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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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Manuscripts

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3 The experience and effects of light acupuncture and five-element music therapy for nurses'  
4 mental health and wellbeing during and post COVID-19: a randomised crossover and  
5 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

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3 all health professionals (1, 2, 5). Though Australia has not experienced the pandemic as  
4  
5 severely as other countries, one study from a local area health service found Australian nurses  
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7 experienced higher anxiety levels than their counterparts in other countries during the  
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9 pandemic (6). This high level of anxiety can result in a lack of motivation and intention to  
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11 leave the nursing and midwifery profession (7), leading to a workforce shortage and its  
12  
13 associated impact on the health of the public. Furthermore, the stress and anxiety associated  
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15 with the pandemic are expected to affect nurses' long-term mental wellbeing (8) and  
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17 intention to stay in the profession.  
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23 Traditional Chinese Medicine (TCM) played a huge role and has been extensively used  
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25 around the world to combat stress and promote mental health well-being (9). During COVID-  
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27 19, TCM has also been used widely in China (10), and the World Health Organization has  
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29 recognised its contribution. Recent systematic reviews have identified high-level evidence  
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31 which supports the safe and effective application of acupuncture for treating depression and  
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33 anxiety (11).  
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38 Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one  
39  
40 of the more recent technological developments in acupuncture that integrates cutting-edge  
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42 laser technology with a centuries old modality TCM (12) . Light acupuncture is non-invasive,  
43  
44 painless, non-infectious, and safe to use (13) . This form of acupuncture has also become  
45  
46 increasingly popular among patients with needle phobias, particularly older people, and  
47  
48 children (14-16). Several studies have documented light acupuncture as a promising modality  
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50 in managing mental wellbeing (17, 18).  
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54 The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of  
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56 Medicine), the earliest and most influential medical text of TCM, states that different  
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58 elements (tunes) of music can help treat different emotional disorders (19, 20). Based on its  
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3 theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi  
4 (*So*), and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal,  
5 wood, fire, water). According to TCM, the five elements in nature also represent five main  
6 human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry,  
7 anger, joy, and fear). For example, the Jiao note, corresponding to the wood element,  
8 influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note  
9 belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a  
10 good combination of the notes can help balance the Yin and Yang and maintain the human  
11 body in a state of equilibrium and good health.  
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25 Acupuncture and five-element music therapy could be an effective regimen for mental  
26 wellbeing. However, research in this field is lacking and to date has proven inconclusive.  
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31 Following the Australian Medical Research Council framework for designing and evaluating  
32 complex interventions, this study is the ‘feasibility and piloting’ stage in the development and  
33 evaluation process (21). Quantitative and qualitative aspects of the feasibility evaluation will  
34 be conducted to understand the holistic interventions.  
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41 The overarching aim of this study is to provide evidence of the feasibility and therapeutic  
42 effects of light acupuncture and five-element music therapy for nurses’ mental health and  
43 wellbeing during and post COVID-19.  
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49 The primary objective for this study is the feasibility of the two-week light acupuncture and  
50 five-element music therapy for nurses working in WA hospitals. The secondary objective  
51 focuses on the therapeutic effects and safety. Figure 1 summarises the schedule of enrolment,  
52 interventions, and assessments.  
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59 **Fig 1. The schedule of enrolment, interventions, and assessments**  
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## 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

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

10 The participants will be advised to wait for two weeks before commencing their treatments.  
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12 Acupuncture can trigger multiple pathways (sensory systems can interact with the  
13  
14 environment and respond to its challenges) and stimulate biological effects by touch and  
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16 pressure (24, 25). Therefore, the sham treatment technique is inadvertently physiologically  
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18 active. The procedure involves touching with pressure, which involves the same pathways as  
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20 the test treatment; this creates a bias against the actual treatment (26). In other words, the  
21  
22 sham acupuncture procedure introduces a risk of bias against acupuncture (27, 28). With such  
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24 understanding, an international expert group suggests that sham acupuncture be discontinued  
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26 at least in clinical trials (29, 30).  
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32 To date, no sham techniques developed capable of acting as placebo treatments; therefore,  
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34 placebo-controlled trials are not achievable for acupuncture studies. Sham acupuncture  
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36 techniques, therefore, should not be used in acupuncture related clinical trials (29); instead,  
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38 pragmatic trials, which are designed to answer a question about decision making in clinical  
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40 care (what sort of clinical care do patients need in the real world?) (31), where the control  
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42 treatment can be an established standard therapy or a no-treatment group should be added  
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44 (29).  
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## 49 Participants

51 The participants will be registered nurses or enrolled nurses working at least 3 shifts per week  
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53 (with each shift >6 hours) from any hospitals within WA. Although it is feasible to recruit 30  
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55 participants (32), dropouts are possible during the trial process. We estimate 15% attrition  
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57 based on the attrition of 12% reported in a previous study (33). Taking these two factors into  
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3 account, the sample size for this study will be 36 to address feasibility issues (recruitment and  
4 completion rates, treatment adherence and compliance, and participants' attitudes,  
5 motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics)  
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7 with a quantitative method and open-ended questions will assess the intervention and study  
8 design feasibility. It will inform future powered therapeutic effect trials for its outcome  
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10 measures, treatment regime, and study design. Participants will be given a unique  
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12 identification number, and the data collected will be treated with confidentiality and stored  
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14 securely within the systems at the chief investigator's university. Only authorised persons will  
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16 have access to the collected data.  
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### 23 24 Eligibility criteria

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28 Participants are eligible for this study if they are registered nurses or enrolled nurses and  
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30 working at least three shifts per week (with each shift >6 hours) in any hospitals within WA;  
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32 scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment.  
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34 People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant  
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36 women will not be eligible.  
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41 Participants will be recruited by the research team through the community. The study will be  
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43 advertised through public advertisements, including posters, flyers, radio, and social media.  
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45 In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals  
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47 within WA. Snowballing techniques will be applied to enhance recruitment. Individuals  
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49 interested in participating in the study will be encouraged to contact the research team via  
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51 email for an eligibility check using the inclusion/exclusion criteria. The study researcher will  
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53 follow-up interested potential participants to facilitate engagement and further understanding  
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55 of the study.  
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3 Our research team will contact those eligible to participate in the study by sending the first 36  
4 eligible potential participants (first come, first served) with a participant information letter  
5 and a link (starting with a consent form) to complete a pre-trial online survey once they have  
6 signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The  
7 online survey should take no longer than 20 minutes to complete.  
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16 The 25-30 minutes treatment sessions will occur outside participants' working hours. As  
17 such, employer approval is not required. The intervention will be delivered in the clinic  
18 located at the corresponding author's university, across a range of days and times and  
19 participants will be expected to choose a session that does not conflict with their normal  
20 working hours. Participation in the research is voluntary, and participants can withdraw  
21 consent at any time without giving any reason, and their care or legal rights will not be  
22 affected.  
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### 32 33 Outcome measurement time points 34

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36 The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of  
37 enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment  
38 adherence (No. of completed sessions and missed sessions) and compliance. An  
39 observational sheet and study-specific questionnaires throughout the trial process to monitor  
40 these outcomes; (3) participants' attitudes, motivation, and challenges to participation,  
41 reasons for withdrawal, missed sessions, and non-compliance with the intervention will be  
42 investigated via open-ended questions in the study-specific online survey at the end of the  
43 trial. Recruitment and completion rates will be assessed during the entire trial process.  
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3 before the commencement of phase 2 intervention (following crossover) (T2), and post-two  
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5 weeks phase 2 intervention (T3).  
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9 The secondary outcomes will include anxiety as measured by mean scores on Generalized  
10  
11 Anxiety Disorder 7 (GAD-7) (34) ; depression as measured by mean scores on the Patient  
12  
13 Health Questionnaire (PHQ-9) (35); work productivity and activity assessment (WPAI:SHP)  
14  
15 (36, 37); and Quality of life assessment (SF-12) (38, 39). These outcomes will be measured  
16  
17 using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the  
18  
19 commencement of new intervention (following crossover) (T2), and post-phase 2  
20  
21 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and  
22  
23 experiences of participating in the trial will also be included, measured at T0 and T3,  
24  
25  
26  
27 respectively.  
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### 30 31 *Anxiety assessment*

#### 32 33 **GAD-7**

34  
35 The Generalized Anxiety Disorder 7 (GAD-7) is a gold-standard measurement tool for  
36  
37 generalised anxiety disorder (34). It is quick, user-friendly, concise, and self-administered  
38  
39 screening and diagnostic tools. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to  
40  
41 the response categories of “not at all”, “several days”, “more than half the days”, and “nearly  
42  
43 every day”, respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores  
44  
45 of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.  
46  
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### 50 51 *Depression assessment*

