

Analgesic Effect of Auricular Point Acupressure for Acute Pain in Patients with Dementia: Study Protocol for a Randomized Controlled Trial

Xiao-Min Chai

School of Nursing, Ningxia Medical University

Hong-Yan Shi

Department of Geriatric Medicine and Special Medical, Ningxia Medical University General Hospital,

Jun-Jun Zhang

Department of Hematology, Shenzhen University General Hospital

Lei Wang

The third Middle school of Yinchuan

Hai-Xaing Gao

Department of Emergency, Yinchuan Second People's Hospital

Ya-Liang Dai

Department of Surgical, The First People's Hospital of Yinchuan

Lu-Lu Gao

School of Nursing, Shandong First Medical University

Jian-Qiang Yu

Department of Pharmacology, Pharmaceutical Institute of Ningxia Medical University

Carol Wang

School of Nursing and Midwifery, Edith Cowan University

Yu-Xiang Li (✉ li_yuxiang@163.com)

Ningxia Medical University

Study protocol

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Abstract

Background: Common and frequent as acute pain is, it is often underestimated and undertreated in older people with dementia in nursing homes and inadequate pain management remains an issue.

Methods: The study is designed to be a randomized, sham-controlled trial and is underway in nursing homes located in China. A total of 206 dementia patients are being recruited from nursing homes in Yinchuan, China. They are randomly allocated to an intervention or a controlled group in a 1:1 ratio. The intervention group will be treated with true APP therapy, while the other group will receive APP at sham points stimulation therapy. The patients will be assessed at baseline (T0), at 5 min during performing the intervention (T1) and at 5 min after completion of the intervention (T2). The primary outcome is the level pain relief at T1, and T2. Physiological parameters, side effects and additional use of analgesics during the procedure, satisfaction from caregivers, acceptance of patients are evaluated as secondary outcomes.

Discussion: The results of this study are expected to verify the analgesic effect of APP for acute pain in patients with mild dementia in nursing homes. It has the potential to prompt APP therapy to be implemented widely in dementia patients with acute pain in nursing homes.

Trial registration: ChiCTR2100047932. <http://www.chictr.org.cn/edit.aspx?pid=128647&htm=4>. Registered on June 27, 2021. Currently, patients recruitment is ongoing. Recruitment is expected to take place from December 2020 to December 2021.

Introduction

For residents in the nursing home, dementia and pain have aroused great public concern and a lot of discussions in the global medical policy, research and education fields for many years [1]. Pain is a common experience for many older adults with dementia in nursing homes. It is estimated that prevalence of pain in dementia patients residing in the nursing home is 19%-83% and pain they are suffering is difficult to assessed and inadequately treated [2–4]. There is also guideline that indicates that the incidence of acute pain is as high as 75% in elderly care facilities, but even higher for chronic pain [5]. Furthermore, uncontrolled pain causes many detrimental consequences for patients with dementia in nursing homes, such as distressing psychological, social isolation, daily activity and function limitation, sleep disturbances, hospital stays prolonging and medical expenses increasing [6–8]. In particular, acute pain in elderly patients can have a serious impact on psychology and even lead to an attempt to suicide [8].

Common and frequent as acute pain is, it is often underestimated and undertreated in older people with dementia in nursing homes and inadequate pain management remains an issue [4]. The complications of acute pain has been well documented, but there are few clear guidelines on the optimal therapies to measure and treat acute pain in the nursing home residents with dementia [6]. Pharmacological and non-pharmacological modalities have been practiced to managing acute pain and its associated

complications in older adults with dementia over the past decade. It is advised that pharmacological treatment to control acute pain in the elderly should generally follow three-step scheme: paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), opioids and the other adjuvant drugs. Although paracetamol is recommended as a first-line analgesic for pain relief in residents with dementia in nursing homes worldwide, limited report is available on its analgesic efficacy [9]. Several studies have also evidenced that the elderly persons with dementia are prescribed fewer NSAIDs and other analgesics than those without dementia in nursing homes, and there are not many opportunities to consider the use of strong analgesics [9, 10]. Patients with dementia are prescribed Opioid analgesics, even though, the doses they were allowed to take is one-third of those who are cognitively intact elder adults, especially in the nursing home residents with dementia [9, 11]. There is little evidence of the effectiveness of adjuvant drugs, such as anti-inflammatory drugs, anticonvulsants, antidepressants, for relieving acute pain in older adults with dementia in nursing homes [11]. Furthermore, they are more prone to have drug-related side effects [7]. These factors also contribute to poor acute pain control in patients with dementia in the nursing home.

