Reminiscent music therapy combined with robot-assisted rehabilitation for older patients with upper limb dysfunction after stroke: protocol for a randomized controlled trial

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Study protocol

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Abstract

Background

Stroke is the main disease that causes the burden of neurological disease in elderly people, leading to upper limb dysfunction and affecting their self-care ability. Robot-assisted rehabilitation therapy has been gradually used in the rehabilitation of upper limb function after stroke. However, it is necessary to add auxiliary intervention to relieve negative emotions and post-stroke fatigue, and improve rehabilitation outcomes. This paper presents a protocol for a randomized controlled trial that aims to evaluate the effectiveness of reminiscent music therapy combined with robot-assisted rehabilitation in older patients with upper limb dysfunction after stroke.

Methods

This trial is a single-blind, three-arm randomized controlled trial. Older stroke patients with upper limb dysfunction will be recruited and followed up for 4 weeks. All participants will be randomly assigned to receive usual rehabilitation treatment and care (control), usual rehabilitation treatment and care plus robot-assisted rehabilitation and reminiscent music therapy (experimental group 1), or usual rehabilitation treatment and care plus robot-assisted rehabilitation (experimental group 2). Usual rehabilitation treatment, including drug treatment, comprehensive training of hemiplegic limbs and physical therapy, will be formulated by rehabilitation doctors and neurologists according to the specific conditions of the participants. Robot-assisted rehabilitation will be conducted by rehabilitation doctors for 4 weeks. In experimental group 1, a reminiscent song list will be played for patients with a wireless headset when they are training. The primary outcome is activities of daily living and secondary outcomes include self-esteem, rehabilitation self-efficacy, positive emotion and upper limb function. All outcomes will be evaluated at baseline, after 2 weeks of the intervention, in the week immediately post-intervention and at 4-week post-intervention.

Discussion

To the best of our knowledge, we are conducting the first randomized controlled trial on the effects of reminiscent music therapy combined with robot-assisted rehabilitation in older stroke patients with upper limb dysfunction. It is expected that this study, if proven effective in improving the activities of daily living in older stroke patients with upper limb dysfunction, will provide evidence-based rehabilitation strategies for medical staffs.

Trial registration: This trial was registered at ChiCTR.org.cn (registration number is ChiCTR2200063738 and registered on September 15, 2022).

1. Background
Stroke is the leading cause of death and disability in the world [1], and it is also the main disease that causes the burden of neurological disease in old people [2]. Under the severe trend of population aging, the incidence rate of stroke increases exponentially with advancing years [3]. Of the stroke patients in China, 50.81% are elderly aged 60 years or above [4]. Stroke is characterized by a high rate of disability and most stroke patients will experience long-term neurological damage. Persistent upper limb disability occurs in up to 80% of stroke patients [5], which leads to the decline of self-care ability and the need to receive long-term rehabilitation training.

With the development of artificial intelligence technology, traditional medical equipment is constantly developing towards intelligence. Attracting attention in clinical practice, robot-assisted rehabilitation therapy has been gradually used in the rehabilitation of upper limb function after stroke. Some studies have suggested that, compared with traditional rehabilitation treatment, robot-assisted rehabilitation could significantly improve muscle coordination, upper limb function and social participation of stroke patients [6–10]. However, the care burden and economic pressure of patients will be aggravated when suffering from stroke, leading to negative emotions in patients, and forming a negative coping style and inducing post-stroke fatigue with an incidence of 25% – 85% [11–13]. Post-stroke fatigue can affect the subjective feelings of the elderly’s independent activities and lead to exercise fatigue [14], contributing to poor rehabilitation prognosis [15–17]. Therefore, it is necessary to add auxiliary intervention to alleviate the negative emotions of the elderly patients with upper limb dysfunction after stroke, so as to relieve post-stroke fatigue, urge them to actively cope with functional rehabilitation treatment, and finally improve rehabilitation outcomes.

Indicated to be physically and mentally helpful, reminiscence therapy has been gradually applied to improve the cognitive function and mental health of elderly patients with stroke [18–20]. Music is one of the most common media to trigger nostalgia, which can not only have a positive effect on patients by evoking nostalgia, but also treat physical or psychological diseases by musical sound and rhythm [21]. A theoretical model suggested that music, when combined with nostalgia, can help summon autobiographical memories, evoke strong emotions, elicit physiological responses to improve physical well-being and immunity, and develop self-definition [22]. Moreover, a previous study believed that adding music elements may increase the intrinsic motivation of patients in the process of rehabilitation treatment [23]. Music activates both the auditory system and sensory-motor system simultaneously, and helps to reorganize and integrate information processing, executive control and emotions, so as to shift attention away from fatigue and promote the acquisition of motor skills [24, 25]. These literature provide a theoretical basis for the combination of reminiscent music therapy with robot-assisted rehabilitation.

