complex interventions, this study is the 'feasibility and piloting' stage in the development and evaluation process (21). Quantitative and qualitative aspects of the feasibility evaluation will be conducted to understand the holistic interventions.

The overarching aim of this study is to provide evidence of the feasibility and therapeutic effects of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19.

The primary objective for this study is the feasibility of the two-week light acupuncture and five-element music therapy for nurses working in WA hospitals. The secondary objective focuses on the therapeutic effects and safety. Figure 1 summarises the schedule of enrolment, interventions, and assessments.

Fig 1. The schedule of enrolment, interventions, and assessments

## Methods and analysis

### Study design

This feasibility study is a randomised crossover trial, and all participants will receive the treatment but at different times, and every participant will act as his or her own control. The procedures of the trial protocol are illustrated in Figure 2. The feasibility study will align with the guidelines proposed by Eldridge *et al.* (22) and will be reported adhering to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting template (23).

Fig 2. Flowchart of the protocol

Considering the high pertinence of this topic even in the absence of COVID-19, our study design aims to assess multiple relevant outcomes and the effectiveness of a feasible intervention in a clinical practice setting to improve practice and inform clinical and policy decisions. Our design can speed the pace and increase efficiency/cost effectiveness of clinical research and has the potential to make it more applicable to the 'real world' clinical settings.

### Patient and Public Involvement statement

Since the planning of the project, we have worked closely with ECU's consumer representative to ensure meaningful and collaborative consumer engagement in our research. The consumer representative has a direct lived experience of mental health who has activity advice on the study design and how to best connect with potential study participants. The consumer representative will also be assisting in conducting interpretation of the findings and dissemination of results.

## Randomisation and blinding

Sequence numbers of each participant will be generated by a computer produced permuted blocks of random sizes. The block sizes will not be disclosed to ensure concealment. The allocation will be performed by an independent, blinded statistician. The randomization list will only be kept by the researcher who performed the intervention. Participants will be randomly assigned to one of the two arms (Group 1 and Group 2) receiving either light acupuncture and five-element music (a total of six sessions) or no treatment for two weeks. Following one week washout period, the two groups will be crossed over whereby the light acupuncture and five-element music group will receive no treatment and vice versa in the no treatment group to receive two weeks treatment (totally six sessions). Outcome assessors and team members who perform data entry and data analysis will be blinded.

## Intervention

This is a crossover study with two weeks of interventions and a week washout period in between. Each participant will receive the combination of light acupuncture treatment and five-element music therapy three times weekly for two weeks from a registered acupuncturist at the clinic located at the corresponding author's university. Each session will last 25-30 minutes, including preparation, treatment, and conclusion of treatment. The 3B Laser Pen (200mW, Lorrach, Germany) used in the intervention will have a wavelength of 808 nm in continuous wave mode to be applied to bare skin on the selected points. Each pressure point will receive 20 seconds of energy (4J), with 20 minutes being the maximum treatment time (240J). During the treatment, the participant will be listening to the five-element music depending on their emotional types (fear, anger, joy, anxiety, and sorrow). For example, if one has anger, frustration, and rage, it could indicate they have too much Yang energy or problems with Liver or detoxification pathways. They will follow the five-element diagram

to listen to the Wood element music. Study-specific questionnaires and an observational sheet will be used throughout the trial process to monitor the adherence to the intervention.

## Control

The participants will be advised to wait for two weeks before commencing their treatments. Acupuncture can trigger multiple pathways (sensory systems can interact with the environment and respond to its challenges) and stimulate biological effects by touch and pressure (24, 25). Therefore, the sham treatment technique is inadvertently physiologically active. The procedure involves touching with pressure, which involves the same pathways as the test treatment; this creates a bias against the actual treatment (26). In other words, the sham acupuncture procedure introduces a risk of bias against acupuncture (27, 28). With such understanding, an international expert group suggests that sham acupuncture be discontinued at least in clinical trials (29, 30).

To date, no sham techniques developed capable of acting as placebo treatments; therefore, placebo-controlled trials are not achievable for acupuncture studies. Sham acupuncture techniques, therefore, should not be used in acupuncture related clinical trials (29); instead, pragmatic trials, which are designed to answer a question about decision making in clinical care (what sort of clinical care do patients need in the real world?) (31), where the control treatment can be an established standard therapy or a no-treatment group should be added (29).

## Participants

The participants will be registered nurses or enrolled nurses working at least 3 shifts per week (with each shift >6 hours) from any hospitals within WA. Although it is feasible to recruit 30 participants (32), dropouts are possible during the trial process. We estimate 15% attrition based on the attrition of 12% reported in a previous study (33). Taking these two factors into

account, the sample size for this study will be 36 to address feasibility issues (recruitment and completion rates, treatment adherence and compliance, and participants' attitudes, motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics) with a quantitative method and open-ended questions will assess the intervention and study design feasibility. It will inform future powered therapeutic effect trials for its outcome measures, treatment regime, and study design. Participants will be given a unique identification number, and the data collected will be treated with confidentiality and stored securely within the systems at the chief investigator's university. Only authorised persons will have access to the collected data.

## Eligibility criteria

Participants are eligible for this study if they are registered nurses or enrolled nurses and working at least three shifts per week (with each shift >6 hours) in any hospitals within WA; scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment. People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant women will not be eligible.

Participants will be recruited by the research team through the community. The study will be advertised through public advertisements, including posters, flyers, radio, and social media. In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals within WA. Snowballing techniques will be applied to enhance recruitment. Individuals interested in participating in the study will be encouraged to contact the research team via email for an eligibility check using the inclusion/exclusion criteria. The study researcher will follow-up interested potential participants to facilitate engagement and further understanding of the study.

Our research team will contact those eligible to participate in the study by sending the first 36 eligible protentional participants (first come, first served) with a participant information letter and a link (starting with a consent form) to complete a pre-trial online survey once they have signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The online survey should take no longer than 20 minutes to complete.

The 25-30 minutes treatment sessions will occur outside participants' working hours. As such, employer approval is not required. The intervention will be delivered in the clinic located at the corresponding author's university, across a range of days and times and participants will be expected to choose a session that does not conflict with their normal working hours. Participation in the research is voluntary, and participants can withdraw consent at any time without giving any reason, and their care or legal rights will not be affected.

### Outcome measurement time points

The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment adherence (No. of completed sessions and missed sessions) and compliance. An observational sheet and study-specific questionnaires throughout the trial process to monitor these outcomes; (3) participants' attitudes, motivation, and challenges to participation, reasons for withdrawal, missed sessions, and non-compliance with the intervention will be investigated via open-ended questions in the study-specific online survey at the end of the trial. Recruitment and completion rates will be assessed during the entire trial process. Treatment adherence and compliance will be assessed during the interventions. Online surveys will be administered at baseline (T0), post-two weeks phase 1 intervention (T1),

before the commencement of phase 2 intervention (following crossover) (T2), and post-two weeks phase 2 intervention (T3).

The secondary outcomes will include anxiety as measured by mean scores on Generalized Anxiety Disorder 7 (GAD-7) (34) ; depression as measured by mean scores on the Patient Health Questionnaire (PHQ-9) (35); work productivity and activity assessment (WPAI:SHP) (36, 37); and Quality of life assessment (SF-12) (38, 39). These outcomes will be measured using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the commencement of new intervention (following crossover) (T2), and post-phase 2 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and experiences of participating in the trial will also be included, measured at T0 and T3, respectively.

*Anxiety assessment*

**GAD-7**

The Generalized Anxiety Disorder 7 (GAD-7) is a gold-standard measurement tool for generalised anxiety disorder (34). It is quick, user-friendly, concise, and self-administered screening and diagnostic tools. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.

*Depression assessment*

**PHQ-9**

The Patient Health Questionnaire (PHQ-9) is a self-administered diagnostic instrument for depression severity (35). It is calculated by assigning scores of 0, 1, 2, and 3 to the response

categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe and severe depression.

*Work productivity and activity assessment*

**WPAI:SHP**

The Work Productivity and Activity Impairment Questionnaire for Specific Health Problem V2.0 (WPAI: SHP) (36, 37) is a 6-item questionnaire that evaluates self-reported productivity and activity during the past week. It includes subscales for absence from work (absenteeism), lost productivity while at work (presenteeism), overall work impairment, and the effects on non-work-related activities. Higher subscale value (0-100%) indicate greater work or activity impairment (36, 37).

*Quality of life assessment*

**SF-12**

The 12-item Short Form Health Survey (SF-12) is a self-reported outcome measure assessing the impact of health on an individual's everyday life and their quality of life (38, 39), including eight domains (1) Limitations in physical activities because of health problems; (2) Limitations in social activities because of physical or emotional problems; (3) Limitations in usual role activities because of physical health problems; (4) Bodily pain; (5) General mental health (psychological distress and well-being); (6) Limitations in usual role activities because of emotional problems; (7) Vitality (energy and fatigue); and (8) General health perceptions. The SF-12 and SF-36 possess similar validity (40-42). Scores on these eight domains are aggregated to form two final components: physical and mental wellbeing scores. An algorithm is used to generate the two components for comparison to normative data: the mean

score is set to 50, scores >50 indicate better physical or mental health than the mean, whereas scores <50 indicate worse physical or mental health than the mean.

