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Light acupuncture and five-element music therapy for nurses' mental health and well-being during and post-COVID-19: protocol for a randomised cross-over feasibility study

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BMJ Open Light acupuncture and five-element music therapy for nurses' mental health and well-being during and post-COVID-19: protocol for a randomised cross-over feasibility study

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ABSTRACT

Introduction Australian nurses have experienced higher levels of anxiety during the COVID-19 pandemic compared with the prepandemic. 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' well-being. 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 well-being during and post-COVID-19.

Methods and analysis This randomised, single blinding, two-arm cross-over 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 weeks. 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 well-being. 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 V.1.1.463.

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

Trial registration number Australian New Zealand Clinical Trials Registry: ACTRN12621000957897p <https://www.anzctr.org.au/ACTRN12621000957897p.aspx>

Strengths and limitations of this study

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

INTRODUCTION

The most affected professionals worldwide throughout the COVID-19 pandemic are healthcare workers, with at least one in five reporting mental health difficulties such as anxiety, depression and stress-related symptoms including sleep disturbances and insomnia attributed to the pandemic.¹⁻⁵ Nurses and midwives are reported to be the most affected of all health professionals.^{1 2 6} Australian nurses experienced higher anxiety levels than their counterparts in other countries during the pandemic.⁷ This high level of anxiety can result in a lack of motivation and intention to leave the nursing and midwifery profession,⁸ leading to a workforce shortage and its associated impact on the health of the public. Furthermore, the stress and anxiety associated with the pandemic are expected to affect nurses' long-term mental well-being⁹ and intention to stay in the profession.



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

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

The five-element music therapy in Huangdi Neijing (The Yellow Emperor's Classic of Medicine), the earliest and most influential medical text of TCM, states that different elements (tunes) of music can help treat different emotional disorders.^{20 21} Based on its theory, the five-element music consisting of five notes—Gong (*Do*), Shang (*Re*), Jiao (*Mi*), Zhi (*So*) and Yu (*La*), are believed to be connected with the five elements of nature (earth, metal, wood, fire and water). According to TCM, the five elements in nature also represent five main human organs (spleen, lung, liver, heart, kidney) and the five emotions (anxiety, worry, anger, joy and fear).^{20 21} For example, the Jiao note, corresponding to the wood element, influences the liver and helps relieve depression due to its spring-like sound; the Zhi note belongs to the fire element, and it helps nourish the heart and invigorate blood flow. Thus, a good combination of the notes can help balance the Yin and Yang and maintain the human body in a state of equilibrium and good health. The study found that five-element music therapy plays a vital role in preventing and treating disease;²² it significantly enhanced ATP and glutathione levels and cells growth rates.²³ It reduced anxiety and depression^{21 24} and improved the quality of life.²⁴ Furthermore, the therapy reduced chronic fatigue and alleviated pain symptoms²⁵ and improved sleep²⁶ in patients with cancer.

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

Following the Australian Medical Research Council framework for designing and evaluating complex interventions, this study is the 'feasibility and piloting' stage in the development and evaluation process.²⁷ Quantitative and qualitative aspects of the feasibility evaluation will be conducted to understand the holistic interventions.

The overarching aim of this study is to provide evidence of the feasibility and short-term therapeutic effect of light

acupuncture and five-element music therapy for nurses' mental health and well-being during and post-COVID-19.

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

The secondary outcomes will include anxiety as measured by mean scores on Generalised Anxiety Disorder 7 (GAD-7) and depression as measured by mean scores on the Patient Health Questionnaire (PHQ-9), work productivity and activity assessment as measured by the Work Productivity and Activity Impairment Questionnaire for Specific Health Problem (WPAI: SHP) and quality of life assessment by the 12-item Short Form Health Survey (SF-12). Questions on participants' non-pharmacological therapy preferences will also be included. **Figure 1** summarises the schedule of enrolment, interventions and assessments.

METHODS AND ANALYSIS

Study design

This feasibility study is a randomised cross-over 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*²⁸ and will be reported adhering to the Standard Protocol Items: Recommendations for Interventional Trials reporting template.²⁹

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 Edith Cowan University's (ECU) 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.