#### 52 53 **PHQ-9**

54  
55 The Patient Health Questionnaire (PHQ-9) is a self-administered diagnostic instrument for  
56  
57 depression severity (35). It is calculated by assigning scores of 0, 1, 2, and 3 to the response  
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3 categories of “not at all”, “several days”, “more than half the days”, and “nearly every day”,  
4  
5 respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15,  
6  
7 and 20 represent cut-off points for mild, moderate, moderately severe and severe depression.  
8  
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### 10 *Work productivity and activity assessment*

#### 11 **WPAI:SHP**

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16 The Work Productivity and Activity Impairment Questionnaire for Specific Health Problem  
17  
18 V2.0 (WPAI: SHP) (36, 37) is a 6-item questionnaire that evaluates self-reported productivity  
19  
20 and activity during the past week. It includes subscales for absence from work (absenteeism),  
21  
22 lost productivity while at work (presenteeism), overall work impairment, and the effects on  
23  
24 non-work-related activities. Higher subscale value (0-100%) indicate greater work or activity  
25  
26 impairment (36, 37).  
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### 30 *Quality of life assessment*

#### 31 **SF-12**

32  
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36 The 12-item Short Form Health Survey (SF-12) is a self-reported outcome measure assessing  
37  
38 the impact of health on an individual’s everyday life and their quality of life (38, 39),  
39  
40 including eight domains (1) Limitations in physical activities because of health problems; (2)  
41  
42 Limitations in social activities because of physical or emotional problems; (3) Limitations in  
43  
44 usual role activities because of physical health problems; (4) Bodily pain; (5) General mental  
45  
46 health (psychological distress and well-being); (6) Limitations in usual role activities because  
47  
48 of emotional problems; (7) Vitality (energy and fatigue); and (8) General health perceptions.  
49  
50  
51 The SF-12 and SF-36 possess similar validity (40-42). Scores on these eight domains are  
52  
53 aggregated to form two final components: physical and mental wellbeing scores. An  
54  
55 algorithm is used to generate the two components for comparison to normative data: the mean  
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3 score is set to 50, scores >50 indicate better physical or mental health than the mean, whereas  
4  
5 scores <50 indicate worse physical or mental health than the mean.  
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## 8 Data analysis 9

10  
11 Descriptive statistics for continuous variables will initially be described by mean and  
12  
13 standard deviation (SD) for normal data, and by median and interquartile range (IQR) for  
14  
15 non-normal data. Categorical data will be summarised by frequencies and proportions. For  
16  
17 the primary outcomes, rates of recruitment (no. consented/eligible), completion (undertaken  
18  
19 baseline and follow-up tests), adherence (participants completed sessions/no. of sessions),  
20  
21 and adverse events (number and number per participant hour) will be calculated and reported.  
22  
23 No formal modelling is planned or required for the primary outcomes. The secondary  
24  
25 outcomes will be assessed following intention-to-treat principles. Linear mixed modelling  
26  
27 with unstructured covariance matrix will be conducted to assess changes in secondary  
28  
29 outcomes throughout the study. This model allows for the inclusion of missing data in an  
30  
31 intention-to-treat analysis without imputations (e.g., last-observation-carried-forward). Post-  
32  
33 hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for  
34  
35 potential confounding factors such as age, gender, education levels and any other potentially  
36  
37 relevant variables where data are available. The corrected Akaike Information Criterion  
38  
39 (AICc) will be used to assess model fit when covariates are added to the model. Normality  
40  
41 assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear  
42  
43 transformations such as the square root and log-transformations, will be applied to normalise  
44  
45 the data. Statistical significance will be set at an alpha level of 0.05. False discovery rate  
46  
47 (FDR). Corrections will be applied to all analysed outcomes to account for multiple  
48  
49 comparisons. Effects sizes, defined by partial eta squared, will be reported and interpreted,  
50  
51 with 0.01, 0.06 and 0.014, respectively, identified as small, medium and large effects (43).  
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53 All analyses will be conducted using R version 4.1.  
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3 The qualitative data collected via open-ended questions across the four online surveys will be  
4 used to help explain or elaborate on the quantitative data. Qualitative data will be analysed  
5 using template thematic analysis. Template thematic analysis uses ‘a priori’ code frames to  
6 analyse and report on the data (44). The initial skeleton code frame is often formulated from  
7 the questions asked of participants and then built upon during analysis in an iterative process.  
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### 15 **Ethics and dissemination**

16  
17 The study will be conducted following the National Statement and the Australian Code for  
18 the Responsible Conduct of Research, 2018 (the ‘Research Code’), and ethical approval was  
19 obtained from Edith Cowan University’s Human Research Ethics Committee (No. 2021-  
20 02728-WANG). The participant Information Letter explains the study, including the purpose  
21 and procedures, the voluntary nature of participation, and the option to withdraw at any time.  
22 Participants are also guaranteed confidentiality and secured data storage. Any adverse events  
23 arising will be reported and managed by the investigators. Data will be securely stored in  
24 ECU’s security location, and no unauthorized persons will have access to the collected data.  
25 The investigator will supply the Ethics Committee on request with any required background  
26 data from the study documentation or clinic records. In case of special problems and/or  
27 governmental queries or requests for audit inspections, it is also necessary to have access to  
28 the complete study records, if participant confidentiality is protected. Any modifications  
29 made to the protocol after receipt of the Independent Ethics Committee approval will also be  
30 submitted by the investigator to the Committee in accordance with local procedures and  
31 regulatory requirements.  
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53 The research findings will be shared in various forms to engage broader audiences, including  
54 at national and international conferences presentations, in open-access peer-reviewed journal  
55 publications, and at local community workshops with healthcare professionals.  
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3 This study will improve understanding of how to provide holistic approaches for nurses'  
4 mental wellbeing in WA hospitals. The interventions in this study compromise light  
5 acupuncture and five-element music therapy, and study will evaluate the feasibility of the  
6 intervention regime and methodological design. Currently, there is no such modality designed  
7 for nurses and their wellbeing, and findings from this study can add value to the evidence  
8 base about how to acceptably involve complementary medicine for nurses' mental wellbeing.  
9  
10 The evaluation will look at the use of light acupuncture and five-element music therapy in the  
11 context of increased mental health difficulties for nurses during and after the COVID-19  
12 pandemic. The findings can provide updated knowledge on the value of non-pharmacological  
13 interventions in alleviating the challenge of reducing the burden of mental health difficulties  
14 for nurses.  
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30 The higher anxiety levels during the pandemic impact on nurses' mental wellbeing,  
31 healthcare workforce and health outcome of the public. The light acupuncture and five-  
32 element music therapy could be an example of a safe, sustainable, and cost-effective  
33 intervention with promise as a complementary modality. This study will determine the  
34 feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental  
35 health caused by the pandemic. The findings will provide evidence for the acceptability of  
36 such modality to inform future strategies for nurses' mental wellbeing.  
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### 47 Acknowledgments

48  
49 We thank all the healthcare professionals, researchers, and public contributors who supported  
50 the project with their willingness to advertise the project in our next phase of recruitment.  
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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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	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
<b>Enrolment:</b>									
✓ Randomisation		X							
✓ Informed consent	X								
✓ Baseline		X							
<b>Intervention:</b> Light acupuncture + Five-element music therapy			X	X			X	X	
			←————→				←————→		
<b>Control:</b> No treatment			X	X			X	X	
			←————→				←————→		
<b>Assessments:</b>									
<b>Demographic data</b>									
Nursing role, gender, age, ethnicity, education level, employment types (PT, FT), and personal annual income		X							
<b>Recruitment and completion rates</b>									
No. of referred, eligible, enrolled, withdrawals, and trial recruitment rate, and trial completion rate	X	X	X	X	X	X	X	X	X
<b>Treatment adherence and compliance</b>									

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No. of completed sessions and missed sessions			X	X			X	X	
<b>Anxiety assessment</b>									
GAD-7		X			X				X
<b>Depression assessment</b>									
PHQ-9		X			X				X
<b>Work productivity and activity assessment</b>									
WPAI:SHP		X			X				X
<b>Quality of life assessment</b>									
SF-12		X			X				X
<b>Non-prescription mental wellbeing therapy preferences</b>									
Past 3-month choice of non-pharmacologic therapy		X							
<b>Enabling and disabling factors</b>									
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