## Data analysis

Descriptive statistics for continuous variables will initially be described by mean and standard deviation (SD) for normal data, and by median and interquartile range (IQR) for non-normal data. Categorical data will be summarised by frequencies and proportions. For the primary outcomes, rates of recruitment (no. consented/eligible), completion (undertaken baseline and follow-up tests), adherence (participants completed sessions/no. of sessions), and adverse events (number and number per participant hour) will be calculated and reported. No formal modelling is planned or required for the primary outcomes. The secondary outcomes will be assessed following intention-to-treat principles. Linear mixed modelling with unstructured covariance matrix will be conducted to assess changes in secondary outcomes throughout the study. This model allows for the inclusion of missing data in an intention-to-treat analysis without imputations (e.g., last-observation-carried-forward). Post-hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for potential confounding factors such as age, gender, education levels and any other potentially relevant variables where data are available. The corrected Akaike Information Criterion (AICc) will be used to assess model fit when covariates are added to the model. Normality assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear transformations such as the square root and log-transformations, will be applied to normalise the data. Statistical significance will be set at an alpha level of 0.05. False discovery rate (FDR). Corrections will be applied to all analysed outcomes to account for multiple comparisons. Effects sizes, defined by partial eta squared, will be reported and interpreted, with 0.01, 0.06 and 0.014, respectively, identified as small, medium and large effects (43). All analyses will be conducted using R version 4.1.

The qualitative data collected via open-ended questions across the four online surveys will be used to help explain or elaborate on the quantitative data. Qualitative data will be analysed using template thematic analysis. Template thematic analysis uses 'a priori' code frames to analyse and report on the data (44). The initial skeleton code frame is often formulated from the questions asked of participants and then built upon during analysis in an iterative process.

## Ethics and dissemination

The study will be conducted following the National Statement and the Australian Code for the Responsible Conduct of Research, 2018 (the 'Research Code'), and ethical approval was obtained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). The participant Information Letter explains the study, including the purpose and procedures, the voluntary nature of participation, and the option to withdraw at any time. Participants are also guaranteed confidentiality and secured data storage. Any adverse events arising will be reported and managed by the investigators. Data will be securely stored in ECU's security location, and no unauthorized persons will have access to the collected data. The investigator will supply the Ethics Committee on request with any required background data from the study documentation or clinic records. In case of special problems and/or governmental queries or requests for audit inspections, it is also necessary to have access to the complete study records, if participant confidentiality is protected. Any modifications made to the protocol after receipt of the Independent Ethics Committee approval will also be submitted by the investigator to the Committee in accordance with local procedures and regulatory requirements.

The research findings will be shared in various forms to engage broader audiences, including at national and international conferences presentations, in open-access peer-reviewed journal publications, and at local community workshops with healthcare professionals.

This study will improve understanding of how to provide holistic approaches for nurses' mental wellbeing in WA hospitals. The interventions in this study compromise light acupuncture and five-element music therapy, and study will evaluate the feasibility of the intervention regime and methodological design. Currently, there is no such modality designed for nurses and their wellbeing, and findings from this study can add value to the evidence base about how to acceptably involve complementary medicine for nurses' mental wellbeing. The evaluation will look at the use of light acupuncture and five-element music therapy in the context of increased mental health difficulties for nurses during and after the COVID-19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological interventions in alleviating the challenge of reducing the burden of mental health difficulties for nurses.

The higher anxiety levels during the pandemic impact on nurses' mental wellbeing, healthcare workforce and health outcome of the public. The light acupuncture and five-element music therapy could be an example of a safe, sustainable, and cost-effective intervention with promise as a complementary modality. This study will determine the feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental health caused by the pandemic. The findings will provide evidence for the acceptability of such modality to inform future strategies for nurses' mental wellbeing.

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## Authors contributions

CW and EA conceived the study. CW, AY, CE-B and JL contributed to the study design. JL provided statistical expertise. CW, AY and JL developed the intervention. CB, RS and CE-B led the nurses and public involvement for the advertisement of the project for recruitment. All authors contributed to the development of the study protocol. CW led the development of the manuscript, wrote the first draft, and led subsequent revisions. AY, RS, EA, JL, CB and CE-B read the manuscripts and provided critical input. All authors approved the final manuscript.

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## Competing interests

None declared.

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44. Brooks J, McCluskey S, Turley E, King N. The Utility of Template Analysis in Qualitative Psychology Research. Qual Res Psychol. 2015;12(2):202-22.

| | Enrolment | Randomisation & Baseline (T0) | Post-allocation | | Close-out (T1) | Crossover & (T2) | Post-allocation | | Close-out (T3) |
|---|---|---|---|---|---|---|---|---|---|
| Time point | Week -1 | Week 0 | Week 1 | Week 2 | Post 2 weeks treatment | | Week 1 | Week 2 | Post 2 weeks treatment |
| **Enrolment:** | | | | | | | | | |
| ✓ Randomisation | | X | | | | | | | |
| ✓ Informed consent | X | | | | | | | | |
| ✓ Baseline | | X | | | | | | | |
| **Intervention:** Light acupuncture + Five-element music therapy | | | X ← | X → | | | X ← | X → | |
| **Control:** No treatment | | | X ← | X → | | | X ← | X → | |
| **Assessments:** | | | | | | | | | |
| **Demographic data** | | | | | | | | | |
| Nursing role, gender, age, ethnicity, education level, employment types (PT, FT), and personal annual income | | X | | | | | | | |
| **Recruitment and completion rates** | | | | | | | | | |
| No. of referred, eligible, enrolled, withdrawals, and trial recruitment rate, and trial completion rate | X | X | X | X | X | X | X | X | X |
| **Treatment adherence and compliance** | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| No. of completed sessions and missed sessions | | | X | X | | | X | X | |
| **Anxiety assessment** | | | | | | | | | |
| GAD-7 | | X | | | X | X | | | X |
| **Depression assessment** | | | | | | | | | |
| PHQ-9 | | X | | | X | X | | | X |
| **Work productivity and activity assessment** | | | | | | | | | |
| WPAI:SHP | | X | | | X | X | | | X |
| **Quality of life assessment** | | | | | | | | | |
| SF-12 | | X | | | X | X | | | X |
| **Non-prescription mental wellbeing therapy preferences** | | | | | | | | | |
| Past 3-month choice of non-pharmacologic therapy | | X | | | | | | | |
| **Enabling and disabling factors** | | | | | | | | | |
| Participants' motivation and challenges to participation, withdrawal, missed sessions, non-compliance with intervention, and attitudes towards and experiences during trial participation | | X | X | X | X | X | X | X | X |

Figure 1. The schedule of enrolment, interventions, and assessments

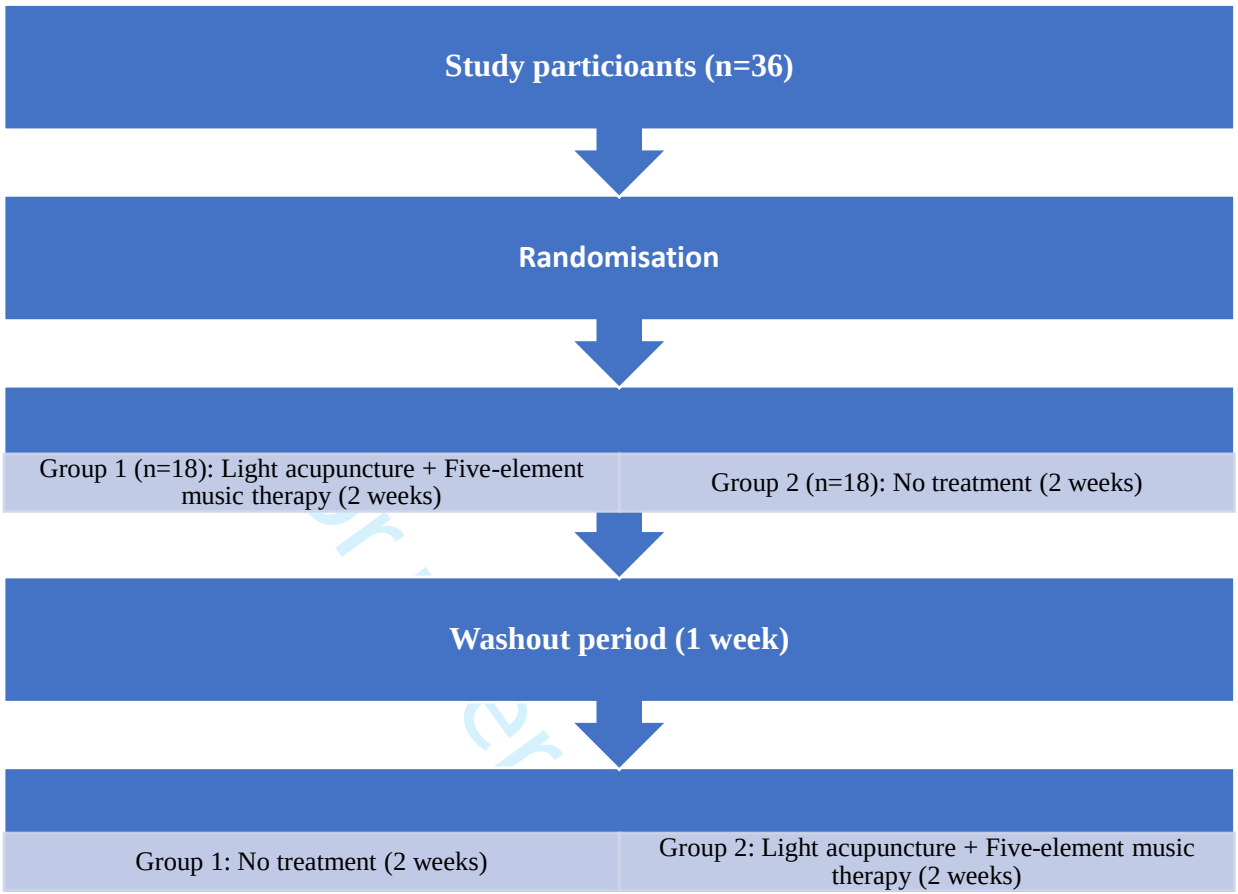


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control


SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _____1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _2__ANZCTR _ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | ____n/a_____ |
| Protocol version | 3 | Date and version identifier | _____2_____ |
| Funding | 4 | Sources and types of financial, material, and other support | ____15_____ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | __15; Tittle page___ |
| | 5b | Name and contact information for the trial sponsor | ____Title page___ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _____n/a_____ _ |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | ____2, 13_____ |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 1, 3-5 |
| | 6b | Explanation for choice of comparators | 7-8 |
| Objectives | 7 | Specific objectives or hypotheses | 5 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 5-6 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 9 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 8-9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 7 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | n/a |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 10 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | n/a |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 10-12 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 10; Figure 1 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 8 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8-9 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 6 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 6 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 6 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 6 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 13 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 10-13 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 10-13 |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 12-13 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 12-13 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | n/a |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 12-13 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 13 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 13 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 5, 13 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 13 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 13 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 13 |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 9,12 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | n/a |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 8, 13 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 15 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 13 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | n/a |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 14 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 15 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | n/a |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Included supporting document |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | n/a |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

