Analgesic effect of auricular point acupressure for acute pain in patients with dementia: study protocol for a randomized controlled trial

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Study protocol

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Abstract

Aim: As many as 83% of patients with dementia living in nursing homes have complained about pain. Acute exacerbation of chronic pain in elderly patients can have a serious impact on psychology and even attempt suicide. However, the effectiveness the drugs recommended for the elderly are limited, and these older people are more prone to have drug-related side effects. The aim of this study is to identify the analgesic efficacy of auricular point acupressure (APA) for acute exacerbation of chronic pain in patients with dementia in nursing homes. Methods: The study is designed to be a randomized, sham-controlled trial and is underway in a nursing home located in northwest of China. A total of 218 dementia patients with acute exacerbation of chronic pain and a score of pain≥4 on the Changhai Pain Rating Scale is being recruited from Bangniqinchun Nursing Home in Yinchuan, China and randomly allocated to accept either an intervention or a sham-controlled group in a 1:1 ratio. While the intervention group will be given APA therapy, the other group will receive sham APP treatment. The recruiters will be assessed at baseline (T0), at 5 min (T1) during treatment, and at 5 min post intervention (T2). The primary endpoint is the Changhai Pain Rating Scale mean change for pain at T0, T1, and T2 after the initial intervention. Physiological parameters, side effects and additional use of analgesics during the intervention, satisfaction from caregivers, acceptance of patients are evaluated as the secondary outcomes. Discussions: The results of this study are expected to prove the analgesic effect of APA for acute pain in patients with dementia. If providing scientifically sound results, it will have the potential to be the basis of the evidence-based guidelines for physical therapists in clinical practice and to be implemented widely in pain patients with dementia in nursing home.

Introduction

For older patients with dementia in 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, 2]. Physical pain is an inherently subjective experience and common symptom for many older adults with dementia in nursing homes. The estimated prevalence of pain among dementia patients residing in the nursing is 19%-83% and pain they suffer is difficult to prove and inadequately treat [3-5]. Furthermore, uncontrolled pain results in many detrimental consequences for older patients with dementia in nursing home, such as distressing psychological, social isolation, impact on daily activity and function, sleep disturbances, prolonging hospital stays and increasing medical expenses [6,7]. In particular, acute exacerbation of chronic pain in elderly patients can have a serious impact on psychology and even attempted suicide [8].

Common and frequent as pain is, it is often underestimated and undertreated among older people with dementia in nursing homes and inadequate pain management remains an issue [9,10]. Well-documented as the complications of pain are, there is a lack of clear guidance on the optimal ways to measure and treat pain in these patients across the range of clinical settings [7]. Over the past decade, both pharmacological and non-pharmacological management techniques have been published for pain-related complications in the context of dementia. The British Geriatrics Society recommended that pharmacological treatment of pain in older people is currently used three stepped-treatment approaches: paracetamol, non-steroidal anti-inflammatory drugs (NSAIDS), opioids and the other adjuvant drugs [11]. While paracetamol is used as a first-line treatment analgesic for pain in nursing homes residents with dementia and the most commonly considered worldwide by far [12], limited evidence is available regarding the value of painkillers. Several studies have evidenced that the elderly persons with dementia are prescribed fewer NSAIDs and other analgesics than those without dementia in nursing home and hospital care, as for strong analgesics are less likely to be considered [13,14]. Patients with dementia are prescribed opioids, though, the doses they were allowed to take is one-third of those who are cognitively intact elder adults, especially, occur consistently in the nursing home residents with dementia [13,15]. So far, there has been little evidence of the efficiency of adjuvant drugs, such as anti-inflammatory drugs, anticonvulsants, antidepressants or new analgesics, thus treatment options for acetaminophen are severely limited [16]. Furthermore, older people are more prone to drug-related side effects, complications and adverse events induced by diagnosis and invasion procedures are more likely in the elderly [17].

Therefore, it is important to seek non-drug therapy for the dementia patients with pain. Traditional Chinese medicine, for example, auricular acupressure, acupuncture, massage, external applications of herbal balms, liniments, ointments and taken internally Chinese herbal, etc., which are commonly used to relieve pain and play an active important role in the treatment of pain. These therapies have become the priority for patients with pain due to less side effects, non-invasive and better safety [18]. In traditional Chinese medicine

(TCM) theory, the ear is where the body' meridians (main twelve meridians:six of which are yin and six which are yang) connect and where essential qi converges. So, stimulating the ear can activate qi and blood circulation, dredge the meridians, and then achieve the purpose of analgesia[19,20]. Analgesic effect of auricular point acupressure (APA) is produced by activating the descending pain-suppressing pathway of the brainstem and thus inhibiting the ascending pain pathway [20]. APA has been widely applied in various types of pain, such as postoperative, dental, musculoskeletal, and anaesthesia related pain [21]. Therefore, we hypothesize that APA can provide the analgesic effect for patients with dementia in nursing home.