Therefore, it is important to seek non-drug therapies for controlling the dementia patients with acute pain. Take traditional Chinese medicine, for example, auricular acupressure, acupuncture, massage, liniments, ointments, etc., which plays an active important role in the treatment of acute pain. Non-pharmacological interventions have become the priority for patients with acute pain due to less side effects, non-invasive and better safety [12]. In traditional Chinese medicine (TCM) theory, the ear is where the body's meridians (main twelve meridians: six of which are yin meridians and six yang) connect and where the essential Qi converges. So, stimulating auricular points can activate Qi and blood circulation, dredge the meridians, and then achieve the purpose of analgesia [13]. Theory of auricular acupuncture, analgesic effect of auricular point acupressure (APP) is produced by activating the descending pain-suppressing pathway of the brainstem and thus inhibiting the ascending pain pathway [13]. Systematic review and meta-analysis have also reported that auricular therapy shows promising effects in pain relief comparing with sham or control groups [14, 15]. APP therapy has been widely applied in various types of pain, such as acute postoperative pain, pain related to dental, musculoskeletal pain in the older adults and as an adjunct analgesic among cancer patients [14, 15]. A dearth of study explored that APP therapy is applied to control acute pain in the nursing home residents with dementia. Therefore, we hypothesize that APP can provide the analgesic effect for acute pain in patients with dementia in nursing homes.

Methods

Study design

This study is a multi-center and single-blind, randomized, sham-controlled clinical trial. It aims to compare and analyze the one-time analgesic effect between intervention group and sham-controlled group (Fig 1, Table 1) for acute pain in patients with dementia. This protocol was designed on the basis of SPIRIT guidelines and the Consolidated Standards of Reporting Trials (CONSORT) statement [16, 17]. The Ningxia Medical University Ethics Committee has given its official approval for the study

protocol, which has been registered at Chinese Clinical Trial Registry (No.: ChiCTR2100047932). Each patient will be given a detailed explanation by the researcher including the purpose, benefits and potential risks of the study. Moreover, they can withdraw from the study at any time. And this will not affect medical services other than research. Subsequently, the qualified recruits signed informed consent entering the study will receive APP or shamed APP treatment by a investigator, a master candidate in nursing science with APP professional training.

Study setting

This randomized controlled trial is being conducted at three nursing homes in Yinchuan, China. These three aged care institutions are the largest and public in the region, with approximately 2,000 permanent residents.

Patients

All 206 patients met inclusion and exclusion criteria are being recruited from the three nursing homes. Recruitment is expected to take place from December 2020 to December 2021. The recruits with informed consent before entering research will be randomly allocated to an intervention or a sham-controlled group in a 1:1 ratio. Furthermore, it is feasible to have enough patients to meet the target sample size in three nursing homes. Inclusion criteria include: (1) aged 60 or above with speaking Chinese; (2) dementia was diagnosed by the Diagnostic and Statistical Manual of Mental Disorders (DMS-V) criteria [18]; (3) diagnosis of mild or moderate dementia based on the Montreal Cognitive Assessment (MoCA) [19]; (4) acute pain and a score of pain ≥ 4 based on the Face Pain Scale Revised (FPS-R); (5) their healthy condition permits the use of a multifunctional pulse oxygen monitor; (6) understanding the meaning of the FPS-R; (7) volunteering to participate in the study and signing the informed consent (caregivers, patients, and/or family members). Exclusion criteria are as follows: (1) moderate or severe dementia; (2) medical contraindication for ear acupuncture (inflammation, ulcers, frostbite in the ear); (3) history of allergy to adhesive tape and alcohol; (4) critically ill patients who have no response to the effectiveness and safety of new treatments (serious heart, brain, liver, kidney, or hematopoietic system diseases); (5) patients who received drugs for pain management.