**Declaration of interests**

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Signed by corresponding author:
Carol Chunfeng WANG

Signed by all authors as follows:

Dr Angela Yang

Dr Johnny Lo

Dr Rosemary Saunders

Dr Esther Adama

Professor Caroline Bulsara

Professor Christopher Etherton-beer

Chief Investigator: Dr Carol Wang
School of Nursing and Midwifery
Edith Cowan University
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JOONDALUP WA 6027
Phone: 6304 3589
Email: c.wang@ecu.edu.au

# Participant Information Letter

**Project title:** The experience and effects of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: a randomised crossover and feasibility study
**Approval Number:** No. 2021-02728-WANG
**Trial registration No.** ACTRN12621000957897p
**Principal Investigator:** Dr Carol Wang

## An invitation to participate in research

You are invited to participate in a project titled **"The experience and effects of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: a randomised crossover and feasibility study**. You are being asked to take part in this project because you hold an active registration as a registered nurse or enrolled nurse.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative or friend.

If you decide you want to take part in the research project, you will be asked to sign a consent form. By signing it, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to be involved in the research described;
- Consent to the use of your personal information as described.

## What is this project about?

Australian nurses experienced higher anxiety levels in the pandemic, which affect their long-term mental health and intention to stay in the profession resulting in a workforce shortage and its associated impact on the health of the public. This study aims to examine the feasibility of light acupuncture and five-element music therapy intervention to involve nurses' mental wellbeing in Western Australian (WA) hospitals.

## Who are the people should not participate in this project?

Nurses who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant will not be eligible.

## What does my participation involve?

Your participation in this research project will involve receiving a combination of light acupuncture treatment and five-element music therapy for two weeks (total 6 sessions). You will be asked to complete 4 online surveys during a 4-week trial period.

You will receive the treatment from a licensed acupuncturist at the ECU Acupuncture Research Clinic. Each session will last 25-30 minutes, including preparation, treatment, and conclusion of treatment; it will be conducted three times weekly for two weeks. During the treatments, you will be advised to listen to the five-element music dependent on your emotional types (fear, anger, joy, anxiety, and sorrow). For example, if you have anger, frustration, and rage, you will follow the diagram and instruction to listen to the Wood element music.

## Do I have to take part in this research project?

Your participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time. If you

decide to withdraw from the project after the data has been analysed, we will not be able to remove your individual data as this cannot be identified.

If you do decide to take part, you will be given a consent form to sign, and you will be given a copy of this information letter to keep. Your decision to take part, or to take part and later withdraw, will not affect your relationship with the research team and any staff within the School of Nursing and Midwifery at ECU.

**Your privacy**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. When all survey responses are returned to the research team, all data are automatically de-identified, and you will not be identifiable by any of your responses to the survey. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of professional forums. In any publication and/or presentation, the information will be provided in such a way that you cannot be identified, except where requested for specific reasons, and then you will be asked to provide written consent.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information that you disagree to be corrected. Please inform the research team member named at the end of this letter if you would like to access your information.

All data collected will be kept in accordance with ECU's Data Management Policy. Electronic data will be stored on a secure Microsoft SharePoint site provisioned by ECU's IT Services and physical records will be stored as required in ECU's Records Management Policy. The data will be retained for a period of seven years and destroyed, if appropriate at the end of the retention period. Data will be de-identified when stored and at the end of the retention period, the data will be destroyed, if appropriate under the State Records Act.

**Possible Benefits**

This study will improve understanding of how to provide holistic approaches for nurses' mental wellbeing in WA hospitals. The interventions in this study compromise light acupuncture and five-element music therapy, and the study will evaluate the feasibility of the intervention regime and methodological design. Currently, there is no such modality designed for nurses and their wellbeing, and findings from this study can add value to the evidence base about how to acceptably involve complementary medicine for nurses' mental wellbeing. The evaluation will look at the use of light acupuncture and five-element music therapy in the context of increased mental health difficulties for nurses during and after the COVID-19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological interventions in reducing the burden of mental health difficulties for nurses. Based on past research, we anticipate that light acupuncture treatment and five-element music therapy may help reduce stress and anxiety levels, increasing work productivity and quality of life. We hope that the results of our research can be used to inform our knowledge about how to manage nursing mental wellbeing better. There are no foreseeable risks associated with your participation in this research project.

**Possible Risks and Risk Management Plan**

Light acupuncture is cleared and approved by the Food and Drug Administration (FDA). It is safe and there are no foreseeable risks associated with participation in this research project. However, both the practitioner and the participants will wear an appropriate laser safety eyewear that match the laser wavelength and have sufficient optical density at that wavelength to protect the eye.

**What happens when this research study stops?**

We will advise you of the outcomes via email communication. We also intend to publish our results in research journals and present them at research conferences locally, nationally and internationally. Your name or any other identifying information will not be included in any of the publications or presentations.

**Has this research been approved?**

This research project has received the approval of Edith Cowan University's Human Research Ethics Committee under the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. The approval number is No. 2021-02728-WANG.

**Contacts**

If you would like to discuss any aspect of this project, please contact the following people.

**Chief Investigator**
Dr Carol Wang
Teaching and research academic
Edith Cowan University
P: 6304 3589
E: c.wang@ecu.edu.au

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

**Independent Person**
Research Ethics Support Officer
Edith Cowan University
P: 6304 2170
E: research.ethics@ecu.edu.au

Chief Investigator: Dr Carol Wang
School of Nursing and Midwifery
Edith Cowan University
270 Joondalup Drive
JOONDALUP WA 6027
Phone: 6304 3589
Email: c.wang@ecu.edu.au

## Participant Consent Form

**Project title:** The experience and effects of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: a randomised crossover and feasibility study
**Approval Number:** No. 2021-02728-WANG
**Trial registration No.** ACTRN12621000957897p
**Principal Investigator:** Dr Carol Wang

I, _____ have read the Participant Information Letter. By signing this consent form, I acknowledge that I:

- have been provided with a copy of the Participant Information Letter, explaining the research study
- have read and understood the information provided
- have been given the opportunity to ask questions and have had questions answered to my satisfaction
- can contact the research team if I have any additional questions
- understand that participation in the research project will involve:
    - complete a set of online surveys for during the trial period,
    - receiving six sessions of light acupuncture therapy and five-element music therapy in two weeks
- understand that the information provided will be kept confidential and that my identity will not be disclosed without consent
- understand that I am free to withdraw from further participation at any time, without explanation or penalty
- freely agree to participate in the project.
- The data collected will be used only for this research project.

Participant name: _____

Signature: _____ Date _____

Approval to conduct this research has been provided by the Edith Cowan University's Human Research Ethics Committee, approval number No. 2021-02728-WANG in accordance with its ethics review and approval procedures.

BMJ Open

# The feasibility of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: protocol for a randomised crossover study

| | |
|---|---|
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| Keywords: | Pain management < ANAESTHETICS, Laser therapy < DERMATOLOGY, PAIN MANAGEMENT, Depression & mood disorders < PSYCHIATRY, MENTAL HEALTH |
| | |

# The feasibility of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: protocol for a randomised crossover study

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keywords or phrases:
Acupuncture; low-level laser acupuncture; photobiomodulation; nursing; mental health.
Word count: 3608

## Abstract

**Introduction:** Australian nurses have experienced higher levels of anxiety during the COVID-19 pandemic compared with the pre-pandemic. This may have affected their long-term mental health and intention to stay in the profession resulting in a workforce shortage which, further impacts the health of the public. Management is urgently required to improve nurses' wellbeing. However, there is limited evidence available. The proposed clinical trial aims to evaluate the feasibility and therapeutic effects of using light acupuncture and five-element music therapy to improve nurses' mental health and wellbeing during and post COVID-19.

**Methods and analysis:** This randomised, single blinding, two-arm crossover feasibility pilot study involves a 1-week run-in period, 2-week intervention and 1-week run in period in between interventions. Thirty-six eligible nurses will be recruited from the community and randomised into either a combination of light acupuncture treatment and five-element music therapy group or no treatment group for 2-week. After a 1-week run in period, they will be swapped to the different group. Participants will be asked to complete a set of online questionnaires throughout the trial period. Data will be analysed by Linear mixed modelling using R software.

**Ethics and dissemination:** Ethical approval was attained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). Research findings will be shared with hospitals and in various forms to engage broader audiences, including national and international conferences presentations, open-access peer-reviewed journal publications, and local community workshop dissemination with healthcare professionals.

**Trial registration:** Australian New Zealand Clinical Trials Registry (ANZCTR):

ACTRN12621000957897p https://www.anzctr.org.au/ACTRN12621000957897p.aspx

**Keywords**

Acupuncture; low-level laser acupuncture; photobiomodulation; nursing; mental health; depression.