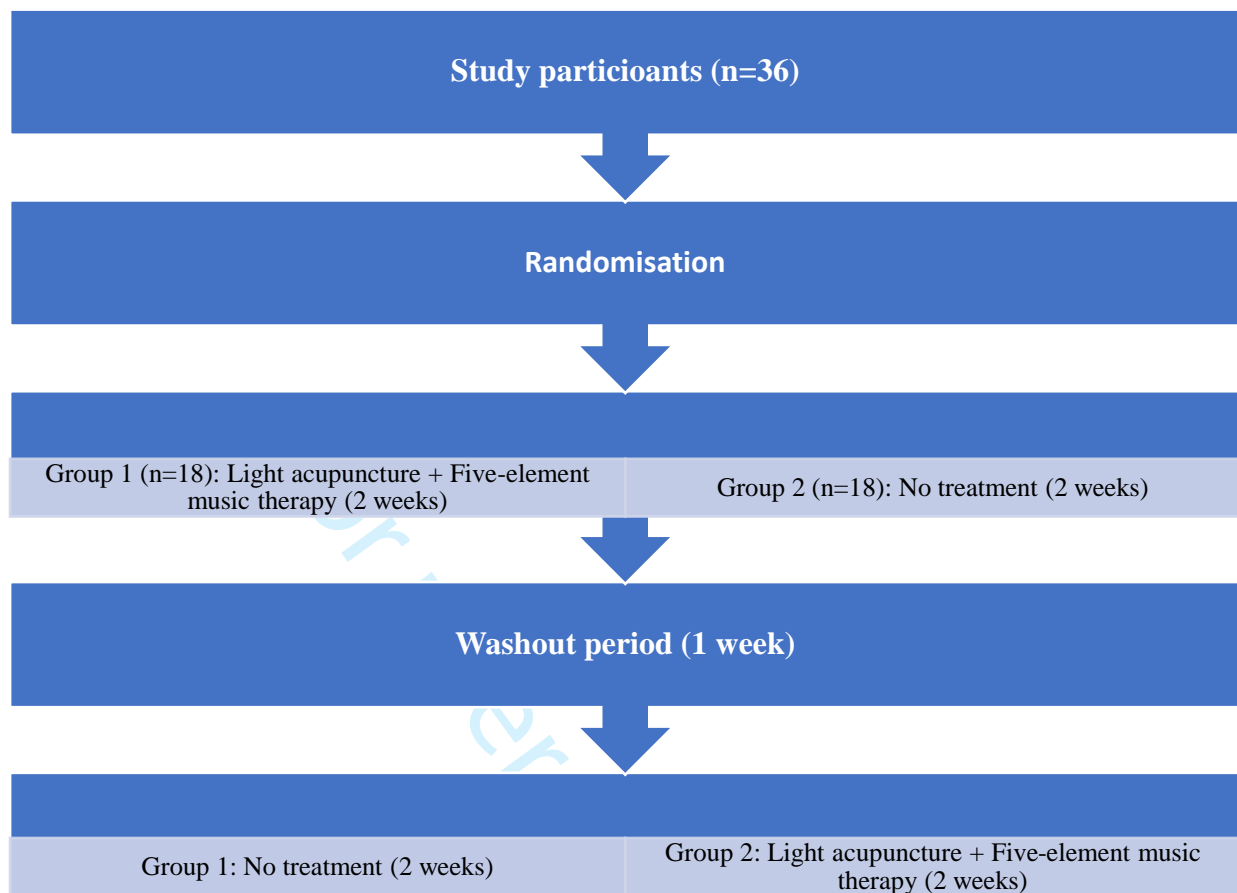


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control



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

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
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; Title 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 ___



1	<b>Introduction</b>			
2				
3	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 _____
4				
5				
6		6b	Explanation for choice of comparators	_____ 7-8 _____
7				
8	Objectives	7	Specific objectives or hypotheses	_____ 5 _____
9				
10	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 _____
11				
12				
13				
14	<b>Methods: Participants, interventions, and outcomes</b>			
15				
16	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 _____
17				
18				
19	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 _____
20				
21				
22	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_____ 7 _____
23				
24		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 _____
25				
26		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____ 10 _____
27				
28		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____ n/a _____
29				
30	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 _____
31				
32				
33				
34	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 _____
35				
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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
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
5				
6				
7	<b>Methods: Assignment of interventions (for controlled trials)</b>			
8	Allocation:			
9				
10	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
11				
12				
13				
14				
15				
16	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
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
28				
29				
30				
31	<b>Methods: Data collection, management, and analysis</b>			
32				
33	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
34				
35				
36				
37				
38				
39		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
40				
41				
42				
43				
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45				
46				

1	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 _____
2				
3				
4				
5	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 _____
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____ n/a _____
9				
10		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 _____
11				
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	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 _____
17				
18				
19				
20				
21				
22		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 _____
23				
24				
25	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 _____
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____ 13 _____
29				
30				
31				
32	<b>Ethics and dissemination</b>			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____ 13 _____
35				
36				
37	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 _____
38				
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46				

1	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_____
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____n/a_____
5				
6				
7	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_____
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____15_____
11				
12				
13	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_____
14				
15				
16	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_____
17				
18				
19				
20	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_____
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	_____15_____
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____n/a_____
27				
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Included supporting document
32				
33				
34				
35	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_____
36				
37				

\*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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

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## 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 improve 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

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

3 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  
4 information letter to keep. Your decision to take part, or to take part and later withdraw, will not affect your  
5 relationship with the research team and any staff within the School of Nursing and Midwifery at ECU.

### 6 **Your privacy**

7  
8 By signing the consent form, you consent to the research team collecting and using personal information about  
9 you for the research project. Any information obtained in connection with this research project that can identify  
10 you will remain confidential. When all survey responses are returned to the research team, all data are  
11 automatically de-identified, and you will not be identifiable by any of your responses to the survey. Your  
12 information will only be used for the purpose of this research project and it will only be disclosed with your  
13 permission, except as required by law.

14  
15 It is anticipated that the results of this research project will be published and/or presented in a variety of  
16 professional forums. In any publication and/or presentation, the information will be provided in such a way that  
17 you cannot be identified, except where requested for specific reasons, and then you will be asked to provide  
18 written consent.

19  
20 In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the  
21 right to request access to the information about you that is collected and stored by the research team. You also  
22 have the right to request that any information that you disagree to be corrected. Please inform the research team  
23 member named at the end of this letter if you would like to access your information.

24  
25 All data collected will be kept in accordance with ECU's Data Management Policy. Electronic data will be stored  
26 on a secure Microsoft SharePoint site provisioned by ECU's IT Services and physical records will be stored as  
27 required in ECU's Records Management Policy. The data will be retained for a period of seven years and  
28 destroyed, if appropriate at the end of the retention period. Data will be de-identified when stored and at the end  
29 of the retention period, the data will be destroyed, if appropriate under the State Records Act.

### 30 **Possible Benefits**

31  
32 This study will improve understanding of how to provide holistic approaches for nurses' mental wellbeing in WA  
33 hospitals. The interventions in this study comprise light acupuncture and five-element music therapy, and the  
34 study will evaluate the feasibility of the intervention regime and methodological design. Currently, there is no  
35 such modality designed for nurses and their wellbeing, and findings from this study can add value to the  
36 evidence base about how to acceptably involve complementary medicine for nurses' mental wellbeing. The  
37 evaluation will look at the use of light acupuncture and five-element music therapy in the context of increased  
38 mental health difficulties for nurses during and after the COVID-19 pandemic. The findings can provide updated  
39 knowledge on the value of non-pharmacological interventions in reducing the burden of mental health difficulties  
40 for nurses. Based on past research, we anticipate that light acupuncture treatment and five-element music  
41 therapy may help reduce stress and anxiety levels, increasing work productivity and quality of life. We hope that  
42 the results of our research can be used to inform our knowledge about how to manage nursing mental wellbeing  
43 better. There are no foreseeable risks associated with your participation in this research project.

### 44 **Possible Risks and Risk Management Plan**

45  
46 Light acupuncture is cleared and approved by the Food and Drug Administration (FDA). It is safe and there are  
47 no foreseeable risks associated with participation in this research project. However, both the practitioner and the  
48 participants will wear an appropriate laser safety eyewear that match the laser wavelength and have sufficient  
49 optical density at that wavelength to protect the eye.

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

51  
52 We will advise you of the outcomes via email communication. We also intend to publish our results in research  
53 journals and present them at research conferences locally, nationally and internationally. Your name or any other  
54 identifying information will not be included in any of the publications or presentations.