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

Figure 1 The schedule of enrolment, interventions and assessments. GAD-7, Generalised Anxiety Disorder 7; PHQ-9, Patient Health Questionnaire; SF-12, 12-item Short Form Health Survey; WPAI: SHP, Work Productivity and Activity Impairment Questionnaire for Specific Health Problem.

Randomisation and blinding

Sequence numbers of each participant will be generated by 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 randomisation 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 2 weeks. Following a 1-week run-in period, the two groups will be crossed over whereby the light acupuncture and five-element music group will receive no treatment and vice versa in the no treatment group to receive 2 weeks treatment

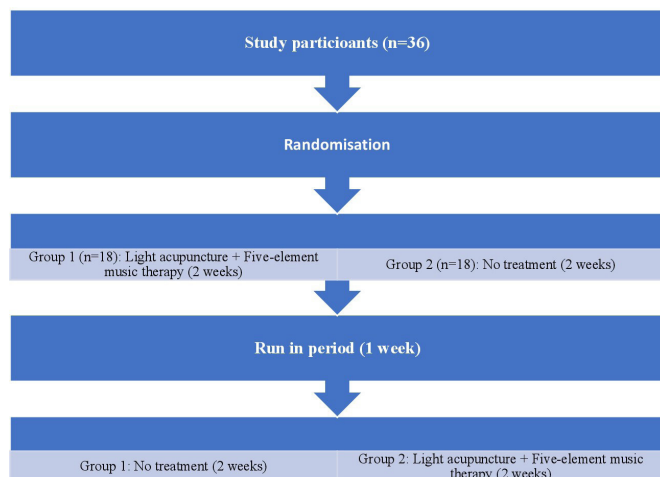


Figure 2 Flow chart of the protocol.

(totally six sessions). Outcome assessors and team members who perform data entry and data analysis will be blinded.

Intervention

This is a cross-over study with 2 weeks of interventions and a 1-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 2 weeks from a registered acupuncturist at the clinic located at the corresponding author's university. Each session will last 25–30 min, including preparation, treatment and conclusion of treatment. The 3B Laser Pen (200 mW, 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 s of energy (4 J), with 20 min being the maximum treatment time (240 J). During the treatment, the participant will be listening to the five-element music depending on their emotion type (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 (eg, symptoms) will be available to ensure they receive evidence-based support (eg, stop treatment or refer to their general practitioner (GP)).

Control

The participants will be advised to wait for 2 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.^{30 31} 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.³² In other words, the sham acupuncture procedure introduces a risk of bias against acupuncture.^{33 34} With such understanding, an international expert group suggests that sham acupuncture be discontinued at least in clinical trials.^{35 36}

To date, no sham techniques developed are 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,³⁵ instead, pragmatic trials should be used, 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?),³⁷ where the control treatment can be an established standard therapy or a no-treatment group should be added.³⁵

Participants

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

Eligibility criteria

Participants are eligible for this study if they are registered nurses or enrolled nurses and are working at least three shifts per week (with each shift >6 hours) in any hospital within WA, and have scored 5 or more for either the GAD-7 or the PHQ-9 during the screening assessment. People who have a fever or are highly sensitive to light, diagnosed with cancer or pregnant women will not be

eligible. If there are any health concerns (eg, high GAD scores), an email to community members will include details of relevant support and mental health services (eg, Lifeline Australia; seek GP advice). For example, the following information will be provided in the email: Lifeline Australia: 13 11 14 (24 hours hotline); Salvo Care Line 1300 36 36 22 (24-hour counselling service).

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

Our research team will contact those eligible to participate in the study by sending the first 36 eligible potential participants (first come, first served) with a participant information letter and a link (starting with a consent form) to complete a pretrial online survey once they have signed the consent form by ticking a box to confirm they agree to the conditions (T0). The online survey should take no longer than 20 min to complete.