## Strengths and limitations of this study

- ✓ A first study evaluating the light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19 in Western Australia hospitals.
- ✓ This study will examine the role of involving nurses in light acupuncture and five-element music therapy, which has remained under-explored in hospitals.
- ✓ Qualitative and quantitative approaches will be used to comprehensively assess the trial outcomes to inform a powered therapeutic effectiveness trial and whether it would be feasible.
- ✓ The outcomes to be assessed by this study have relevance to the healthcare workforce, patient outcome and policymakers.

## Introduction

The most affected professionals worldwide throughout the COVID-19 pandemic are healthcare workers, with at least one in five reporting mental health difficulties such as anxiety, depression, and stress-related symptoms including sleep disturbances and insomnia attributed to the pandemic (1-5). Nurses and midwives are reported to be the most affected of all health professionals (1, 2, 6). Australian nurses experienced higher anxiety levels than their counterparts in other countries during the pandemic (7). This high level of anxiety can result in a lack of motivation and intention to leave the nursing and midwifery profession (8), leading to a workforce shortage and its associated impact on the health of the public.

Furthermore, the stress and anxiety associated with the pandemic are expected to affect nurses' long-term mental wellbeing (9) and intention to stay in the profession.

Traditional Chinese Medicine (TCM) played a huge role and has been extensively used around the world to combat stress and promote mental health well-being (10). During COVID-19, TCM has also been used widely in China (11), and the World Health Organization has recognised its contribution. Recent systematic reviews have identified high-level evidence which supports the safe and effective application of acupuncture for treating depression and anxiety (12).

Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one of the more recent technological developments in acupuncture that integrates cutting-edge laser technology with a centuries old modality TCM (13) . Light acupuncture is non-invasive, painless, non-infectious, and safe to use (14) . This form of acupuncture has also become increasingly popular among patients with needle phobias, particularly older people, and children (15-17). Several studies have documented light acupuncture as a promising modality in managing mental wellbeing (18, 19).

The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of Medicine), the earliest and most influential medical text of TCM, states that different elements (tunes) of music can help treat different emotional disorders (20, 21). Based on its theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi (*So*), and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal, wood, fire, water). According to TCM, the five elements in nature also represent five main human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry, anger, joy, and fear) (20, 21). For example, the Jiao note, corresponding to the wood element, influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note

belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a good combination of the notes can help balance the Yin and Yang and maintain the human body in a state of equilibrium and good health. The study found that five-element music therapy plays a vital role in preventing and treating disease (22), it significantly enhanced adenosine triphosphate (ATP) and glutathione (GSH) levels and cells growth rates (23). It reduced anxiety and depression (24, 25) and improved the quality of life (25). Furthermore, the therapy reduced chronic fatigue and alleviated pain symptoms (26) and improved sleep (27) in cancer patients.

Acupuncture and five-element music therapy could be an effective regimen for mental wellbeing. However, research in this field is lacking and to date has proven inconclusive.

Following the Australian Medical Research Council framework for designing and evaluating complex interventions, this study is the 'feasibility and piloting' stage in the development and evaluation process (28). Quantitative and qualitative aspects of the feasibility evaluation will be conducted to understand the holistic interventions.

The overarching aim of this study is to provide evidence of the feasibility and a short-term therapeutic effect of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19.

The primary objective for this study is the feasibility of the two-week light acupuncture and five-element music therapy for nurses working in WA hospitals. The secondary objective focuses on the short-term therapeutic effect and safety. Figure 1 summarises the schedule of enrolment, interventions, and assessments.

Fig 1. The schedule of enrolment, interventions, and assessments

## Methods and analysis

## Study design

This feasibility study is a randomised crossover trial, and all participants will receive the treatment but at different times, and every participant will act as his or her own control. The procedures of the trial protocol are illustrated in Figure 2. The feasibility study will align with the guidelines proposed by Eldridge *et al.* (29) and will be reported adhering to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting template (30).

Fig 2. Flowchart of the protocol

Considering the high pertinence of this topic even in the absence of COVID-19, our study design aims to assess multiple relevant outcomes and a short-term effect of a feasible intervention in a clinical practice setting to improve practice and inform clinical and policy decisions. Our design can speed the pace and increase efficiency/cost effectiveness of clinical research and has the potential to make it more applicable to the 'real world' clinical settings.

## Patient and Public Involvement statement

Since the planning of the project, we have worked closely with ECU's research consumer representative to ensure meaningful and collaborative consumer engagement in our research. The consumer representative has a direct lived experience of mental health and access to the local healthcare communities and hospitals. The consumer representative can actively advise on the study design and how to best connect with potential study participants. The consumer representative will also be assisting in conducting interpretation of the findings and dissemination of results.

## Randomisation and blinding

Sequence numbers of each participant will be generated by a computer produced permuted blocks of random sizes. The block sizes will not be disclosed to ensure concealment. The

allocation will be performed by an independent, blinded statistician. The randomization list will only be kept by the researcher who performed the intervention. Participants will be randomly assigned to one of the two arms (Group 1 and Group 2) receiving either light acupuncture and five-element music (a total of six sessions) or no treatment for two weeks. Following one week run in period, the two groups will be crossed over whereby the light acupuncture and five-element music group will receive no treatment and vice versa in the no treatment group to receive two weeks treatment (totally six sessions). Outcome assessors and team members who perform data entry and data analysis will be blinded.

## Intervention

This is a crossover study with two weeks of interventions and a week run in period in between. Each participant will receive the combination of light acupuncture treatment and five-element music therapy three times weekly for two weeks from a registered acupuncturist at the clinic located at the corresponding author's university. Each session will last 25-30 minutes, including preparation, treatment, and conclusion of treatment. The 3B Laser Pen (200mW, Lorrach, Germany) used in the intervention will have a wavelength of 808 nm in continuous wave mode to be applied to bare skin on the selected points. Each pressure point will receive 20 seconds of energy (4J), with 20 minutes being the maximum treatment time (240J). During the treatment, the participant will be listening to the five-element music depending on their emotional types (fear, anger, joy, anxiety, and sorrow). For example, if one has anger, frustration, and rage, it could indicate they have too much Yang energy or problems with Liver or detoxification pathways. They will follow the five-element diagram to listen to the Wood element music. Study-specific questionnaires and an observational sheet will be used throughout the trial process to monitor the adherence to the intervention. A plan for participants with potentially acute or urgent needs (e.g., symptoms) to ensure they receive evidence-based support (e.g., stop treatment or refer to GP).

## Control

The participants will be advised to wait for two weeks before commencing their treatments. Study-specific questionnaires will be used throughout the trial process to monitor the trial outcomes.

Acupuncture can trigger multiple pathways (sensory systems can interact with the environment and respond to its challenges) and stimulate biological effects by touch and pressure (31, 32). Therefore, the sham treatment technique is inadvertently physiologically active. The procedure involves touching with pressure, which involves the same pathways as the test treatment; this creates a bias against the actual treatment (33). In other words, the sham acupuncture procedure introduces a risk of bias against acupuncture (34, 35). With such understanding, an international expert group suggests that sham acupuncture be discontinued at least in clinical trials (36, 37).

To date, no sham techniques developed capable of acting as placebo treatments; therefore, placebo-controlled trials are not achievable for acupuncture studies. Sham acupuncture techniques, therefore, should not be used in acupuncture related clinical trials (36); instead, pragmatic trials, which are designed to answer a question about decision making in clinical care (what sort of clinical care do patients need in the real world?) (38), where the control treatment can be an established standard therapy or a no-treatment group should be added (36).

## Participants

The participants will be registered nurses or enrolled nurses working at least 3 shifts per week (with each shift >6 hours) from any hospitals within WA. Although it is feasible to recruit 30 participants (39), dropouts are possible during the trial process. We estimate 15% attrition based on the attrition of 12% reported in a previous study (40). Taking these two factors into

account, the sample size for this study will be 36 to address feasibility issues (recruitment and completion rates, treatment adherence and compliance, and participants' attitudes, motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics) with a quantitative method and open-ended questions will assess the intervention and study design feasibility. It will inform future powered therapeutic effect trials for its outcome measures, treatment regime, and study design. Participants will be given a unique identification number, and the data collected will be treated with confidentiality and stored securely within the systems at the chief investigator's university. Only authorised persons will have access to the collected data.

## Eligibility criteria

Participants are eligible for this study if they are registered nurses or enrolled nurses and working at least three shifts per week (with each shift >6 hours) in any hospitals within WA; scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment. People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant women will not be eligible. If there are any health concerns (e.g., high GAD scores), an email to community members will include details of relevant support and mental health services (e.g., lifeline Australia; seek GP advice). For example, the following information will be provided in the email: Lifeline Australia: 13 11 14 (24 hours hotline); Salvo Care Line 1300 36 36 22 (24-hour counselling service).

Participants will be recruited by the research team through the community. The study will be advertised through public advertisements, including posters, flyers, radio, and social media. In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals within WA. Snowballing techniques will be applied to enhance recruitment. Individuals interested in participating in the study will be encouraged to contact the research team via

email for an eligibility check using the inclusion/exclusion criteria. The study researcher will follow-up interested potential participants to facilitate engagement and further understanding of the study.

Our research team will contact those eligible to participate in the study by sending the first 36 eligible protentional participants (first come, first served) with a participant information letter and a link (starting with a consent form) to complete a pre-trial online survey once they have signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The online survey should take no longer than 20 minutes to complete.