Interventions

The intervention group will be planned to receive auricular-plaster therapy, with one piece of Semen Vaccariae[®] (about 2 mm in diameter, Taicheng Technology and Development Co., LTD, Shanghai, China) attaching to the center of a piece of medical adhesive tape (6 mm × 6 mm). This study initially selected four active acupoints including shenmen (TF4), subcortex (AT4), adrenal (TG2P) and two auricular points corresponding to pain sites based on Nogier auricular point diagram for managing pain [20]. A researcher will bring required items to the participants' bedside and assist them in taking position that is easy to operate. Subsequently, the researcher holds the helix with left hand and identifies sensitive points by virtue of an ear probe with the right. The medical adhesive tapes with Semen Vaccariae[®] will be pasted on the selected auricular points with forceps by the researcher after checking and sterilizing the skin of

the patients' ears using 75% alcohol. Then, each auricular point will be pressed gently 1~2 times with lasting 1 minute each times. There is no time interval during the operation unless adverse reactions occur or until finishing the procedure. The pressure should be moderate and enough within individual's endurance (the subject feels swelling pain, numb, and warm sensation). After the whole intervention, these tapes will be removed. The control group will be treated with sham APP (at sham points stimulation), its procedures are described in the intervention group. However, the subject simply experiences the warm sensation on their ears.

Randomization and blinding

Sequence numbers of each patient will be generated by a computer-produced random list, which is performed by an independent, blinded statistical expert from Ningxia Medical University. The randomization list will only be kept by the researcher who performed the intervention. To ensure the concealment of data distribution and minimize selection bias, other researches (the manager who is responsible for the study protocol, data collectors, etc.) and caregivers (nurses and unlicensed assistive personnel) are blinded to the randomized controlled trial lists. Furthermore, no recruiters who signed informed consent forms know whether they are receiving real APP or sham APP treatment.

Measurement

Each patient's demographic data (age, sex, nationality, educational background, marital status, occupation before retirement, personal income per month, history of taking medicine, chronic case history) will be recorded by a self-designed questionnaire. Other information including physiological parameters (heart rate, blood pressure and oxygen saturation), sore spot, pain score, adverse effects, the use of analgesics in the intervention, satisfaction of caregivers as well as acceptance of patients will be more rigorously documented. The MoCA is made to identify the severity of dementia among the patient. And locality of the pain will be shown clearly according to the Brief Pain Inventory (BPI-C) [21]. The FPS-R with great reliability and validity will be elected to assess pain intensity, and three physiological parameters are monitored with electronic sphygmomanometer (OMRON, HEM-7120) and Fingertip Oximeter (PC-60B). The data required for the study include pain score, noninvasive monitoring of blood pressure, heart rate collected at baseline (before performing the intervention, T0), at 5 min during performing the intervention (T1) and at 5 min after the intervention finished (T2) as well as digital monitoring of oxygen saturation. Any adverse effects observed of APP treatment should be well planned to handle and detailed recorded. even if there is no reports of it. Simultaneously, the use of analgesics in the intervention also will be carefully recorded to enhance analysis the safety and analgesic effect of APP. Satisfaction from caregivers will be surveyed via a five-point satisfaction scale (5, very satisfied; 4, satisfied; 3, uncertain; 2, dissatisfied; 1, very dissatisfied) at T2 [22]. However, acceptance of patients will be measured by just asking them if they'd like to accept the APP treatment once again.

Outcome measurement

Primary outcome measure

The level pain relief at T1, and T2 will be considered as the primary outcome. It is accurately recorded by a researcher in charge of recording on the basis of the FPS-R.

Secondary outcomes measure

The secondary endpoints are consisted of physiological parameters, any adverse reactions observed, satisfaction from caregivers, acceptance of participants, additional use of analgesics during the intervention. The duration of the intervention will also be included in the secondary outcomes.

Sample size estimation

After obtaining the ethical approval of our study protocol, a preliminary experiment with a sample size of 30 was conducted in Nursing Home, Yinchuan on January 2020. The results of the pilot study indicated that in the FPS-R score of the control group and the intervention group was 5.97 ± 1.81 and 4.79 ± 1.96 , respectively. We have consulted a statistician from the School of Medical Statistics and Epidemiology in Ningxia Medical University, who finished the randomization list of the recruits. With type-1 error rate of 0.05 ($\alpha= 0.05$, two-tail) and a 90% power ($\beta= 0.10$), the sample size of the study scheme was calculated by the statistical expert, which was 86 patients in each group. According to our study design and considering the particularity of this research subject (they are less likely to complete the entire experiment), we assume a 20% drop-out rate. The total sample size 206 cases (per group was 103 cases) are required to reduce the underpower of the study.