Methods

Study design

This study is a single-center and blind, randomized, sham-controlled, parallel clinical trial to compare and analyze the analgesic effect between intervention group and sham-controlled group (Figure 1, Table 1) for acute exacerbation of chronic pain in patients with dementia. This protocol was designed on the basis of SPIRIT guidelines [22] (see Additional file 1) and the Consolidated Standards of Reporting Trials (CONSORT) statement [23] (see Additional file 2). The Ningxia Medical University Ethics Committee has given its give official approval for the study protocol, which has been registered at Chinese Clinical Trial Registry (No. ChiCTR1800019146).

Participants

All 218 participants met inclusion and exclusion criteria are being recruited from the Bangniqinchun Nursing Home in Yinchuan, northwest of China. Recruitment is expected to take place from January 2019 to December 2019. The recruits with informed consent before entering research will be randomly allocated either an intervention or a sham-controlled group in a 1:1 ratio. Furthermore, it is feasible for the nursing home to have enough patients to meet the target sample size.

Inclusion criteria

(1) Aged 60 or above with speaking Chinese;

(2) Dementia was diagnosed by the Diagnostic and Statistical Manual of Mental Disorders (DMS-VI) criteria [24],

- Diagnosis of mild or moderate dementia based on the Montreal Cognitive Assessment (MoCA) [25];

(4) Acute exacerbation of chronic pain and a score of pain≥4 based on the Changhai Pain Rating Scale;

(5) Their healthy condition permits the use of a multifunctional pulse oxygen monitor;

(6) Understanding the meaning of the Changhai Pain Rating Scale;

(7) Volunteering to participate in the study and signing the informed consent (caregivers, patients, and/or family members).

Exclusion criteria

- Severe dementia;

(2) Medical contraindication for ear acupressure (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).

Interventions

Each patient will be given a detailed explanation by the researcher including the purpose, benefits and potential risks of the study. Moreover, they are free and can withdraw from

the study at any time and not affect their other medical services. Subsequently, the qualified recruits signed informed consent entering the study will receive APA or shamed APA treatment by the regular investigator, a master candidate in nursing science with APA professional training.

The intervention group will be planned to use 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 [26] for managing pain. The investigator will bring required items to the participants' bedside and assist them in taking position that is easy to operate, subsequently, hold the helix with left hand and identify sensitive points through an ear probe with the right. After checking and sterilizing the skin of the participants' ears using 75 % alcohol, the medical adhesive tapes with Semen Vaccariae® will be pasted onto the selected auricular points above with hemostatic forceps by the operator, 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, until the subject feels swelling pain, numb, and warm sensation. The pressure should be moderate enough for the individual' s endurance. After the whole intervention, these tapes will be removed. The control group will be treated with sham APA (the medical adhesive tapes without seeds), its procedures are described in the intervention group. However, the subject simply experiences the warm sensation on their ears.

Randomization, allocation concealment, and blinding

Sequence numbers of each participant will be generated by a computer-produced random list, which is performed by an independent,blinded statistical expert from Ningxia Medical University. The randomization schedule will be kept only by the operator who performed the intervention. To ensure the concealment of data distribution and minimize selection bias and confounding factors, other researches (the manager who is responsible for the study

protocol, data collectors, etc.) or caregivers (nurses and unlicensed assistive personnel who were primarily older previously unemployed women who were retrained) are blind to the randomized controlled trial lists. Furthermore, no recruiters who entered the study and signed informed consent forms know whether they are receiving real APA or sham APA treatment.

Measurement

Each participant's demographic data (age, sex, nationality, educational background, marital status, pre-retirement occupation, personal income per month, family size, frequency of families visit, 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), severity of dementia, sore spot, pain score, adverse effects, the use of analgesics in the intervention, satisfaction of caregivers as well as participant's acceptance will be more rigorously documented. The MMSE is made to identify the severity of dementia among the participants. And locality of the pain will be shown clearly according to the Brief Pain Inventory (BPI-C) [27]. The Changhai Pain Rating Scale with great reliability and validity is frequently used will be elected to assess pain intensity, coupled with three physiological parameters are monitored with electronic sphygmomanometer (OMRON, HEM-7120) and Fingertip OXIMETER (PC-60B). Data required at baseline (T0 before performing the intervention), 5 min (T1) during performing the intervention, and at 5 min (T2) after the intervention finished regarding the pain score, noninvasive monitoring of blood pressure, heart rate as well as digital monitoring of oxygen saturation. Any occurred adverse effects of APA treatment should be well planned to handle and detailed recorded during administrating the invention, even if there is no reports of this. Simultaneously, the use of analgesics in the intervention also will be carefully recorded to enhance analysis the safety and analgesic effect of APA. Satisfaction of caregivers will be surveyed via a five-point satisfaction scale (5, very satisfied; 4, satisfied; 3, uncertain; 2, dissatisfied; 1, very dissatisfied) [28] at T2. However, participant's acceptance will be measured by just asking them if they'd like to accept the APA treatment at T2.