The 25-30 minutes treatment sessions will occur outside participants' working hours. As such, employer approval is not required. The intervention will be delivered in the clinic located at the corresponding author's university, across a range of days and times and participants will be expected to choose a session that does not conflict with their normal working hours. Participation in the research is voluntary, and participants can withdraw consent at any time without giving any reason, and their care or legal rights will not be affected.

## Outcome measurement time points

The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment adherence (No. of completed sessions and missed sessions) and compliance. An observational sheet and study-specific questionnaires throughout the trial process to monitor these outcomes; (3) participants' attitudes, motivation, and challenges to participation, reasons for withdrawal, missed sessions, and non-compliance with the intervention will be investigated via open-ended questions in the study-specific online survey at the end of the

trial. Recruitment and completion rates will be assessed during the entire trial process. Treatment adherence and compliance will be assessed during the interventions. Online surveys will be administered at baseline (T0), post-two weeks phase 1 intervention (T1), before the commencement of phase 2 intervention (following crossover) (T2), and post-two weeks phase 2 intervention (T3).

The secondary outcomes will include anxiety as measured by mean scores on Generalized Anxiety Disorder 7 (GAD-7) (41) ; depression as measured by mean scores on the Patient Health Questionnaire (PHQ-9) (42); work productivity and activity assessment (WPAI:SHP) (43, 44); and Quality of life assessment (SF-12) (45, 46). These outcomes will be measured using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the commencement of new intervention (following crossover) (T2), and post-phase 2 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and experiences of participating in the trial will also be included, measured at T0 and T3, respectively.

*Anxiety assessment*

**GAD-7**

The Generalized Anxiety Disorder 7 (GAD-7) is a gold-standard measurement tool for generalised anxiety disorder (41). It is quick, user-friendly, concise, and self-administered screening and diagnostic tools. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.

*Depression assessment*

**PHQ-9**

The Patient Health Questionnaire (PHQ-9) is a self-administered diagnostic instrument for depression severity (42). It is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe and severe depression.

*Work productivity and activity assessment*

**WPAI:SHP**

The Work Productivity and Activity Impairment Questionnaire for Specific Health Problem V2.0 (WPAI: SHP) (43, 44) is a 6-item questionnaire that evaluates self-reported productivity and activity during the past week. It includes subscales for absence from work (absenteeism), lost productivity while at work (presenteeism), overall work impairment, and the effects on non-work-related activities. Higher subscale value (0-100%) indicate greater work or activity impairment (43, 44).

*Quality of life assessment*

**SF-12**

The 12-item Short Form Health Survey (SF-12) is a self-reported outcome measure assessing the impact of health on an individual's everyday life and their quality of life (45, 46), including eight domains (1) Limitations in physical activities because of health problems; (2) Limitations in social activities because of physical or emotional problems; (3) Limitations in usual role activities because of physical health problems; (4) Bodily pain; (5) General mental health (psychological distress and well-being); (6) Limitations in usual role activities because of emotional problems; (7) Vitality (energy and fatigue); and (8) General health perceptions. The SF-12 and SF-36 possess similar validity (47-49). Scores on these eight domains are aggregated to form two final components: physical and mental wellbeing scores. An

algorithm is used to generate the two components for comparison to normative data: the mean score is set to 50, scores >50 indicate better physical or mental health than the mean, whereas scores <50 indicate worse physical or mental health than the mean.

## Data analysis

Descriptive statistics for continuous variables will initially be described by mean and standard deviation (SD) for normal data, and by median and interquartile range (IQR) for non-normal data. Categorical data will be summarised by frequencies and proportions. For the primary outcomes, rates of recruitment (no. consented/eligible), completion (undertaken baseline and follow-up tests), adherence (participants completed sessions/no. of sessions), and adverse events (number and number per participant hour) will be calculated and reported. No formal modelling is planned or required for the primary outcomes. The secondary outcomes will be assessed following intention-to-treat principles. Linear mixed modelling with unstructured covariance matrix will be conducted to assess changes in secondary outcomes throughout the study. This model allows for the inclusion of missing data in an intention-to-treat analysis without imputations (e.g., last-observation-carried-forward). Post-hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for potential confounding factors such as age, gender, education levels and any other potentially relevant variables where data are available. The corrected Akaike Information Criterion (AICc) will be used to assess model fit when covariates are added to the model. Normality assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear transformations such as the square root and log-transformations, will be applied to normalise the data. Statistical significance will be set at an alpha level of 0.05. False discovery rate (FDR) corrections will be applied to all analysed outcomes to account for multiple comparisons. Effects sizes, defined by partial eta squared, will be reported and interpreted,

with 0.01, 0.06 and 0.014, respectively, identified as small, medium and large effects (50). All analyses will be conducted using R version 4.1.

The qualitative data collected via open-ended questions across the four online surveys will be used to help explain or elaborate on the quantitative data. Qualitative data will be analysed using template thematic analysis. Template thematic analysis uses 'a priori' code frames to analyse and report on the data (51). The initial skeleton code frame is often formulated from the questions asked of participants and then built upon during analysis in an iterative process.

## Ethics and dissemination

The study will be conducted following the National Statement and the Australian Code for the Responsible Conduct of Research, 2018 (the 'Research Code'), and ethical approval was obtained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). The participant Information Letter explains the study, including the purpose and procedures, the voluntary nature of participation, and the option to withdraw at any time. Participants are also guaranteed confidentiality and secured data storage. Any adverse events arising will be reported and managed by the investigators. Data will be securely stored in ECU's security location, and no unauthorized persons will have access to the collected data. The investigator will supply the Ethics Committee on request with any required background data from the study documentation or clinic records. In case of special problems and/or governmental queries or requests for audit inspections, it is also necessary to have access to the complete study records, if participant confidentiality is protected. Any modifications made to the protocol after receipt of the Independent Ethics Committee approval will also be submitted by the investigator to the Committee in accordance with local procedures and regulatory requirements.

The research findings will be shared in various forms to engage broader audiences, including at national and international conferences presentations, in open-access peer-reviewed journal publications, and at local community workshops with healthcare professionals.

This study will improve understanding of how to provide holistic approaches for nurses' mental wellbeing in WA hospitals. The interventions in this study compromise light acupuncture and five-element music therapy, and study will evaluate the feasibility of the intervention regime and methodological design. Currently, there is no such modality designed for nurses and their wellbeing, and findings from this study can add value to the evidence base about how to acceptably involve complementary medicine for nurses' mental wellbeing. The evaluation will look at the use of light acupuncture and five-element music therapy in the context of increased mental health difficulties for nurses during and after the COVID-19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological interventions in alleviating the challenge of reducing the burden of mental health difficulties for nurses.

The higher anxiety levels during the pandemic impact on nurses' mental wellbeing, healthcare workforce and health outcome of the public. The light acupuncture and five-element music therapy could be an example of a safe, sustainable, and cost-effective intervention with promise as a complementary modality. This study will determine the feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental health caused by the pandemic. The findings will provide evidence for the acceptability of such modality to inform future strategies for nurses' mental wellbeing.

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## Author contributions

CW and EA conceived the study. CW, AY, CE-B and JL contributed to the study design. JL provided statistical expertise. CW, AY and JL developed the intervention. CB, RS and CE-B led the nurses and public involvement for the advertisement of the project for recruitment. All authors contributed to the development of the study protocol. CW led the development of the manuscript, wrote the first draft, and led subsequent revisions. AY, RS, EA, JL, CB and CE-B read the manuscripts and provided critical input. All authors approved the final manuscript.

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## Competing interests

None declared.

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| | Enrolment | Randomisation & Baseline (T0) | Post-allocation | | Close-out (T1) | Crossover & (T2) | Post-allocation | | Close-out (T3) |
|---|---|---|---|---|---|---|---|---|---|
| Time point | Week -1 | Week 0 | Week 1 | Week 2 | Post 2 weeks treatment | | Week 1 | Week 2 | Post 2 weeks treatment |
| **Enrolment:** | | | | | | | | | |
| ✓ Randomisation | | X | | | | | | | |
| ✓ Informed consent | X | | | | | | | | |
| ✓ Baseline | | X | | | | | | | |
| **Intervention:** Light acupuncture + Five-element music therapy | | | X ← | X → | | | X ← | X → | |
| **Control:** No treatment | | | X ← | X → | | | X ← | X → | |
| **Assessments:** | | | | | | | | | |
| **Demographic data** | | | | | | | | | |
| Nursing role, gender, age, ethnicity, education level, employment types (PT, FT), and personal annual income | | X | | | | | | | |
| **Recruitment and completion rates** | | | | | | | | | |
| No. of referred, eligible, enrolled, withdrawals, and trial recruitment rate, and trial completion rate | X | X | X | X | X | X | X | X | X |
| **Treatment adherence and compliance** | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| No. of completed sessions and missed sessions | | | X | X | | | X | X | |
| **Anxiety assessment** | | | | | | | | | |
| GAD-7 | | X | | | X | X | | | X |
| **Depression assessment** | | | | | | | | | |
| PHQ-9 | | X | | | X | X | | | X |
| **Work productivity and activity assessment** | | | | | | | | | |
| WPAI:SHP | | X | | | X | X | | | X |
| **Quality of life assessment** | | | | | | | | | |
| SF-12 | | X | | | X | X | | | X |
| **Non-prescription mental wellbeing therapy preferences** | | | | | | | | | |
| Past 3-month choice of non-pharmacologic therapy | | X | | | | | | | |
| **Enabling and disabling factors** | | | | | | | | | |
| Participants' motivation and challenges to participation, withdrawal, missed sessions, non-compliance with intervention, and attitudes towards and experiences during trial participation | | X | X | X | X | X | X | X | X |