### 55 **Has this research been approved?**

56  
57 This research project has received the approval of Edith Cowan University's Human Research Ethics Committee  
58 under the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human  
59 Research 2007 (Updated 2018)*. The approval number is No. 2021-02728-WANG  
60 [https://www.nhmrc.gov.au/guidelines.xhtml](#)



## 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





1 Chief Investigator: Dr Carol Wang  
2 School of Nursing and Midwifery  
3 Edith Cowan University  
4 270 Joondalup Drive  
5 JOONDALUP WA 6027  
6 Phone: 6304 3589  
7 Email: [c.wang@ecu.edu.au](mailto:c.wang@ecu.edu.au)

## 8 Participant Consent Form

9  
10  
11 **Project title:** The experience and effects of light acupuncture and five-element music therapy for nurses' mental  
12 health and wellbeing during and post COVID-19: a randomised crossover and feasibility study

13 **Approval Number:** No. 2021-02728-WANG

14 **Trial registration No.** ACTRN12621000957897p

15 **Principal Investigator:** Dr Carol Wang

16  
17  
18 I, \_\_\_\_\_ have read the Participant Information Letter. By signing this  
19 consent form, I acknowledge that I:

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

34  
35  
36  
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38  
39  
40  
41  
42  
43  
44 Participant name: \_\_\_\_\_

45  
46 Signature: \_\_\_\_\_

Date \_\_\_\_\_

47  
48  
49  
50 Approval to conduct this research has been provided by the Edith Cowan University's Human Research Ethics Committee, approval  
51 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-057106.R1
Article Type:	Protocol
Date Submitted by the Author:	24-Jan-2022
Complete List of Authors:	Wang, Carol Chunfeng; Edith Cowan University; Edith Cowan University Lo, Johnny; Edith Cowan University, School of Science Saunders, Rosemary; Edith Cowan University, Centre for Research in Aged Care, School of Nursing & Midwifery Adama, Esther; Edith Cowan University, School of Nursing and Midwifery Bulsara, Caroline; University of Notre Dame Australia, School of Nursing and Midwifery Etherton-Beer, Christopher; The University of Western Australia, Medical School Yang, Angela; RMIT University, Division of Chinese Medicine
<b>Primary Subject Heading</b>:	Nursing
Secondary Subject Heading:	Mental health, Nursing, Public health
Keywords:	Pain management < ANAESTHETICS, Laser therapy < DERMATOLOGY, PAIN MANAGEMENT, Depression & mood disorders < PSYCHIATRY, MENTAL HEALTH

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Manuscripts

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3 The feasibility of light acupuncture and five-element music therapy for nurses' mental health  
4  
5 and wellbeing during and post COVID-19: protocol for a randomised crossover study  
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7

8 Carol Chunfeng Wang<sup>1</sup>, PhD; Johnny Lo<sup>2</sup>, PhD; Rosemary Saunders<sup>1</sup>, PhD; Esther Adama<sup>1</sup>,  
9 PhD; Caroline Bulsara<sup>3</sup>, PhD; Christopher Etherton-beer<sup>4</sup>, PhD; Angela Wei Hong Yang<sup>5</sup>,  
10 PhD;  
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52 keywords or phrases:

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

54 Word count: 3608  
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60

## 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.

1  
2  
3 Furthermore, the stress and anxiety associated with the pandemic are expected to affect  
4  
5 nurses' long-term mental wellbeing (9) and intention to stay in the profession.  
6  
7

8  
9 Traditional Chinese Medicine (TCM) played a huge role and has been extensively used  
10  
11 around the world to combat stress and promote mental health well-being (10). During  
12  
13 COVID-19, TCM has also been used widely in China (11), and the World Health  
14  
15 Organization has recognised its contribution. Recent systematic reviews have identified high-  
16  
17 level evidence which supports the safe and effective application of acupuncture for treating  
18  
19 depression and anxiety (12).  
20  
21

22  
23 Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one  
24  
25 of the more recent technological developments in acupuncture that integrates cutting-edge  
26  
27 laser technology with a centuries old modality TCM (13) . Light acupuncture is non-invasive,  
28  
29 painless, non-infectious, and safe to use (14) . This form of acupuncture has also become  
30  
31 increasingly popular among patients with needle phobias, particularly older people, and  
32  
33 children (15-17). Several studies have documented light acupuncture as a promising modality  
34  
35 in managing mental wellbeing (18, 19).  
36  
37

38  
39 The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of  
40  
41 Medicine), the earliest and most influential medical text of TCM, states that different  
42  
43 elements (tunes) of music can help treat different emotional disorders (20, 21). Based on its  
44  
45 theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi  
46  
47 (*So*), and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal,  
48  
49 wood, fire, water). According to TCM, the five elements in nature also represent five main  
50  
51 human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry,  
52  
53 anger, joy, and fear) (20, 21). For example, the Jiao note, corresponding to the wood element,  
54  
55 influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note  
56  
57  
58  
59  
60

1  
2  
3 belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a  
4  
5 good combination of the notes can help balance the Yin and Yang and maintain the human  
6  
7 body in a state of equilibrium and good health. The study found that five-element music  
8  
9 therapy plays a vital role in preventing and treating disease (22), it significantly enhanced  
10  
11 adenosine triphosphate (ATP) and glutathione (GSH) levels and cells growth rates (23). It  
12  
13 reduced anxiety and depression (24, 25) and improved the quality of life (25). Furthermore,  
14  
15 the therapy reduced chronic fatigue and alleviated pain symptoms (26) and improved sleep  
16  
17 (27) in cancer patients.  
18  
19  
20  
21

22  
23 Acupuncture and five-element music therapy could be an effective regimen for mental  
24  
25 wellbeing. However, research in this field is lacking and to date has proven inconclusive.  
26  
27

28  
29 Following the Australian Medical Research Council framework for designing and evaluating  
30  
31 complex interventions, this study is the 'feasibility and piloting' stage in the development and  
32  
33 evaluation process (28). Quantitative and qualitative aspects of the feasibility evaluation will  
34  
35 be conducted to understand the holistic interventions.  
36  
37

38  
39 The overarching aim of this study is to provide evidence of the feasibility and a short-term  
40  
41 therapeutic effect of light acupuncture and five-element music therapy for nurses' mental  
42  
43 health and wellbeing during and post COVID-19.  
44  
45

46  
47 The primary objective for this study is the feasibility of the two-week light acupuncture and  
48  
49 five-element music therapy for nurses working in WA hospitals. The secondary objective  
50  
51 focuses on the short-term therapeutic effect and safety. Figure 1 summarises the schedule of  
52  
53 enrolment, interventions, and assessments.  
54  
55

56  
57 **Fig 1. The schedule of enrolment, interventions, and assessments**  
58  
59

## 60 **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



1  
2  
3 allocation will be performed by an independent, blinded statistician. The randomization list  
4  
5 will only be kept by the researcher who performed the intervention. Participants will be  
6  
7 randomly assigned to one of the two arms (Group 1 and Group 2) receiving either light  
8  
9 acupuncture and five-element music (a total of six sessions) or no treatment for two weeks.  
10  
11 Following one week run in period, the two groups will be crossed over whereby the light  
12  
13 acupuncture and five-element music group will receive no treatment and vice versa in the no  
14  
15 treatment group to receive two weeks treatment (totally six sessions). Outcome assessors and  
16  
17 team members who perform data entry and data analysis will be blinded.  
18  
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22

### 23 Intervention

24  
25 This is a crossover study with two weeks of interventions and a week run in period in  
26  
27 between. Each participant will receive the combination of light acupuncture treatment and  
28  
29 five-element music therapy three times weekly for two weeks from a registered acupuncturist  
30  
31 at the clinic located at the corresponding author's university. Each session will last 25-30  
32  
33 minutes, including preparation, treatment, and conclusion of treatment. The 3B Laser Pen  
34  
35 (200mW, Lorrach, Germany) used in the intervention will have a wavelength of 808 nm in  
36  
37 continuous wave mode to be applied to bare skin on the selected points. Each pressure point  
38  
39 will receive 20 seconds of energy (4J), with 20 minutes being the maximum treatment time  
40  
41 (240J). During the treatment, the participant will be listening to the five-element music  
42  
43 depending on their emotional types (fear, anger, joy, anxiety, and sorrow). For example, if  
44  
45 one has anger, frustration, and rage, it could indicate they have too much Yang energy or  
46  
47 problems with Liver or detoxification pathways. They will follow the five-element diagram  
48  
49 to listen to the Wood element music. Study-specific questionnaires and an observational sheet  
50  
51 will be used throughout the trial process to monitor the adherence to the intervention. A plan  
52  
53 for participants with potentially acute or urgent needs (e.g., symptoms) to ensure they receive  
54  
55 evidence-based support (e.g., stop treatment or refer to GP).  
56  
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## 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

1  
2  
3 account, the sample size for this study will be 36 to address feasibility issues (recruitment and  
4 completion rates, treatment adherence and compliance, and participants' attitudes,  
5 motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics)  
6 with a quantitative method and open-ended questions will assess the intervention and study  
7 design feasibility. It will inform future powered therapeutic effect trials for its outcome  
8 measures, treatment regime, and study design. Participants will be given a unique  
9 identification number, and the data collected will be treated with confidentiality and stored  
10 securely within the systems at the chief investigator's university. Only authorised persons will  
11 have access to the collected data.  
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### 23 Eligibility criteria