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

Outcome measurement time points

The primary measure includes (1) Recruitment and completion rates (number of eligible, number of enrolled, number of withdrawals, trial recruitment rate and trial completion rate); (2) Treatment adherence (number of completed sessions and missed sessions) and compliance. An observational sheet and study-specific questionnaires throughout the trial process to monitor these outcomes; (3) Participants' attitudes, motivation, and challenges to participation, reasons for withdrawal, missed sessions, and non-compliance with the intervention will be investigated via open-ended questions in the study-specific online survey at the end of the trial. Recruitment and completion rates will be assessed during the entire trial process. Treatment adherence and compliance will be assessed during the interventions. Online surveys will be administered at baseline (T0), post-2 weeks phase I intervention (T1), before the commencement of phase II intervention (following cross-over) (T2), and post-2 weeks phase II intervention (T3).

The secondary outcomes will include anxiety as measured by mean scores on GAD-7;⁴⁰ depression as measured by mean scores on the PHQ-9;⁴¹ work productivity and activity assessment (WPAI: SHP);^{42 43} and quality of life assessment (SF-12).^{44 45} These outcomes will be measured using four online surveys: at baseline (T0), post phase I intervention (T1), before the commencement of a new intervention (following cross-over) (T2), and post phase II intervention (T3). Questions on participants' non-pharmacological therapy preferences and experiences of participating in the trial will also be included, measured at T0 and T3, respectively.

Anxiety assessment

Generalised Anxiety Disorder 7

The GAD-7 is a gold-standard measurement tool for generalised anxiety disorder.⁴⁰ It is a quick, user-friendly, concise, and self-administered screening and diagnostic tool. GAD-7 is calculated by assigning scores of 0, 1, 2 and 3 to the response categories of 'not at all', 'several days', 'more than half the days' and 'nearly every day', respectively. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10 and 15 represent cut-off points for mild, moderate and severe anxiety, respectively.

Depression assessment

Patient Health Questionnaire 9

The PHQ-9 is a self-administered diagnostic instrument for depression severity.⁴¹ It is calculated by assigning scores of 0, 1, 2 and 3 to the response categories of 'not at all', 'several days', 'more than half the days' and 'nearly every day', respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15 and 20 represent cut-off points for mild, moderate, moderately severe and severe depression, respectively.

Work productivity and activity assessment

Work Productivity and Activity Impairment Questionnaire for Specific Health Problem

The WPAI: SHP V.2.0^{42 43} is a six-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%) indicates greater work or activity impairment.^{42 43}

Quality of life assessment

12-item Short Form Health Survey

The SF-12 is a self-reported outcome measure assessing the impact of health on an individual's everyday life and their quality of life,^{44 45} 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.^{46–48} Scores on these eight domains are aggregated to form two final components: physical and mental well-being 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 SD for normal data, and by median and 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 χ^2 tests. For the primary outcomes, rates of recruitment (number consented/eligible), completion (undertaken baseline and follow-up tests), adherence (participants completed sessions/number 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 (LMM) 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 (eg, last-observation-carried-forward). The outcomes of GAD-7, PHQ-9, WPAI: SHP and SF-12 will be summarised by the mean and SE. LMM, with participants as a random factor, will be used to assess the main and interaction effects of the fixed factors in time point (preintervention and postintervention) and group (Control vs Intervention) to each of these outcomes. All analyses will be performed in R Studio V.1.1.463.⁴⁹ 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.⁵⁰

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 will be used to assess model fit when covariates are added to the model. Normality assumptions will be assessed using the Shapiro-Wilk test. If required, non-linear transformations such as the square root and log transformations, will be applied to normalise the data. All analyses will be performed in R Studio V.1.1.463.

The qualitative data collected via open-ended questions across the four online surveys will be used to help explain or elaborate on the quantitative data. Qualitative data will be analysed using template thematic analysis. Template



thematic analysis uses 'a priori' code frames to analyse and report on the data.⁵¹ The initial skeleton code frame is often formulated from the questions asked of participants and then built on during analysis in an iterative process.

ETHICS AND DISSEMINATION

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

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

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

The higher anxiety levels during the pandemic impact on nurses' mental well-being, the healthcare workforce and health outcome of the public. The light acupuncture and five-element music therapy could be an example of

a safe, sustainable and cost-effective intervention with promise as a complementary modality. This study will determine the feasibility and acceptability of a non-pharmacological intervention to improve nurses' mental health caused by the pandemic. The findings will provide evidence for the acceptability of such modality to inform future strategies for nurses' mental well-being.

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