Figure 1. The schedule of enrolment, interventions, and assessments

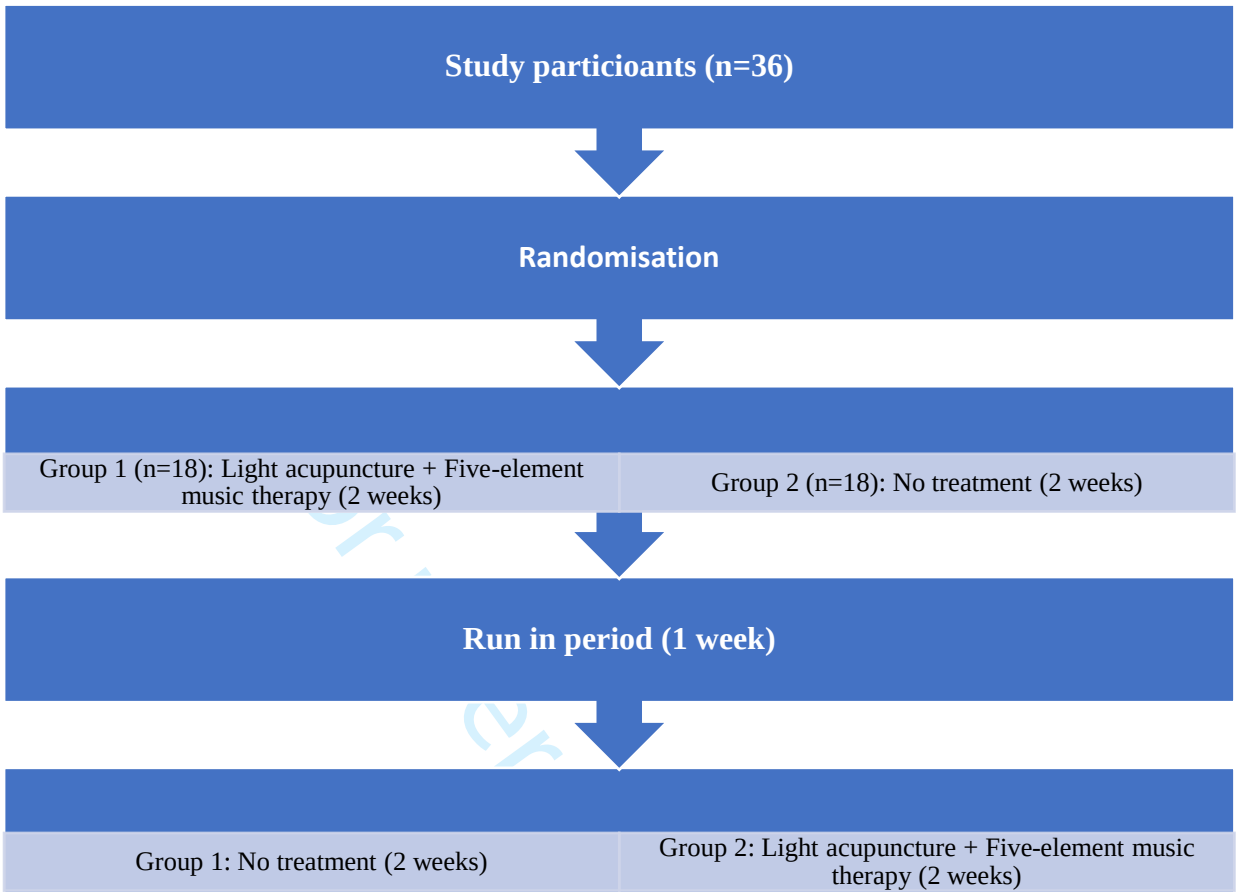


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control

BMJ Open

# Light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: protocol for a randomised crossover feasibility study

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| | |

# Light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19: protocol for a randomised crossover feasibility study

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## Abstract

**Introduction:** Australian nurses have experienced higher levels of anxiety during the COVID-19 pandemic compared with the pre-pandemic. This may have affected their long-term mental health and intention to stay in the profession resulting in a workforce shortage which, further impacts the health of the public. Management is urgently required to improve nurses' wellbeing. However, there is limited evidence available. The proposed clinical trial aims to evaluate the feasibility and therapeutic effects of using a combination of light acupuncture and five-element music therapy to improve nurses' mental health and wellbeing during and post COVID-19.

**Methods and analysis:** This randomised, single blinding, two-arm crossover feasibility study involves a 1-week run-in period, 2-week intervention and 1-week run in period in between interventions. Thirty-six eligible nurses will be recruited from the community and randomised into either a combination of light acupuncture treatment and five-element music therapy group or no treatment group for 2-week. After a 1-week run in period, they will be swapped to the different group. The primary outcome of this study is to evaluate the feasibility of a combination of light acupuncture treatment and five-element music therapy to improve nurses' mental health and wellbeing. The secondary outcomes will include anxiety and depression, work productivity and activity, and quality of life assessments. Participants will be asked to complete a set of online questionnaires throughout the trial period. All analyses will be performed in R Studio version 1.1.463.

**Ethics and dissemination:** Ethical approval was attained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). Research findings will be shared with hospitals and in various forms to engage broader audiences, including national

and international conferences presentations, open-access peer-reviewed journal publications, and local community workshop dissemination with healthcare professionals.

**Trial registration:** Australian New Zealand Clinical Trials Registry (ANZCTR):

ACTRN12621000957897p https://www.anzctr.org.au/ACTRN12621000957897p.aspx

**Keywords**

Acupuncture; low-level laser acupuncture; photobiomodulation; nursing; mental health; depression.

## Strengths and limitations of this study

- ✓ A first study evaluating the light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19 in Western Australia hospitals.
- ✓ This study will examine the role of involving nurses in light acupuncture and five-element music therapy, which has remained under-explored in hospitals.
- ✓ Qualitative and quantitative approaches will be used to comprehensively assess the trial outcomes to inform a powered therapeutic effectiveness trial and whether it would be feasible.
- ✓ The outcomes to be assessed by this study have relevance to the healthcare workforce, patient outcome and policymakers.

## Introduction

The most affected professionals worldwide throughout the COVID-19 pandemic are healthcare workers, with at least one in five reporting mental health difficulties such as anxiety, depression, and stress-related symptoms including sleep disturbances and insomnia

attributed to the pandemic (1-5). Nurses and midwives are reported to be the most affected of all health professionals (1, 2, 6). Australian nurses experienced higher anxiety levels than their counterparts in other countries during the pandemic (7). This high level of anxiety can result in a lack of motivation and intention to leave the nursing and midwifery profession (8), leading to a workforce shortage and its associated impact on the health of the public. Furthermore, the stress and anxiety associated with the pandemic are expected to affect nurses' long-term mental wellbeing (9) and intention to stay in the profession.

Traditional Chinese Medicine (TCM) played a huge role and has been extensively used around the world to combat stress and promote mental health well-being (10). During COVID-19, TCM has also been used widely in China (11), and the World Health Organization has recognised its contribution. Recent systematic reviews have identified high-level evidence which supports the safe and effective application of acupuncture for treating depression and anxiety (12).

Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one of the more recent technological developments in acupuncture that integrates cutting-edge laser technology with a centuries old modality TCM (13) . Light acupuncture is non-invasive, painless, non-infectious, and safe to use (14) . This form of acupuncture has also become increasingly popular among patients with needle phobias, particularly older people, and children (15-17). Several studies have documented light acupuncture as a promising modality in managing mental wellbeing (18, 19).

The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of Medicine), the earliest and most influential medical text of TCM, states that different elements (tunes) of music can help treat different emotional disorders (20, 21). Based on its theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi

(*So*), and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal, wood, fire, water). According to TCM, the five elements in nature also represent five main human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry, anger, joy, and fear) (20, 21). For example, the Jiao note, corresponding to the wood element, influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a good combination of the notes can help balance the Yin and Yang and maintain the human body in a state of equilibrium and good health. The study found that five-element music therapy plays a vital role in preventing and treating disease (22), it significantly enhanced adenosine triphosphate (ATP) and glutathione (GSH) levels and cells growth rates (23). It reduced anxiety and depression (24, 25) and improved the quality of life (25). Furthermore, the therapy reduced chronic fatigue and alleviated pain symptoms (26) and improved sleep (27) in cancer patients.

Acupuncture and five-element music therapy could be an effective regimen for mental wellbeing. However, research in this field is lacking and to date has proven inconclusive.

Following the Australian Medical Research Council framework for designing and evaluating complex interventions, this study is the 'feasibility and piloting' stage in the development and evaluation process (28). Quantitative and qualitative aspects of the feasibility evaluation will be conducted to understand the holistic interventions.

The overarching aim of this study is to provide evidence of the feasibility and a short-term therapeutic effect of light acupuncture and five-element music therapy for nurses' mental health and wellbeing during and post COVID-19.

The primary objective for this study is to evaluate the feasibility of a combination of light acupuncture treatment and five-element music therapy to improve nurses' mental health and wellbeing, as measured by recruitment and completion rates and treatment adherence and compliance. Participants' attitudes, motivation, challenges to participation, intervention non-compliance, and experience of participating in the trial will be investigated via qualitative data.

The secondary outcomes will include anxiety as measured by mean scores on Generalized Anxiety Disorder 7 (GAD-7) and depression as measured by mean scores on the Patient Health Questionnaire (PHQ-9), work productivity and activity assessment (WPAI:SHP), and quality of life assessment (SF-12). Questions on participants' non-pharmacologic therapy preferences will also be included. Figure 1 summarises the schedule of enrolment, interventions, and assessments.

Fig 1. The schedule of enrolment, interventions, and assessments

## Methods and analysis

### Study design

This feasibility study is a randomised crossover trial, and all participants will receive the treatment but at different times, and every participant will act as his or her own control. The procedures of the trial protocol are illustrated in Figure 2. The feasibility study will align with the guidelines proposed by Eldridge *et al.* (29) and will be reported adhering to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting template (30).