Management and safety monitoring

Prior to the study, research team members will receive a training program, which will cover research design, procedure, evaluation of outcome measures, randomization, data collection and data monitoring. For example, data recorders will be trained how to collect and manage data to ensure the objectivity, quality and safety of data as far as possible. Participants information will be protected confidentiality before, during, and after the trial. With the consent of the project leader, only members of the research team have access to the collected information for a reasonable reason. It should be also noted that the information of patients who withdrawn will not be included in the final analysis, and other researchers will investigate what led them to withdraw from the trial. Data Management and Safety Monitoring Committee is not necessary due to the APP treatment was the least risky. But regular monitoring and auditing data will be required. Finally, an independent statistician is responsible for the evaluation and processing of the final data.

Data statistical analysis

On the basis of the intention-to-treat (ITT) principle, SPSS version 22.0 (Chicago, IL, USA) will be recommended to run the data statistical analysis on both real APP group and sham APP group. Information on all patients in the random list should be included in the final analysis. If data is missing, the missing data imputation should be used to analyze the validity of the statistical analysis. Statistical description of categorical variables (the population demographic data) will be mainly presented by the

relative number (rate, proportion and ratio). The continuous variables (repeated measurement data of three physiological parameters) will be compared by analysis of variance (ANOVA) or the Kruskal-Wallis test (or Chi-squared tests) for two groups. Other categorical variables (data on satisfaction from caregiver, acceptance from patient and additional use of analgesics) will be described by the nonparametric test (Wilcoxon's rank sum test). A two-sided P values <0.05 will be considered to be statistical significance.

Discussion

Every patient is endowed with his or her basic and undeniable right of eliminating pain. Meanwhile, within the scope of our expertise, medical professionals have an obligation to consider giving patients reasonable pain management [23]. But many studies indicated that pain in people with dementia is often underestimated and undertreated, and even overlooked and missed in nursing home settings [4, 24, 25]. In addition, the toxic side effects caused by analgesic drugs, such as acute respiratory depression, addiction, ulcers, hemorrhage, etc., make Chinese medical staffs and patients concern about their use [26]. This study aims to find a better evidence-based and alternative therapy for dementia patients with pain in the nursing home, China. The study of Xia et al. showed a significant reduction in pain scores in patients with axial neck pain after anterior cervical discectomy and fusion in the APP group compared with sham APP group [27]. However, there is also study demonstrated that no significant difference in pain scores reduction was found on acute postpartum perineal pain between the intervention and control groups [28]. In this study, we will illuminate the role of APP treatment in managing acute pain in patients with dementia in nursing homes.

What we know is that our study protocol is the first randomized controlled trial to identify the analgesic effectiveness of APP for acute pain in patients with dementia in nursing homes, China. It has the potential to develop preliminary evidence-based guidance for therapists in clinical practice if the analgesic efficacy of APP appears beneficial and safe. So this study can contribute to a new approach to relieving pain in patients with dementia in nursing homes.

One of the biggest limitations of this study is that it only evaluates one-time efficacy of the intervention. But this trial really only evaluates the analgesic effect of APP therapy for dementia patients with acute pain in nursing homes. We also plan to move forward with the study after certifying the analgesic effect of APP therapy.

Abbreviations

APP: auricular point acupressure; ANCOVA: Analysis of covariant; BPI-C: Brief Pain Inventory; CONSORT: Consolidated Standards of Reporting Trials; DMS-VI: Diagnostic and Statistical Manual of Mental Disorders -VI; FPS-R: Face Pain Scale Revised; ITT: intention- to-treat; MoCA: Montreal Cognitive Assessment; NSAIDS: non-steroidal anti-inflammatory drugs; TCM: traditional Chinese medicine.

Declarations

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Authors' contributions

X-M C, J-J Z and C W drafted the manuscript and contributed to the conception, design, and critical revision of the manuscript in collaboration with H-Y S. L W, H-X G and J-Q Y contributed to the development of the intervention and the critical revision of the manuscript. Statistical analyses were performed by Y-L D and L-L G. All authors read and approved the final manuscript. Y-X L is the principal investigator of the study.

Funding

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Availability of data and materials

Trial data are available on reasonable request to the principal investigator of the study.

Ethics approval and consent to participate

The Ningxia Medical University Ethics Committee (2018–232) has given its give official approval for the study protocol. Participates have signed the conformed consent after researchers provided them with detailed information regarding to the study process and the right they have.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Tables

Due to technical limitations, table 1 is only available as a download in the Supplemental Files section.