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28 Participants are eligible for this study if they are registered nurses or enrolled nurses and  
29 working at least three shifts per week (with each shift >6 hours) in any hospitals within WA;  
30 scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment.  
31  
32 People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant  
33 women will not be eligible. If there are any health concerns (e.g., high GAD scores), an email  
34 to community members will include details of relevant support and mental health services  
35 (e.g., lifeline Australia; seek GP advice). For example, the following information will be  
36 provided in the email: Lifeline Australia: 13 11 14 (24 hours hotline); Salvo Care Line 1300  
37 36 36 22 (24-hour counselling service).  
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50 Participants will be recruited by the research team through the community. The study will be  
51 advertised through public advertisements, including posters, flyers, radio, and social media.  
52  
53 In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals  
54 within WA. Snowballing techniques will be applied to enhance recruitment. Individuals  
55 interested in participating in the study will be encouraged to contact the research team via  
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1  
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3 email for an eligibility check using the inclusion/exclusion criteria. The study researcher will  
4  
5 follow-up interested potential participants to facilitate engagement and further understanding  
6  
7 of the study.  
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10  
11 Our research team will contact those eligible to participate in the study by sending the first 36  
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13 eligible potential participants (first come, first served) with a participant information letter  
14  
15 and a link (starting with a consent form) to complete a pre-trial online survey once they have  
16  
17 signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The  
18  
19 online survey should take no longer than 20 minutes to complete.  
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24 The 25-30 minutes treatment sessions will occur outside participants' working hours. As  
25  
26 such, employer approval is not required. The intervention will be delivered in the clinic  
27  
28 located at the corresponding author's university, across a range of days and times and  
29  
30 participants will be expected to choose a session that does not conflict with their normal  
31  
32 working hours. Participation in the research is voluntary, and participants can withdraw  
33  
34 consent at any time without giving any reason, and their care or legal rights will not be  
35  
36 affected.  
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#### 40 41 Outcome measurement time points 42 43

44  
45 The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of  
46  
47 enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment  
48  
49 adherence (No. of completed sessions and missed sessions) and compliance. An  
50  
51 observational sheet and study-specific questionnaires throughout the trial process to monitor  
52  
53 these outcomes; (3) participants' attitudes, motivation, and challenges to participation,  
54  
55 reasons for withdrawal, missed sessions, and non-compliance with the intervention will be  
56  
57 investigated via open-ended questions in the study-specific online survey at the end of the  
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1  
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3 trial. Recruitment and completion rates will be assessed during the entire trial process.  
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5 Treatment adherence and compliance will be assessed during the interventions. Online  
6  
7 surveys will be administered at baseline (T0), post-two weeks phase 1 intervention (T1),  
8  
9 before the commencement of phase 2 intervention (following crossover) (T2), and post-two  
10  
11 weeks phase 2 intervention (T3).  
12  
13

14  
15 The secondary outcomes will include anxiety as measured by mean scores on Generalized  
16  
17 Anxiety Disorder 7 (GAD-7) (41) ; depression as measured by mean scores on the Patient  
18  
19 Health Questionnaire (PHQ-9) (42); work productivity and activity assessment (WPAI:SHP)  
20  
21 (43, 44); and Quality of life assessment (SF-12) (45, 46). These outcomes will be measured  
22  
23 using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the  
24  
25 commencement of new intervention (following crossover) (T2), and post-phase 2  
26  
27 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and  
28  
29 experiences of participating in the trial will also be included, measured at T0 and T3,  
30  
31 respectively.  
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### 36 37 *Anxiety assessment*

#### 38 39 **GAD-7**

40  
41 The Generalized Anxiety Disorder 7 (GAD-7) is a gold-standard measurement tool for  
42  
43 generalised anxiety disorder (41). It is quick, user-friendly, concise, and self-administered  
44  
45 screening and diagnostic tools. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to  
46  
47 the response categories of “not at all”, “several days”, “more than half the days”, and “nearly  
48  
49 every day”, respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores  
50  
51 of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.  
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### 56 57 *Depression assessment*

#### 58 59 **PHQ-9**

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

#### 16 **WPAI:SHP**

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

#### 36 **SF-12**

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38 The 12-item Short Form Health Survey (SF-12) is a self-reported outcome measure assessing  
39 the impact of health on an individual’s everyday life and their quality of life (45, 46),  
40 including eight domains (1) Limitations in physical activities because of health problems; (2)  
41 Limitations in social activities because of physical or emotional problems; (3) Limitations in  
42 usual role activities because of physical health problems; (4) Bodily pain; (5) General mental  
43 health (psychological distress and well-being); (6) Limitations in usual role activities because  
44 of emotional problems; (7) Vitality (energy and fatigue); and (8) General health perceptions.  
45  
46 The SF-12 and SF-36 possess similar validity (47-49). Scores on these eight domains are  
47 aggregated to form two final components: physical and mental wellbeing scores. An  
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3 algorithm is used to generate the two components for comparison to normative data: the mean  
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5 score is set to 50, scores >50 indicate better physical or mental health than the mean, whereas  
6  
7 scores <50 indicate worse physical or mental health than the mean.  
8  
9

## 10 Data analysis

11  
12  
13 Descriptive statistics for continuous variables will initially be described by mean and  
14  
15 standard deviation (SD) for normal data, and by median and interquartile range (IQR) for  
16  
17 non-normal data. Categorical data will be summarised by frequencies and proportions. For  
18  
19 the primary outcomes, rates of recruitment (no. consented/eligible), completion (undertaken  
20  
21 baseline and follow-up tests), adherence (participants completed sessions/no. of sessions),  
22  
23 and adverse events (number and number per participant hour) will be calculated and reported.  
24  
25  
26 No formal modelling is planned or required for the primary outcomes. The secondary  
27  
28 outcomes will be assessed following intention-to-treat principles. Linear mixed modelling  
29  
30 with unstructured covariance matrix will be conducted to assess changes in secondary  
31  
32 outcomes throughout the study. This model allows for the inclusion of missing data in an  
33  
34 intention-to-treat analysis without imputations (e.g., last-observation-carried-forward). Post-  
35  
36 hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for  
37  
38 potential confounding factors such as age, gender, education levels and any other potentially  
39  
40 relevant variables where data are available. The corrected Akaike Information Criterion  
41  
42 (AICc) will be used to assess model fit when covariates are added to the model. Normality  
43  
44 assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear  
45  
46 transformations such as the square root and log-transformations, will be applied to normalise  
47  
48 the data. Statistical significance will be set at an alpha level of 0.05. False discovery rate  
49  
50 (FDR) corrections will be applied to all analysed outcomes to account for multiple  
51  
52 comparisons. Effects sizes, defined by partial eta squared, will be reported and interpreted,  
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3 with 0.01, 0.06 and 0.014, respectively, identified as small, medium and large effects (50).

4  
5 All analyses will be conducted using R version 4.1.

6  
7  
8 The qualitative data collected via open-ended questions across the four online surveys will be  
9  
10 used to help explain or elaborate on the quantitative data. Qualitative data will be analysed  
11  
12 using template thematic analysis. Template thematic analysis uses ‘a priori’ code frames to  
13  
14 analyse and report on the data (51). The initial skeleton code frame is often formulated from  
15  
16 the questions asked of participants and then built upon during analysis in an iterative process.  
17  
18