Fig 2. Flowchart of the protocol

Considering the high pertinence of this topic even in the absence of COVID-19, our study design aims to assess multiple relevant outcomes and a short-term effect of a feasible

intervention in a clinical practice setting to improve practice and inform clinical and policy decisions. Our design can speed the pace and increase efficiency/cost effectiveness of clinical research and has the potential to make it more applicable to the 'real world' clinical settings.

## Patient and Public Involvement statement

Since the planning of the project, we have worked closely with ECU's research consumer representative to ensure meaningful and collaborative consumer engagement in our research. The consumer representative has a direct lived experience of mental health and access to the local healthcare communities and hospitals. The consumer representative can actively advise on the study design and how to best connect with potential study participants. The consumer representative will also be assisting in conducting interpretation of the findings and dissemination of results.

## Randomisation and blinding

Sequence numbers of each participant will be generated by a computer produced permuted blocks of random sizes. The block sizes will not be disclosed to ensure concealment. The allocation will be performed by an independent, blinded statistician. The randomization list will only be kept by the researcher who performed the intervention. Participants will be randomly assigned to one of the two arms (Group 1 and Group 2) receiving either light acupuncture and five-element music (a total of six sessions) or no treatment for two weeks. Following one week run in period, the two groups will be crossed over whereby the light acupuncture and five-element music group will receive no treatment and vice versa in the no treatment group to receive two weeks treatment (totally six sessions). Outcome assessors and team members who perform data entry and data analysis will be blinded.

## Intervention

This is a crossover study with two weeks of interventions and a week run in period in between. Each participant will receive the combination of light acupuncture treatment and five-element music therapy three times weekly for two weeks from a registered acupuncturist at the clinic located at the corresponding author's university. Each session will last 25-30 minutes, including preparation, treatment, and conclusion of treatment. The 3B Laser Pen (200mW, Lorrach, Germany) used in the intervention will have a wavelength of 808 nm in continuous wave mode to be applied to bare skin on the selected points. Each pressure point will receive 20 seconds of energy (4J), with 20 minutes being the maximum treatment time (240J). During the treatment, the participant will be listening to the five-element music depending on their emotional types (fear, anger, joy, anxiety, and sorrow). For example, if one has anger, frustration, and rage, it could indicate they have too much Yang energy or problems with Liver or detoxification pathways. They will follow the five-element diagram to listen to the Wood element music. Study-specific questionnaires and an observational sheet will be used throughout the trial process to monitor the adherence to the intervention. A plan for participants with potentially acute or urgent needs (e.g., symptoms) to ensure they receive evidence-based support (e.g., stop treatment or refer to GP).

## Control

The participants will be advised to wait for two weeks before commencing their treatments. Study-specific questionnaires will be used throughout the trial process to monitor the trial outcomes.

Acupuncture can trigger multiple pathways (sensory systems can interact with the environment and respond to its challenges) and stimulate biological effects by touch and pressure (31, 32). Therefore, the sham treatment technique is inadvertently physiologically

active. The procedure involves touching with pressure, which involves the same pathways as the test treatment; this creates a bias against the actual treatment (33). In other words, the sham acupuncture procedure introduces a risk of bias against acupuncture (34, 35). With such understanding, an international expert group suggests that sham acupuncture be discontinued at least in clinical trials (36, 37).

To date, no sham techniques developed capable of acting as placebo treatments; therefore, placebo-controlled trials are not achievable for acupuncture studies. Sham acupuncture techniques, therefore, should not be used in acupuncture related clinical trials (36); instead, pragmatic trials, which are designed to answer a question about decision making in clinical care (what sort of clinical care do patients need in the real world?) (38), where the control treatment can be an established standard therapy or a no-treatment group should be added (36).

## Participants

The participants will be registered nurses or enrolled nurses working at least 3 shifts per week (with each shift >6 hours) from any hospitals within WA. Although it is feasible to recruit 30 participants (39), dropouts are possible during the trial process. We estimate 15% attrition based on the attrition of 12% reported in a previous study (40). Taking these two factors into account, the sample size for this study will be 36 to address feasibility issues (recruitment and completion rates, treatment adherence and compliance, and participants' attitudes, motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics) with a quantitative method and open-ended questions will assess the intervention and study design feasibility. It will inform future powered therapeutic effect trials for its outcome measures, treatment regime, and study design. Participants will be given a unique identification number, and the data collected will be treated with confidentiality and stored

securely within the systems at the chief investigator's university. Only authorised persons will have access to the collected data.

## Eligibility criteria

Participants are eligible for this study if they are registered nurses or enrolled nurses and working at least three shifts per week (with each shift >6 hours) in any hospitals within WA; scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment. People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant women will not be eligible. If there are any health concerns (e.g., high GAD scores), an email to community members will include details of relevant support and mental health services (e.g., lifeline Australia; seek GP advice). For example, the following information will be provided in the email: Lifeline Australia: 13 11 14 (24 hours hotline); Salvo Care Line 1300 36 36 22 (24-hour counselling service).

Participants will be recruited by the research team through the community. The study will be advertised through public advertisements, including posters, flyers, radio, and social media. In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals within WA. Snowballing techniques will be applied to enhance recruitment. Individuals interested in participating in the study will be encouraged to contact the research team via email for an eligibility check using the inclusion/exclusion criteria. The study researcher will follow-up interested potential participants to facilitate engagement and further understanding of the study.

Our research team will contact those eligible to participate in the study by sending the first 36 eligible protentional participants (first come, first served) with a participant information letter and a link (starting with a consent form) to complete a pre-trial online survey once they have

signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The online survey should take no longer than 20 minutes to complete.

The 25-30 minutes treatment sessions will occur outside participants' working hours. As such, employer approval is not required. The intervention will be delivered in the clinic located at the corresponding author's university, across a range of days and times and participants will be expected to choose a session that does not conflict with their normal working hours. Participation in the research is voluntary, and participants can withdraw consent at any time without giving any reason, and their care or legal rights will not be affected.

## Outcome measurement time points

The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment adherence (No. of completed sessions and missed sessions) and compliance. An observational sheet and study-specific questionnaires throughout the trial process to monitor these outcomes; (3) participants' attitudes, motivation, and challenges to participation, reasons for withdrawal, missed sessions, and non-compliance with the intervention will be investigated via open-ended questions in the study-specific online survey at the end of the trial. Recruitment and completion rates will be assessed during the entire trial process. Treatment adherence and compliance will be assessed during the interventions. Online surveys will be administered at baseline (T0), post-two weeks phase 1 intervention (T1), before the commencement of phase 2 intervention (following crossover) (T2), and post-two weeks phase 2 intervention (T3).

The secondary outcomes will include anxiety as measured by mean scores on Generalized Anxiety Disorder 7 (GAD-7) (41) ; depression as measured by mean scores on the Patient Health Questionnaire (PHQ-9) (42); work productivity and activity assessment (WPAI:SHP) (43, 44); and Quality of life assessment (SF-12) (45, 46). These outcomes will be measured using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the commencement of new intervention (following crossover) (T2), and post-phase 2 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and experiences of participating in the trial will also be included, measured at T0 and T3, respectively.

*Anxiety assessment*

**GAD-7**

The Generalized Anxiety Disorder 7 (GAD-7) is a gold-standard measurement tool for generalised anxiety disorder (41). It is quick, user-friendly, concise, and self-administered screening and diagnostic tools. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.

*Depression assessment*

**PHQ-9**

The Patient Health Questionnaire (PHQ-9) is a self-administered diagnostic instrument for depression severity (42). It is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all", "several days", "more than half the days", and "nearly every day", respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe and severe depression.

*Work productivity and activity assessment*

**WPAI:SHP**

The Work Productivity and Activity Impairment Questionnaire for Specific Health Problem V2.0 (WPAI: SHP) (43, 44) is a 6-item questionnaire that evaluates self-reported productivity and activity during the past week. It includes subscales for absence from work (absenteeism), lost productivity while at work (presenteeism), overall work impairment, and the effects on non-work-related activities. Higher subscale value (0-100%) indicate greater work or activity impairment (43, 44).

*Quality of life assessment*

**SF-12**

The 12-item Short Form Health Survey (SF-12) is a self-reported outcome measure assessing the impact of health on an individual's everyday life and their quality of life (45, 46), including eight domains (1) Limitations in physical activities because of health problems; (2) Limitations in social activities because of physical or emotional problems; (3) Limitations in usual role activities because of physical health problems; (4) Bodily pain; (5) General mental health (psychological distress and well-being); (6) Limitations in usual role activities because of emotional problems; (7) Vitality (energy and fatigue); and (8) General health perceptions. The SF-12 and SF-36 possess similar validity (47-49). Scores on these eight domains are aggregated to form two final components: physical and mental wellbeing scores. An algorithm is used to generate the two components for comparison to normative data: the mean score is set to 50, scores >50 indicate better physical or mental health than the mean, whereas scores <50 indicate worse physical or mental health than the mean.