Figures

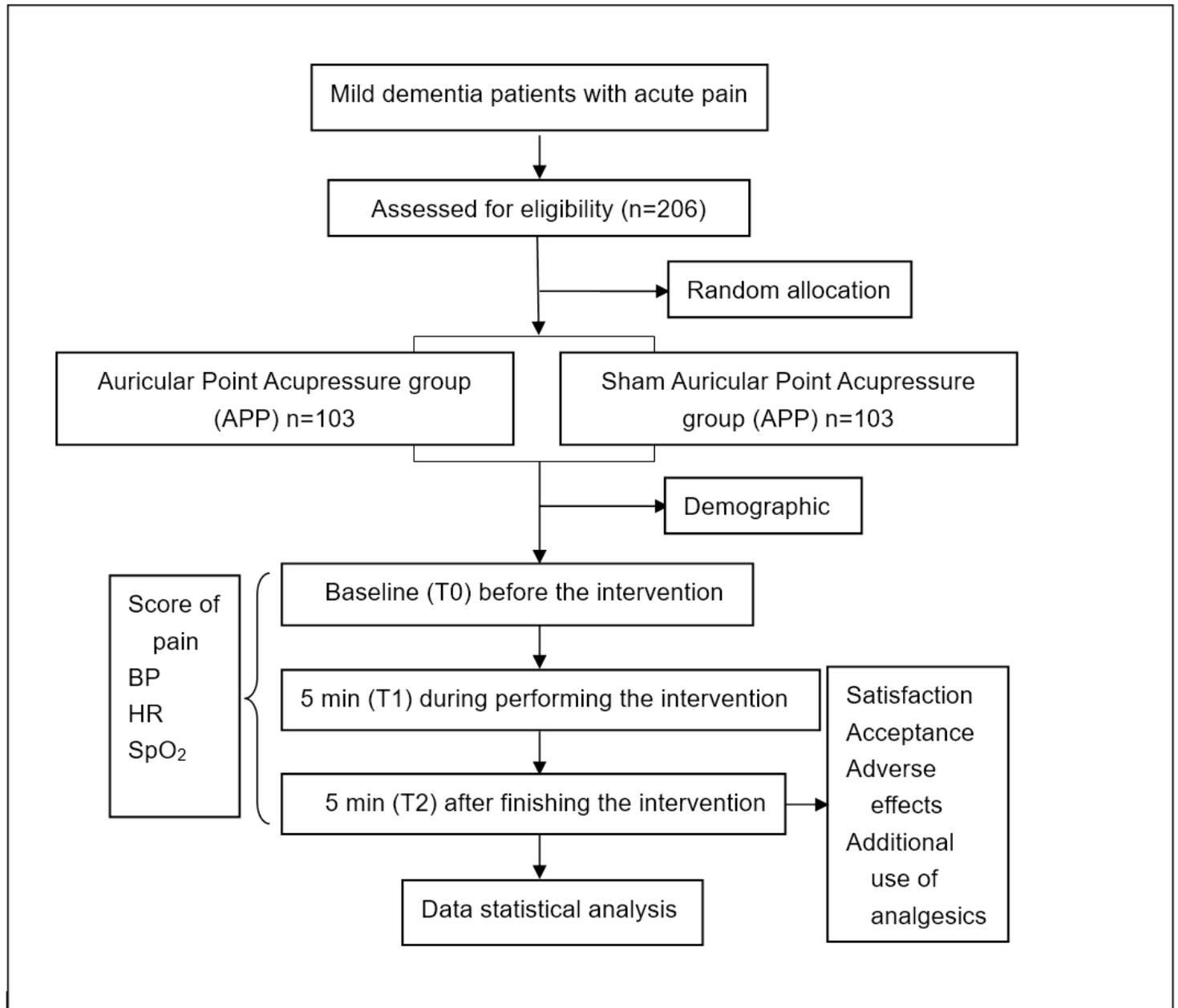


Figure 1

Study design framework BP, blood pressure; HR, heart rate; SpO₂, oxygen saturation; APP, Auricular Point Acupressure; Score of pain, the Face Pain Scale Revised.

Supplementary Files

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- [Table1.docx](#)
- [SPIRITChecklist.doc](#)