### 19 20 21 **Ethics and dissemination**

22  
23 The study will be conducted following the National Statement and the Australian Code for  
24  
25 the Responsible Conduct of Research, 2018 (the ‘Research Code’), and ethical approval was  
26  
27 obtained from Edith Cowan University’s Human Research Ethics Committee (No. 2021-  
28  
29 02728-WANG). The participant Information Letter explains the study, including the purpose  
30  
31 and procedures, the voluntary nature of participation, and the option to withdraw at any time.  
32  
33 Participants are also guaranteed confidentiality and secured data storage. Any adverse events  
34  
35 arising will be reported and managed by the investigators. Data will be securely stored in  
36  
37 ECU’s security location, and no unauthorized persons will have access to the collected data.  
38  
39 The investigator will supply the Ethics Committee on request with any required background  
40  
41 data from the study documentation or clinic records. In case of special problems and/or  
42  
43 governmental queries or requests for audit inspections, it is also necessary to have access to  
44  
45 the complete study records, if participant confidentiality is protected. Any modifications  
46  
47 made to the protocol after receipt of the Independent Ethics Committee approval will also be  
48  
49 submitted by the investigator to the Committee in accordance with local procedures and  
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51 regulatory requirements.  
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3 The research findings will be shared in various forms to engage broader audiences, including  
4 at national and international conferences presentations, in open-access peer-reviewed journal  
5 publications, and at local community workshops with healthcare professionals.  
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11 This study will improve understanding of how to provide holistic approaches for nurses'  
12 mental wellbeing in WA hospitals. The interventions in this study compromise light  
13 acupuncture and five-element music therapy, and study will evaluate the feasibility of the  
14 intervention regime and methodological design. Currently, there is no such modality designed  
15 for nurses and their wellbeing, and findings from this study can add value to the evidence  
16 base about how to acceptably involve complementary medicine for nurses' mental wellbeing.  
17 The evaluation will look at the use of light acupuncture and five-element music therapy in the  
18 context of increased mental health difficulties for nurses during and after the COVID-19  
19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological  
20 interventions in alleviating the challenge of reducing the burden of mental health difficulties  
21 for nurses.  
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38 The higher anxiety levels during the pandemic impact on nurses' mental wellbeing,  
39 healthcare workforce and health outcome of the public. The light acupuncture and five-  
40 element music therapy could be an example of a safe, sustainable, and cost-effective  
41 intervention with promise as a complementary modality. This study will determine the  
42 feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental  
43 health caused by the pandemic. The findings will provide evidence for the acceptability of  
44 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
<b>Enrolment:</b>									
✓ Randomisation		X							
✓ Informed consent	X								
✓ Baseline		X							
<b>Intervention:</b> Light acupuncture + Five-element music therapy			X	X			X	X	
			←————→				←————→		
<b>Control:</b> No treatment			X	X			X	X	
			←————→				←————→		
<b>Assessments:</b>									
<b>Demographic data</b>									
Nursing role, gender, age, ethnicity, education level, employment types (PT, FT), and personal annual income		X							
<b>Recruitment and completion rates</b>									
No. of referred, eligible, enrolled, withdrawals, and trial recruitment rate, and trial completion rate	X	X	X	X	X	X	X	X	X
<b>Treatment adherence and compliance</b>									

No. of completed sessions and missed sessions			X	X			X	X	
<b>Anxiety assessment</b>									
GAD-7		X			X				X
<b>Depression assessment</b>									
PHQ-9		X			X				X
<b>Work productivity and activity assessment</b>									
WPAI:SHP		X			X				X
<b>Quality of life assessment</b>									
SF-12		X			X				X
<b>Non-prescription mental wellbeing therapy preferences</b>									
Past 3-month choice of non-pharmacologic therapy		X							
<b>Enabling and disabling factors</b>									
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

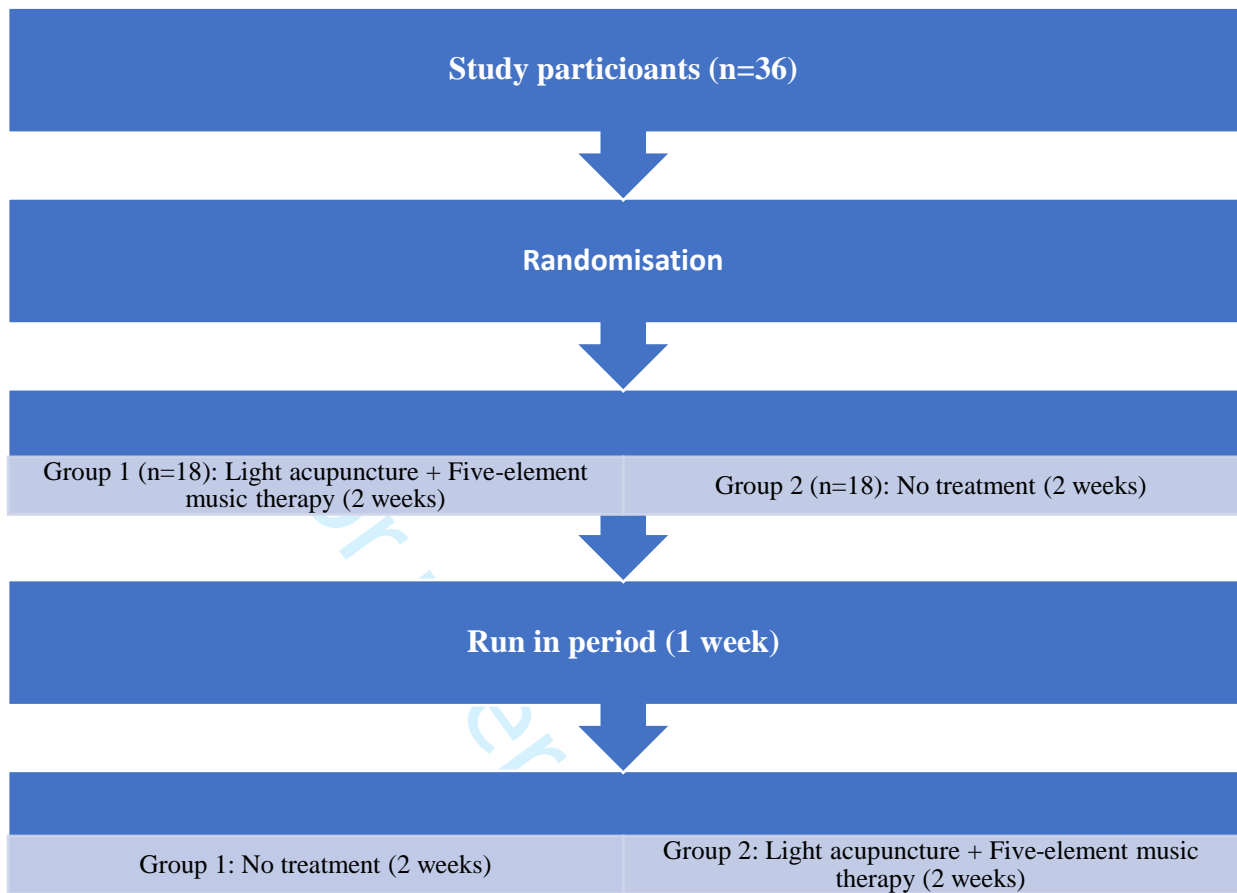


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control



# 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

Journal:	<i>BMJ Open</i>
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Manuscripts

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3 Light acupuncture and five-element music therapy for nurses' mental health and wellbeing  
4  
5 during and post COVID-19: protocol for a randomised crossover feasibility study  
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7

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55 Word count: 3608  
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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

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3 and international conferences presentations, open-access peer-reviewed journal publications,  
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5 and local community workshop dissemination with healthcare professionals.  
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8 **Trial registration:** Australian New Zealand Clinical Trials Registry (ANZCTR):  
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10  
11 ACTRN12621000957897p <https://www.anzctr.org.au/ACTRN12621000957897p.aspx>  
12  
13

## 14 15 **Keywords**

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18 Acupuncture; low-level laser acupuncture; photobiomodulation; nursing; mental health;  
19  
20 depression.  
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## 23 24 **Strengths and limitations of this study**

- 25  
26 ✓ A first study evaluating the light acupuncture and five-element music therapy for  
27  
28 nurses' mental health and wellbeing during and post COVID-19 in Western Australia  
29  
30 hospitals.  
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- 33 ✓ This study will examine the role of involving nurses in light acupuncture and five-  
34  
35 element music therapy, which has remained under-explored in hospitals.  
36  
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- 38 ✓ Qualitative and quantitative approaches will be used to comprehensively assess the  
39  
40 trial outcomes to inform a powered therapeutic effectiveness trial and whether it  
41  
42 would be feasible.  
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- 45 ✓ The outcomes to be assessed by this study have relevance to the healthcare workforce,  
46  
47 patient outcome and policymakers.  
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49

## 50 51 **Introduction**

52  
53 The most affected professionals worldwide throughout the COVID-19 pandemic are  
54  
55 healthcare workers, with at least one in five reporting mental health difficulties such as  
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57 anxiety, depression, and stress-related symptoms including sleep disturbances and insomnia  
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3 attributed to the pandemic (1-5). Nurses and midwives are reported to be the most affected of  
4  
5 all health professionals (1, 2, 6). Australian nurses experienced higher anxiety levels than  
6  
7 their counterparts in other countries during the pandemic (7). This high level of anxiety can  
8  
9 result in a lack of motivation and intention to leave the nursing and midwifery profession (8),  
10  
11 leading to a workforce shortage and its associated impact on the health of the public.  
12  
13

14 Furthermore, the stress and anxiety associated with the pandemic are expected to affect  
15  
16 nurses' long-term mental wellbeing (9) and intention to stay in the profession.  
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19  
20 Traditional Chinese Medicine (TCM) played a huge role and has been extensively used  
21  
22 around the world to combat stress and promote mental health well-being (10). During  
23  
24 COVID-19, TCM has also been used widely in China (11), and the World Health  
25  
26 Organization has recognised its contribution. Recent systematic reviews have identified high-  
27  
28 level evidence which supports the safe and effective application of acupuncture for treating  
29  
30 depression and anxiety (12).  
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32