## Data analysis

Descriptive statistics for continuous variables will initially be described by mean and standard deviation (SD) for normal data, and by median and interquartile range (IQR) for non-normal data. Categorical data will be summarised by frequencies and proportions. All demographic variables will be summarised and reported as frequencies (n) and proportions (%). Comparisons of the distributions of the demographic variables between the Control and Intervention groups will be assessed using Chi-square tests. For the primary outcomes, rates of recruitment (no. consented/eligible), completion (undertaken baseline and follow-up tests), adherence (participants completed sessions/no. of sessions), and adverse events (number and number per participant hour) will be calculated and reported. No formal modelling is planned or required for the primary outcomes. The secondary outcomes will be assessed following intention-to-treat principles. Linear mixed modelling with unstructured covariance matrix will be conducted to assess changes in secondary outcomes throughout the study. This model allows for the inclusion of missing data in an intention-to-treat analysis without imputations (e.g., last-observation-carried-forward). The outcomes of GAD-7, PHQ-9, WPAI:SHP, and SF-12 will be summarised by the mean and standard error (SE). Linear mixed modelling (LMM), with participants as a random factor, will be used to assess the main and interaction effects of the fixed factors in time point (pre-and post-intervention) and group (Control vs Intervention) to each of these outcomes. All analyses will be performed in R Studio version 1.1.463 (50). Significant effects will be noted at $p < 0.05$. Effect sizes were given by Cohen's d, where 0.2, 0.5 and 0.8, respectively, define small, medium, and large effects (51).

Post-hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for potential confounding factors such as age, gender, education levels and any other potentially relevant variables where data are available. The corrected Akaike Information Criterion (AICc) will be used to assess model fit when covariates are added to the model.

Normality assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear transformations such as the square root and log-transformations, will be applied to normalise the data. All analyses will be performed in R Studio version 1.1.463.

The qualitative data collected via open-ended questions across the four online surveys will be used to help explain or elaborate on the quantitative data. Qualitative data will be analysed using template thematic analysis. Template thematic analysis uses 'a priori' code frames to analyse and report on the data (52). The initial skeleton code frame is often formulated from the questions asked of participants and then built upon during analysis in an iterative process.

## Ethics and dissemination

The study will be conducted following the National Statement and the Australian Code for the Responsible Conduct of Research, 2018 (the 'Research Code'), and ethical approval was obtained from Edith Cowan University's Human Research Ethics Committee (No. 2021-02728-WANG). The participant Information Letter explains the study, including the purpose and procedures, the voluntary nature of participation, and the option to withdraw at any time. Participants are also guaranteed confidentiality and secured data storage. Any adverse events arising will be reported and managed by the investigators. Data will be securely stored in ECU's security location, and no unauthorized persons will have access to the collected data. The investigator will supply the Ethics Committee on request with any required background data from the study documentation or clinic records. In case of special problems and/or governmental queries or requests for audit inspections, it is also necessary to have access to the complete study records, if participant confidentiality is protected. Any modifications made to the protocol after receipt of the Independent Ethics Committee approval will also be submitted by the investigator to the Committee in accordance with local procedures and regulatory requirements.

The research findings will be shared in various forms to engage broader audiences, including at national and international conferences presentations, in open-access peer-reviewed journal publications, and at local community workshops with healthcare professionals.

This study will improve understanding of how to provide holistic approaches for nurses' mental wellbeing in WA hospitals. The interventions in this study compromise light acupuncture and five-element music therapy, and study will evaluate the feasibility of the intervention regime and methodological design. Currently, there is no such modality designed for nurses and their wellbeing, and findings from this study can add value to the evidence base about how to acceptably involve complementary medicine for nurses' mental wellbeing. The evaluation will look at the use of light acupuncture and five-element music therapy in the context of increased mental health difficulties for nurses during and after the COVID-19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological interventions in alleviating the challenge of reducing the burden of mental health difficulties for nurses.

The higher anxiety levels during the pandemic impact on nurses' mental wellbeing, healthcare workforce and health outcome of the public. The light acupuncture and five-element music therapy could be an example of a safe, sustainable, and cost-effective intervention with promise as a complementary modality. This study will determine the feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental health caused by the pandemic. The findings will provide evidence for the acceptability of such modality to inform future strategies for nurses' mental wellbeing.

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## Author contributions

CW and EA conceived the study. CW, AY, CE-B and JL contributed to the study design. JL provided statistical expertise. CW, AY and JL developed the intervention. CB, RS and CE-B led the nurses and public involvement for the advertisement of the project for recruitment. All authors contributed to the development of the study protocol. CW led the development of the manuscript, wrote the first draft, and led subsequent revisions. AY, RS, EA, JL, CB and CE-B read the manuscripts and provided critical input. All authors approved the final manuscript.

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## Competing interests

None declared.

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| | Enrolment | Randomisation Baseline (T0) | Post allocation | | Close-out (T1) | Crossover & (T2) | Post allocation | | Close-out (T3) |
|---|---|---|---|---|---|---|---|---|---|
| Time point | Week -1 | Week 0 | Week 1 | Week 2 | Post 2 weeks treatment | | Week 1 | Week 2 | Post 2 weeks treatment |
| **Enrolment:** | | | | | | | | | |
| ✓ Randomisation | | X | | | | | | | |
| ✓ Informed consent | X | | | | | | | | |
| ✓ Baseline | | X | | | | | | | |
| **Intervention:** Light acupuncture + Five-element music therapy | | | X ← | → X | | | X ← | → X | |
| **Control:** No treatment | | | X ← | → X | | | X ← | → X | |
| **Assessments:** | | | | | | | | | |
| **Recruitment and completion rates** | | | | | | | | | |
| No. of referred, eligible, enrolled, withdrawals, and trial recruitment and completion rates | X | X | X | X | X | X | X | X | X |
| **Treatment adherence and compliance** | | | | | | | | | |
| No. of completed sessions and missed sessions | | | X | X | | | X | X | |
| **Anxiety assessment** | | | | | | | | | |
| GAD-7 | | X | | | X | X | | | X |
| **Depression assessment** | | | | | | | | | |
| PHQ-9 | | X | | | X | X | | | X |
| **Work productivity and activity assessment** | | | | | | | | | |
| WPAI:SHP | | X | | | X | X | | | X |
| **Quality of life assessment** | | | | | | | | | |
| SF-12 | | X | | | X | X | | | X |
| **Non-prescription mental wellbeing therapy preferences** | | | | | | | | | |
| Past 3-month choice of non-pharmacologic therapy | | X | | | | | | | |
| **Enabling and disabling factors** | | | | | | | | | |
| Participants' motivation and challenges and experiences during trial participation | | X | X | X | X | X | X | X | X |

Figure 1. The schedule of enrolment, interventions, and assessments

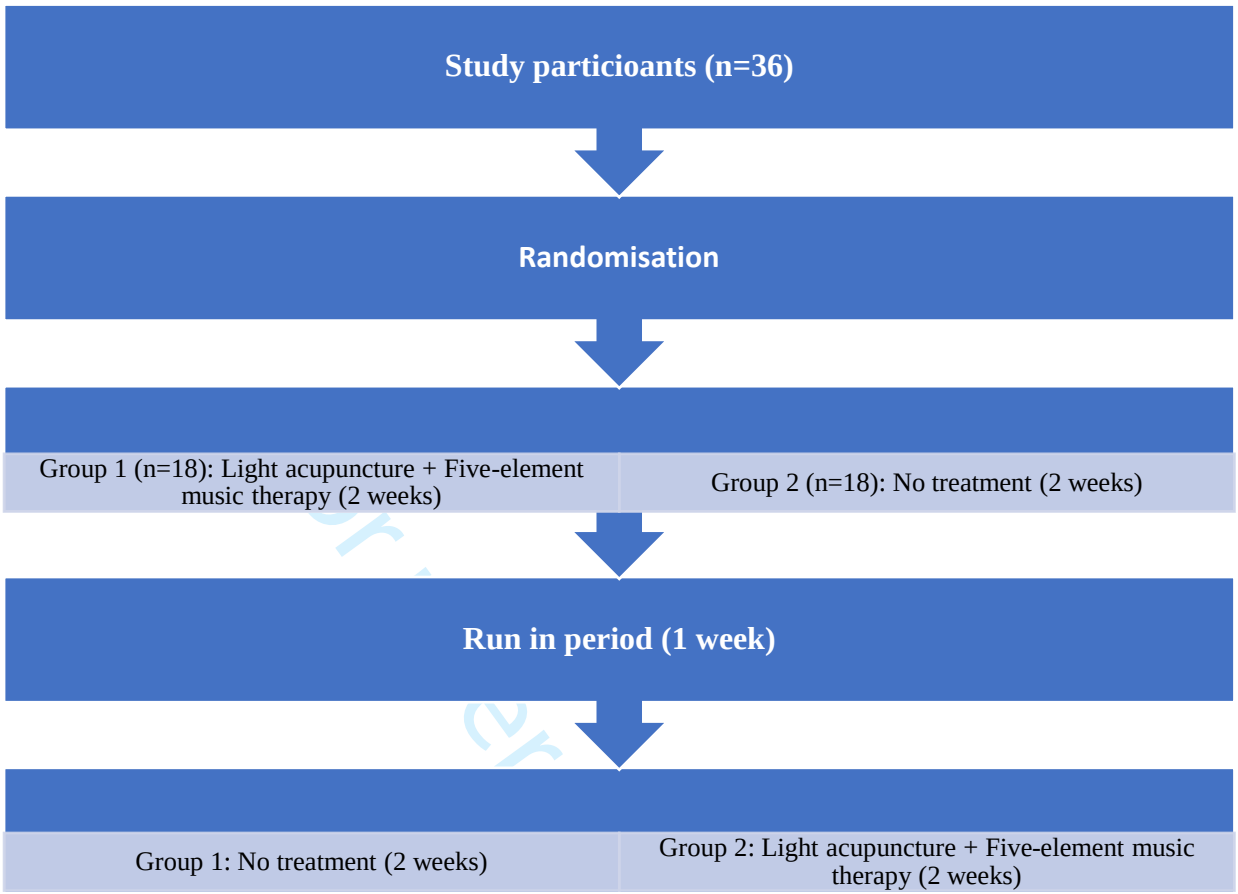


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control