Therefore, the aim of this study is to evaluate the efficacy of reminiscent music therapy combined with robot-assisted rehabilitation in improving the physical and mental health, and promoting self-care abilities of older stroke patients with upper limb dysfunction by conducting a randomized controlled trial.

2. Methods/design
This study is a single-blind, three-arm randomized controlled trial with randomization at the participant level. This trial was approved by the Ethics Committee of West China Hospital of Sichuan University (number: 2022-852) and was registered on Chinese Clinical Trial Registry (number: ChiCTR2200063738). Activities of daily living will be the primary endpoint to examine whether usual rehabilitation treatment and care plus robot-assisted rehabilitation and reminiscent music therapy for elderly patients with upper limb dysfunction after stroke improve physical and mental health. All outcomes will be collected for three groups at baseline (T0), after 2 weeks of the intervention (T1), in the week immediately post-intervention (T2) and at 4-week post-intervention (T3). The overview of the study design is shown in Fig. 1, and this study protocol followed the statement of the Consolidated Standard of Reporting Trials (CONSORT) [26].

2.1 Study setting

This trial will be conducted at the West China Hospital of Sichuan University in Chengdu, China. Stroke patients aged 60 years and older with upper limb dysfunction who are hospitalized in the Department of Neurology of this hospital will be recruited and followed up for 4 weeks. The department is a national key clinical specialized departments, which ensures that enough participants can be recruited for this trial. The sample size will be calculated after the pilot study.

2.2 Recruitment

Participants will be recruited from the Department of Neurology of West China Hospital of Sichuan University. Researchers will recruit participants through approaching potentially eligible participants in the neurology ward. Inclusion criteria of participants are (1) newly admitted patients diagnosed as stroke for the first time, (2) 60 years old and above, (3) conscious and in stable condition with stable vital sign, (4) with upper limb dysfunction, (5) normal cognitive function, (6) normal vision, hearing and communication, (7) no music-related learning experience and accept music, (8) participate in this study voluntarily and sign the informed consent form. Exclusion criteria are (1) with severe primary diseases of heart, liver, kidney and hematopoietic system, (2) with a history of mental disease, (3) joint dislocation or skin damage of upper limb, (4) excessive area of cerebral infarction or cerebral hemorrhage, (5) uncooperative participants. After determining the eligibility of interested patients, the researchers will describe the details of this study to them again, obtain written consent forms, and collect baseline data.

2.3 Randomization

The random number table was generated based on the RV.Uniform function of SPSS 22.0 software. All participants will be randomly assigned to one of three groups in a 1:1:1 ratio after initial evaluation. Participants will be randomly allocated via an online service provided by the Innovation Center of Nursing Research at the West China Hospital.

2.4 Blinding
Blinding of participants is not possible due to the obvious difference of intervention content. Participants of different groups would not live in the same ward, and the intervention will be implemented in a separate room. For practical reasons, researchers cannot be blinded because they need to clearly know the intervention process and content. In addition, follow-up of all participants, management and other study tasks will be completed by the same researchers. A separation of tasks and blinding will be impossible. However, we will ensure the full concealment of allocation. The randomization of participants was conducted by a non intervener by using the sealed envelopes. Finally, the data collector and study statistician will be blinded to participants’ allocation.

2.5 Interventions

All participants will be randomly assigned to receive usual rehabilitation treatment and care (control), usual rehabilitation treatment and care plus robot-assisted rehabilitation and reminiscent music therapy (experimental group 1), or usual rehabilitation treatment and care plus robot-assisted rehabilitation (experimental group 2) in a 1:1:1 ratio after initial evaluation.

2.5.1 Usual rehabilitation treatment and care

Usual rehabilitation treatment mainly includes drug treatment, comprehensive training of hemiplegic limbs, physical therapy and so on, which will be formulated and implemented by rehabilitation doctors and neurologists according to the specific conditions of the participants. Usual rehabilitation care includes basic environmental care, diet care, drug care, health education, psychological care, rehabilitation care and so on, which will be formulated and implemented by specialized nurses according to the specific conditions of the participants.