33  
34 Low-level laser acupuncture, also known as photobiomodulation, or light acupuncture, is one  
35  
36 of the more recent technological developments in acupuncture that integrates cutting-edge  
37  
38 laser technology with a centuries old modality TCM (13). Light acupuncture is non-invasive,  
39  
40 painless, non-infectious, and safe to use (14). This form of acupuncture has also become  
41  
42 increasingly popular among patients with needle phobias, particularly older people, and  
43  
44 children (15-17). Several studies have documented light acupuncture as a promising modality  
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46 in managing mental wellbeing (18, 19).  
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51 The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of  
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53 Medicine), the earliest and most influential medical text of TCM, states that different  
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55 elements (tunes) of music can help treat different emotional disorders (20, 21). Based on its  
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57 theory, the five-element music consists of five notes— Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi  
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3 (So), and Yu (La), are believed to be connected with the five elements of nature (earth, metal,  
4 wood, fire, water). According to TCM, the five elements in nature also represent five main  
5 human organs (Spleen, Lung, Liver, Heart, Kidney), and the five emotions (anxiety, worry,  
6 anger, joy, and fear) (20, 21). For example, the Jiao note, corresponding to the wood element,  
7 influences the Liver and helps relieve depression due to its spring-like sound; the Zhi note  
8 belongs to the fire element, and it helps nourish the Heart and invigorate blood flow. Thus, a  
9 good combination of the notes can help balance the Yin and Yang and maintain the human  
10 body in a state of equilibrium and good health. The study found that five-element music  
11 therapy plays a vital role in preventing and treating disease (22), it significantly enhanced  
12 adenosine triphosphate (ATP) and glutathione (GSH) levels and cells growth rates (23). It  
13 reduced anxiety and depression (24, 25) and improved the quality of life (25). Furthermore,  
14 the therapy reduced chronic fatigue and alleviated pain symptoms (26) and improved sleep  
15 (27) in cancer patients.

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

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

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

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3 The primary objective for this study is to evaluate the feasibility of a combination of light  
4 acupuncture treatment and five-element music therapy to improve nurses' mental health and  
5 wellbeing, as measured by recruitment and completion rates and treatment adherence and  
6 compliance. Participants' attitudes, motivation, challenges to participation, intervention non-  
7 compliance, and experience of participating in the trial will be investigated via qualitative  
8 data.  
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12 The secondary outcomes will include anxiety as measured by mean scores on Generalized  
13 Anxiety Disorder 7 (GAD-7) and depression as measured by mean scores on the Patient  
14 Health Questionnaire (PHQ-9), work productivity and activity assessment (WPAI:SHP), and  
15 quality of life assessment (SF-12). Questions on participants' non-pharmacologic therapy  
16 preferences will also be included. Figure 1 summarises the schedule of enrolment,  
17 interventions, and assessments.  
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32 **Fig 1. The schedule of enrolment, interventions, and assessments**

## 33 34 35 **Methods and analysis**

### 36 37 38 **Study design**

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

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

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

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33 Sequence numbers of each participant will be generated by a computer produced permuted  
34 blocks of random sizes. The block sizes will not be disclosed to ensure concealment. The  
35 allocation will be performed by an independent, blinded statistician. The randomization list  
36 will only be kept by the researcher who performed the intervention. Participants will be  
37 randomly assigned to one of the two arms (Group 1 and Group 2) receiving either light  
38 acupuncture and five-element music (a total of six sessions) or no treatment for two weeks.  
39  
40 Following one week run in period, the two groups will be crossed over whereby the light  
41 acupuncture and five-element music group will receive no treatment and vice versa in the no  
42 treatment group to receive two weeks treatment (totally six sessions). Outcome assessors and  
43 team members who perform data entry and data analysis will be blinded.  
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## 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

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3 active. The procedure involves touching with pressure, which involves the same pathways as  
4 the test treatment; this creates a bias against the actual treatment (33). In other words, the  
5 sham acupuncture procedure introduces a risk of bias against acupuncture (34, 35). With such  
6 understanding, an international expert group suggests that sham acupuncture be discontinued  
7 at least in clinical trials (36, 37).  
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15 To date, no sham techniques developed capable of acting as placebo treatments; therefore,  
16 placebo-controlled trials are not achievable for acupuncture studies. Sham acupuncture  
17 techniques, therefore, should not be used in acupuncture related clinical trials (36); instead,  
18 pragmatic trials, which are designed to answer a question about decision making in clinical  
19 care (what sort of clinical care do patients need in the real world?) (38), where the control  
20 treatment can be an established standard therapy or a no-treatment group should be added  
21 (36).  
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## 32 Participants

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34 The participants will be registered nurses or enrolled nurses working at least 3 shifts per week  
35 (with each shift >6 hours) from any hospitals within WA. Although it is feasible to recruit 30  
36 participants (39), dropouts are possible during the trial process. We estimate 15% attrition  
37 based on the attrition of 12% reported in a previous study (40). Taking these two factors into  
38 account, the sample size for this study will be 36 to address feasibility issues (recruitment and  
39 completion rates, treatment adherence and compliance, and participants' attitudes,  
40 motivation, and challenges to participation). The online questionnaires (hosted on Qualtrics)  
41 with a quantitative method and open-ended questions will assess the intervention and study  
42 design feasibility. It will inform future powered therapeutic effect trials for its outcome  
43 measures, treatment regime, and study design. Participants will be given a unique  
44 identification number, and the data collected will be treated with confidentiality and stored  
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3 securely within the systems at the chief investigator's university. Only authorised persons will  
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5 have access to the collected data.  
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### 8 Eligibility criteria 9

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11 Participants are eligible for this study if they are registered nurses or enrolled nurses and  
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13 working at least three shifts per week (with each shift >6 hours) in any hospitals within WA;  
14  
15 scored five or more for either the GAD-7 or the PHQ-9 during the screening assessment.  
16  
17 People who have a fever or are highly sensitive to light, diagnosed with cancer, or pregnant  
18  
19 women will not be eligible. If there are any health concerns (e.g., high GAD scores), an email  
20  
21 to community members will include details of relevant support and mental health services  
22  
23 (e.g., lifeline Australia; seek GP advice). For example, the following information will be  
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25 provided in the email: Lifeline Australia: 13 11 14 (24 hours hotline); Salvo Care Line 1300  
26  
27 36 36 22 (24-hour counselling service).  
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33  
34 Participants will be recruited by the research team through the community. The study will be  
35  
36 advertised through public advertisements, including posters, flyers, radio, and social media.  
37  
38 In addition, an email invitation will be sent to all Directors of Clinical Services of hospitals  
39  
40 within WA. Snowballing techniques will be applied to enhance recruitment. Individuals  
41  
42 interested in participating in the study will be encouraged to contact the research team via  
43  
44 email for an eligibility check using the inclusion/exclusion criteria. The study researcher will  
45  
46 follow-up interested potential participants to facilitate engagement and further understanding  
47  
48 of the study.  
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52  
53 Our research team will contact those eligible to participate in the study by sending the first 36  
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55 eligible potential participants (first come, first served) with a participant information letter  
56  
57 and a link (starting with a consent form) to complete a pre-trial online survey once they have  
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3 signed the consent form by ticking a box to confirm they agree to the conditions (T 0). The  
4  
5 online survey should take no longer than 20 minutes to complete.  
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9 The 25-30 minutes treatment sessions will occur outside participants' working hours. As  
10  
11 such, employer approval is not required. The intervention will be delivered in the clinic  
12  
13 located at the corresponding author's university, across a range of days and times and  
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15 participants will be expected to choose a session that does not conflict with their normal  
16  
17 working hours. Participation in the research is voluntary, and participants can withdraw  
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19 consent at any time without giving any reason, and their care or legal rights will not be  
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21 affected.  
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#### 24 25 26 Outcome measurement time points 27

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29 The primary measure includes (1) recruitment and completion rates (No. of eligible, No. of  
30  
31 enrolled, No. of withdrawals, trial recruitment rate, and trial completion rate); (2) treatment  
32  
33 adherence (No. of completed sessions and missed sessions) and compliance. An  
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35 observational sheet and study-specific questionnaires throughout the trial process to monitor  
36  
37 these outcomes; (3) participants' attitudes, motivation, and challenges to participation,  
38  
39 reasons for withdrawal, missed sessions, and non-compliance with the intervention will be  
40  
41 investigated via open-ended questions in the study-specific online survey at the end of the  
42  
43 trial. Recruitment and completion rates will be assessed during the entire trial process.  
44  
45 Treatment adherence and compliance will be assessed during the interventions. Online  
46  
47 surveys will be administered at baseline (T0), post-two weeks phase 1 intervention (T1),  
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49 before the commencement of phase 2 intervention (following crossover) (T2), and post-two  
50  
51 weeks phase 2 intervention (T3).  
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3 The secondary outcomes will include anxiety as measured by mean scores on Generalized  
4 Anxiety Disorder 7 (GAD-7) (41) ; depression as measured by mean scores on the Patient  
5 Health Questionnaire (PHQ-9) (42); work productivity and activity assessment (WPAI:SHP)  
6 (43, 44); and Quality of life assessment (SF-12) (45, 46). These outcomes will be measured  
7 using four online surveys: at baseline (T0), post-phase 1 intervention (T1), before the  
8 commencement of new intervention (following crossover) (T2), and post-phase 2  
9 intervention (T3). Questions on participants' non-pharmacologic therapy preferences and  
10 experiences of participating in the trial will also be included, measured at T0 and T3,  
11 respectively.  
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### 25 *Anxiety assessment*