Outcome measurement

Primary endpoint measure

The mean change of pain score in the Changhai Pain Rating Scale from baseline at

T1 and T2 after carrying out the intervention will be considered as the primary endpoint measure. It is accurately recorded and analyzed by a researcher in charge of recording on the basis of the scale.

Secondary endpoint measures

The secondary endpoint measures will be consisted of three physiological parameters, any adverse reactions observed, satisfaction from caregivers, acceptance of participants, additional use of analgesics. The times and duration of interventions will also be included in the secondary endpoint measures.

Sample size estimation

After obtaining the ethical approval of our study protocol, a preliminary experiment with a sample size of 30 was conducted in Bonniqinchun Nursing Home,Yinchuan on September 2018. The results of the pilot study indicated that in the Changhai Pain Rating Scale score of the control group and the intervention group was 5.97 ± 1.71 and 3.29 ± 0.76, respectively. We have consulted a statistician from the School of Medical Statistics and Epidemiology in Ningxia Medical University, who finished random grouping of the recruits. With type-1 error rate of 0.05 (α= 0.05, two-tail) and a 90% power (β= 0.10), the sample size of the study scheme was calculated by the statistical expert, which was 91 participants 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). Therefore, assuming a 20% drop-out rate, yielding the total sample size 218 cases (per group was 109 cases) are needed to reduce the underpower of the study.

Data collection, management, and safety monitoring

Before performing the study, all of them on the research team will receive a training program, which will cover research design, intervention procedure, evaluation of outcome measures, more important, including 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. With the consent of the project leader, only members of the research team have access to the information collected for a reasonable reason. It should be also noted that the information of participants who withdrawn will not be included in the analysis of the final results, and other researchers will check causes lead to them quit this trial. A Data Management and Safety Monitoring Committee is not necessary due to the APA treatment was the least risky. But regular monitoring and auditing data will be needed, and so is double-check the data values. Finally, only the first author and an independent statistician are 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 for both real APA group and sham APA group. Information on all randomized patients should be included in the analysis and if data is missing, this part of the missing data imputation should be used to analyze the validity of the primary outcome 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 one-factor analysis of variance (ANOVA) or the Kruskal-Wallis test (or Chi-squared tests) for comparison between two groups, and 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, it is the basis of the obligations of medical professionals to consider giving patients reasonable pain management [29]. But many studies [6,7,30] indicated that pain in people with dementia is often underestimated and undertreated, and even overlooked and missed in nursing home setting. 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, and older adults are more likely to have drug-related side effects [17]. These lead to effective pain management for patients with dementia remains a challenging task in nursing home. This study aims to find a better evidence-based and alternative medication for dementia patients with pain in China. The study of Xia et al. on axial neck pain after anterior cervical discectomy and fusion showed pain reduction for the APA group [31]. However, there are also studies demonstrated that no significant difference reduction in pain scores was found on acute postpartum perineal pain between the intervention and control groups [32]. In this study, we will elucidate the role of APA treatment in managing acute exacerbation of chronic pain in patients with dementia in nursing homes and satisfaction from caregivers.

What we know is that our study protocol is the first randomized controlled trial in nursing home to identify the analgesic effectiveness of APA for acute pain in patients with dementia in China. If the analgesic efficacy of APA appears beneficial and safe, this study can contribute to develop preliminary pain guidelines in patients with dementia in the future. We believe that the findings of the study can be introduced to the nursing home for pain management and propagated to international journals and conferences.

Trial Status

Currently, patient recruitment is ongoing. **Trial registration:** ChiCTR1800019146. Registered on October 27, 2018. Recruitment is expected to take place from January 2019 to December 2019.

Abbreviations

APA: 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; ITT: intention-to-treat; MMSE: Mini-mental Status Examination; NSAIDS: non-steroidal anti-inflammatory drugs.

Declarations

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.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that there is no conflict of interest regarding the publication of this paper.

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Author contributions

Study concept and design: Dr. Y-X L, J-Q Y;

Acquisition of subjects and/or data: MS. H-X G, L Z, Y-L D, T T and Y-L W Analysis and interpretation of data: Dr. J-Y T, L-L G and MS. X-M C, W-J Z;

Preparation of manuscript: Dr. Y-X L and MS. J-J Z and T-T Z.