2.5.2 Robot-assisted rehabilitation

According to the specific conditions of the patients, the rehabilitation doctors will use the rehabilitation robot for upper limb to carry out 30 minutes of rehabilitation training for the patients, once a day, five days a week, and a total of four weeks. The individualized rehabilitation scheme will be formulated by rehabilitation doctors and neurologists according to the specific situation of the patients. The robot equipment used in this study is a three-dimensional upper limb rehabilitation robot (model: A6) produced by Guangzhou Yikang medical equipment industry Co Ltd. Rehabilitation doctors need to undergo strict training from the manufacturer before they can operate the equipment. Rehabilitation doctors need to undergo strict training from the manufacturer before they can operate the equipment. This robot equipment has five training modes: passive mode, active-passive mode, active mode, prescription mode and track editing mode.

2.5.3 Reminiscent music therapy

The same research group has developed a music library of reminiscent songs in the early stage, including 100 Chinese songs released from 1935 to 1980, which are divided into 10 song lists and each list has 10 reminiscent songs. Each time the robot-assisted rehabilitation training of upper limb is carried out, a
reminiscent song list will be played for patients with a wireless headset. When playing music, the music beat and intensity will be between 45 and 60 decibels. After the robot-assisted rehabilitation training of upper limb, the patients will be asked to sit down in a comfortable position and concentrate on breathing for 5 minutes. Patients should first slowly inhale for 3 seconds, pause for 1 second, then slowly exhale for 5 seconds, exhale all the residual gas in the lungs and imagine that the annoyance and unhappiness could be dissipated with the exhalation of the gas. The whole process of breathing relaxation is slow and uniform with rhythm, with a total of 5 cycles.

2.6 Outcomes and measurements

A research assistant who does not know the randomization scheme will perform the data collection and examinations at baseline (T0), after 2 weeks of the intervention (T1), in the week immediately post-intervention (T2) and at 4-week post-intervention (T3). The first time to measure data is face-to-face with participants. Each participant will be followed up either in their ward or by telephone. We expect the intervention to improve the abilities of patients to take care of themselves. Therefore, we choose the activities of daily living measured in the week immediately post-intervention (T2) as the primary outcome. As secondary outcomes we will measure self-esteem, rehabilitation self-efficacy, positive emotion and upper limb function.

2.6.1 Demographic data (T0)

To characterize the participants, the sex, age, educational level, marital status, residence, nationality, religion, monthly income per capita of family, type of medical insurance, diagnosis, type of combined chronic disease, brunnstrom stage, main caregivers will be collected.

2.6.2 Self-esteem (T0, T1, T2, T3)

Self-esteem was evaluated by the Self-Esteem Scale with a single dimension and 10 items, which was compiled by Rosenberg in 1965 [27]. Each item of Chinese version of Self-Efficacy Scale is scored from 1 (quite wrong) to 4 (quite right). The total score ranges from 10 ~ 40 and higher total score indicates higher sense of self-efficacy. The Cronbach's alpha of this scale is 0.83 [28], meaning good reliability.

2.6.3 Rehabilitation self-efficacy (T0, T1, T2, T3)

Rehabilitation self-efficacy was measured by the Stroke Self-Efficacy Questionnaire compiled by Jones et al. in 2008, which is used to evaluate the to measure the functional performance and confidence of self-management of patients with stroke in the recovery period [29]. Li et al. translated and revised it into Chinese with 2 dimensions including activity of daily living efficiency and self-management efficiency [30]. This scale has 11 items and each item is scored from 1 (very unconfident) to 10 (very confident). The total score ranges from 11 to 110 and higher total score indicates higher sense of rehabilitation self-efficacy. The Cronbach's alpha of this scale is 0.969 [30].

2.6.4 Positive emotion (T0, T1, T2, T3)
The positive emotion dimension of the Positive Affect and Negative Affect Scale was used to measure positive emotion in patients with stroke. This scale was developed by Watson et al. in 1988 and revised by Qiu et al. in 2008 [31]. The positive emotion dimension has 9 items and each item is scored from 1 (never) to 5 (almost). The total score ranges from 9 to 45 and higher total score indicates more positive emotions. The Cronbach's alpha of this scale is 0.92 [32].

2.6.5 Upper limb function (T0, T1, T2, T3)

Upper limb function was measured by the Fugl-Meyer Assessment, which is one of the important scales for evaluating motor function of stroke patients, with the advantages of reliability and high sensitivity [33]. Upper limb dimension of the simplified Fugl-Meyer Assessment has 33 items. Each item is scored from 0 (cannot complete) to 2 (complete). The total score ranges from 0 to 66. The higher the total score, the better the motor function of upper limbs and hands.