#### 26 **GAD-7**

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

#### 45 **PHQ-9**

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

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3 Normality assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear  
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5 transformations such as the square root and log-transformations, will be applied to normalise  
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7 the data. All analyses will be performed in R Studio version 1.1.463.  
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10 The qualitative data collected via open-ended questions across the four online surveys will be  
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12 used to help explain or elaborate on the quantitative data. Qualitative data will be analysed  
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14 using template thematic analysis. Template thematic analysis uses ‘a priori’ code frames to  
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16 analyse and report on the data (52). The initial skeleton code frame is often formulated from  
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18 the questions asked of participants and then built upon during analysis in an iterative process.  
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### 23 **Ethics and dissemination**

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25 The study will be conducted following the National Statement and the Australian Code for  
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27 the Responsible Conduct of Research, 2018 (the ‘Research Code’), and ethical approval was  
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29 obtained from Edith Cowan University’s Human Research Ethics Committee (No. 2021-  
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31 02728-WANG). The participant Information Letter explains the study, including the purpose  
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33 and procedures, the voluntary nature of participation, and the option to withdraw at any time.  
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35 Participants are also guaranteed confidentiality and secured data storage. Any adverse events  
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37 arising will be reported and managed by the investigators. Data will be securely stored in  
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39 ECU’s security location, and no unauthorized persons will have access to the collected data.  
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42 The investigator will supply the Ethics Committee on request with any required background  
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44 data from the study documentation or clinic records. In case of special problems and/or  
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46 governmental queries or requests for audit inspections, it is also necessary to have access to  
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48 the complete study records, if participant confidentiality is protected. Any modifications  
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50 made to the protocol after receipt of the Independent Ethics Committee approval will also be  
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52 submitted by the investigator to the Committee in accordance with local procedures and  
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54 regulatory requirements.  
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3 The research findings will be shared in various forms to engage broader audiences, including  
4 at national and international conferences presentations, in open-access peer-reviewed journal  
5 publications, and at local community workshops with healthcare professionals.  
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11 This study will improve understanding of how to provide holistic approaches for nurses'  
12 mental wellbeing in WA hospitals. The interventions in this study compromise light  
13 acupuncture and five-element music therapy, and study will evaluate the feasibility of the  
14 intervention regime and methodological design. Currently, there is no such modality designed  
15 for nurses and their wellbeing, and findings from this study can add value to the evidence  
16 base about how to acceptably involve complementary medicine for nurses' mental wellbeing.  
17 The evaluation will look at the use of light acupuncture and five-element music therapy in the  
18 context of increased mental health difficulties for nurses during and after the COVID-19  
19 pandemic. The findings can provide updated knowledge on the value of non-pharmacological  
20 interventions in alleviating the challenge of reducing the burden of mental health difficulties  
21 for nurses.  
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38 The higher anxiety levels during the pandemic impact on nurses' mental wellbeing,  
39 healthcare workforce and health outcome of the public. The light acupuncture and five-  
40 element music therapy could be an example of a safe, sustainable, and cost-effective  
41 intervention with promise as a complementary modality. This study will determine the  
42 feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental  
43 health caused by the pandemic. The findings will provide evidence for the acceptability of  
44 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
<b>Enrolment:</b>									
✓ Randomisation		X							
✓ Informed consent	X								
✓ Baseline		X							
<b>Intervention:</b> Light acupuncture + Five-element music therapy			← X	X →			← X	X →	
<b>Control:</b> No treatment			← X	X →			← X	X →	
<b>Assessments:</b>									
<b>Recruitment and completion rates</b>									
No. of referred, eligible, enrolled, withdrawals, and trial recruitment and completion rates	X	X	X	X	X	X	X	X	X
<b>Treatment adherence and compliance</b>									
No. of completed sessions and missed sessions			X	X			X	X	
<b>Anxiety assessment</b>									
GAD-7		X			X	X			X
<b>Depression assessment</b>									
PHQ-9		X			X	X			X
<b>Work productivity and activity assessment</b>									
WPAI:SHP		X			X	X			X
<b>Quality of life assessment</b>									
SF-12		X			X	X			X
<b>Non-prescription mental wellbeing therapy preferences</b>									
Past 3-month choice of non-pharmacologic therapy		X							
<b>Enabling and disabling factors</b>									
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

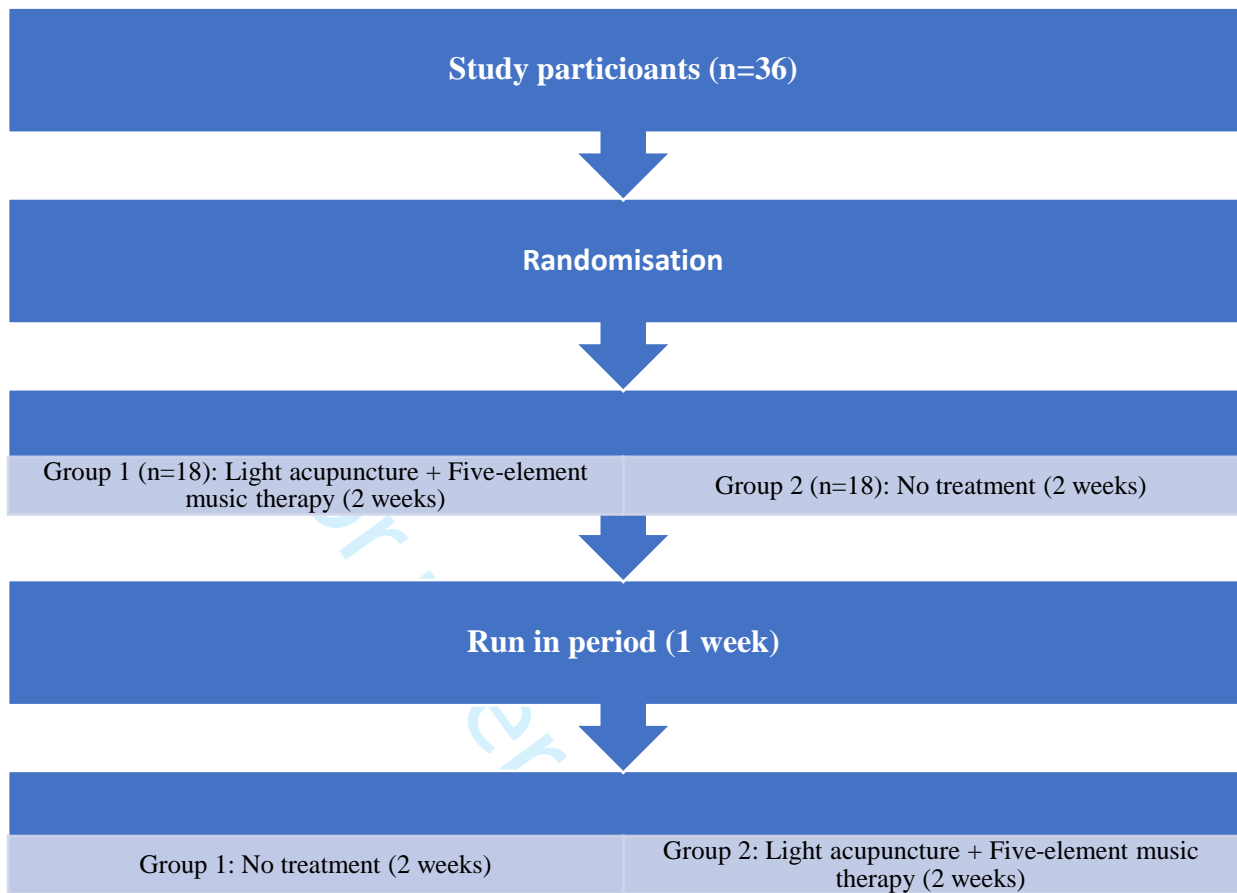


Figure 2. Participants receives the treatment but at different times, every participant act as his or her own control