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Table

Table 1 Schedule of enrolment, interventions, and assessments

	Study period			
	Enrolment	Post-allocation		
	Dementia patients with acute exacerbation of chronic pain	T0	T1	T2
Enrolment				
Eligibility screen	×			
Informed consent	×			
Allocation	×			
Interventions				
Control group			×	×
Treatment groups			×	×
Assessments				
Changhai Pain Rating Scale	×	×	×	×
Blood pressure		×	×	×
Oxygen saturation		×	×	×
Heart rate		×	×	×
Satisfaction				×
Acceptance				×
Side effect			×	×
Additional use of analgesics				×

Table 1 Schedule of enrolment, interventions, and assessments

Figures

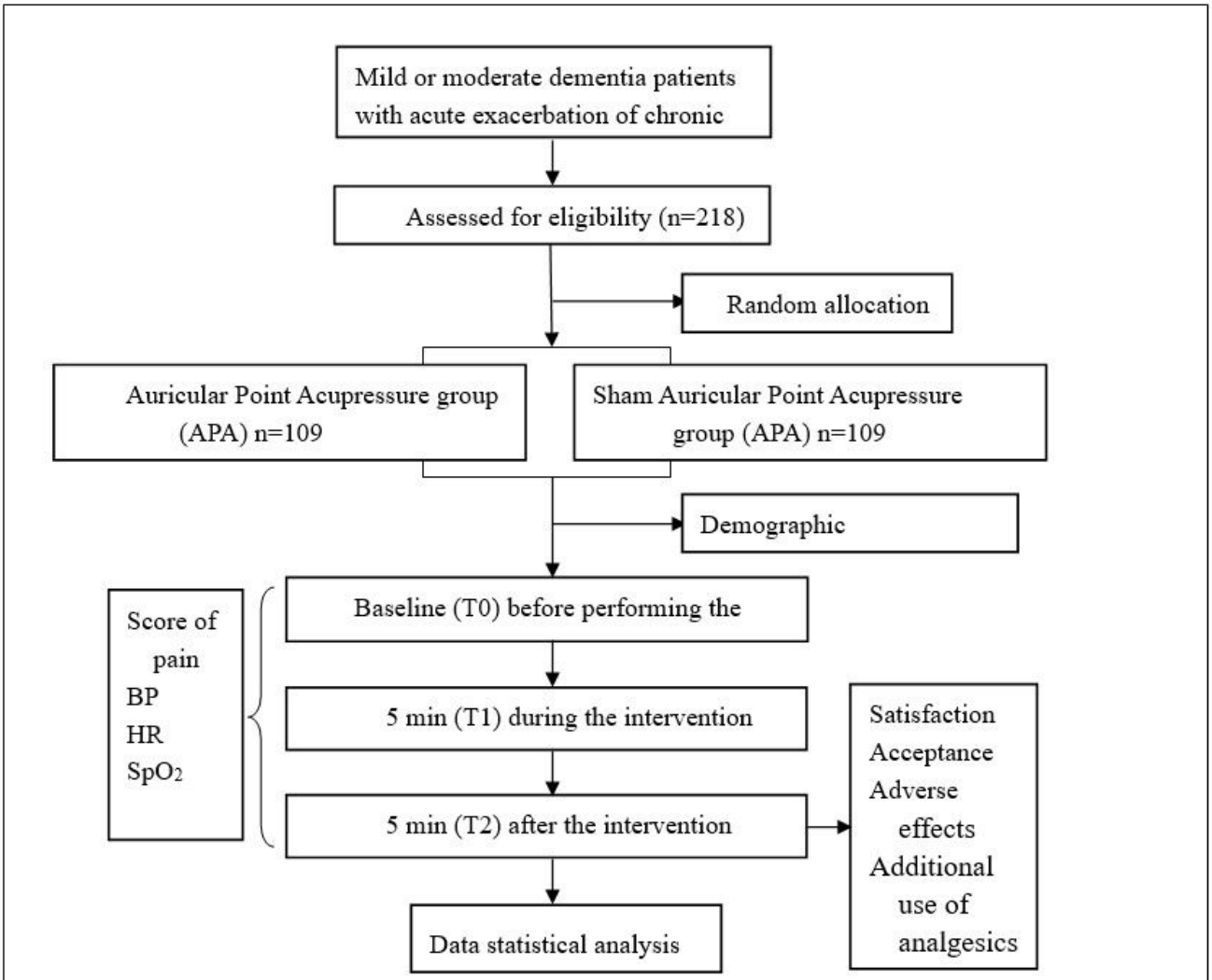

Fig. 1 Study design framework. BP, blood pressure; HR, heart rate; SpO_2, oxygen saturation; APA, Auricular Point Acupressure; Score of pain, Changhai Pain Rating Scale.

Figure 1

Study design and framework

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITChecklist.doc
- FundingDocumentation.docx
- EthicalApprovalDocument.doc