2.6.6 Activities of daily living (T0, T1, T2, T3)

The modified Barthel Index was used to evaluated the activities of daily living. This scale has 10 items, and each item is divided into five levels according to the degree of dependence [34]. The total score ranges from 0 to 100. The higher the total score, the better the self-care ability.

2.7 Statistical analysis

We will use IBM SPSS Statistics 22 to analyze data. P-P diagram, Q-Q diagram and histogram will be used to test the normal distribution of measurement data. The statistical description of measurement data will use the mean and standard deviation when following normal distribution, otherwise use the median and quartile. When following normal distribution and homogeneity of variance, the measurement data will be compared by the analysis of variance, otherwise the Kruskal-Wallis H Test will be adopted. Counting data will be described by number and percentage. Chi-square test and Fisher exact test will be used to analyze the counting data. All tests are 2-sided, and statistical significance is defined as $P < 0.05$.

2.8 Trial status

At the time of submission of this paper, we are conducting the preliminary study of the intervention. Recruitment of the preliminary study began on 25 December 2022. By the time of submission of this manuscript (8 January 2023), 5 participants were already enrolled.

3. Discussion

This paper presents a study protocol of a randomized controlled trial, targeting older stroke patients with upper limb dysfunction. With this study, we will measure reminiscent music therapy combined with robot-assisted rehabilitation intervention and expect this intervention to promote the health status and self-care abilities of older patients with upper limb dysfunction after stroke. The novelty of reminiscent music therapy combined with robot-assisted rehabilitation lies in the combination of music therapy, reminiscence therapy and robot-assisted rehabilitation. Given the fatigue and negative emotions that are
easily generated by older stroke patients in the process of rehabilitation training, which affects their cooperation in rehabilitation treatment and hinders the rehabilitation progress, we combine reminiscent music therapy with robot-assisted rehabilitation.

Neurological rehabilitation is of great significance for the prognosis of stroke. Upper limb dysfunction especially in hand leads to more disability, because its functions are more complex and vital to daily life [35]. To deal with this problem, many approaches including robot-assisted rehabilitation have been suggested for upper limb and hand rehabilitation following stroke [36]. The robot-assisted upper limb training is purposed to improve hand function and motor, sensory and cognitive function by combining visual feedback with motivation [36]. The clinical utility of robot-assisted rehabilitation has been increasing [37]. Adding robot-assisted rehabilitation to usual rehabilitation could provide greater changes in upper limb rehabilitation of stroke patients compared to usual rehabilitation alone [38]. Reminiscence therapy has become one of the feasible and effective social psychological interventions and can guide the elderly to review and re-experience the past life, which generates new interpretation of life and helps the elderly to understand themselves, to reduce the sense of loss, and to increase self-esteem [39]. Recalling happy events helps individuals to maintain a positive self and improve self-esteem and happiness. On the contrary, recalling sad events helps individuals to examine the past situations, so as to increase the ability to adapt to the existing environment and achieve self-integration [40, 41]. Music is one of the most common triggers of nostalgia, and touching off memories with familiar songs could significantly improve the mental health of the elderly [22]. Importantly, some studies suggest that the combination of music and rehabilitation will significantly improve the effect of rehabilitation training [24, 42].

Therefore, this study intends to combine reminiscent music therapy with robot-assisted rehabilitation in order to enable older stroke patients to carry out upper limb rehabilitation training under the stimulation of reminiscent music. To the authors’ knowledge, this is the first study to examine the effects of reminiscent music therapy combined with robot-assisted rehabilitation in older stroke patients with upper limb dysfunction. In our opinion, using reminiscent music to stimulate nostalgia may help stroke patients to obtain a sense of perfection and satisfaction from memory, and help them to maintain self-concept and enhance the sense of self-worth, so as to improve self-esteem, decrease negative emotions and accept the conditions. It is conducive to improving rehabilitation self-efficacy, changing into a positive attitude towards disease and reducing post-stroke fatigue. If patient participates in the treatment and rehabilitation of the disease with a right and positive attitude and action, it will help to promote the recovery of disease and improve the prognosis.

**Declarations**

**Ethics approval and consent to participate**

The study protocol, informed consent forms, and questionnaires were approved by the Ethics Committee of West China Hospital of Sichuan University (number: 2022-852). All methods will be carried out in
accordance with the Declaration of Helsinki. Written informed consent to take part in the trial will be obtained from all participants or their legal guardian.

**Consent for publication**

Not applicable.

**Availability of data and materials**

Not applicable.

**Competing interests**

All authors declare that they have no known competing financial interests or personal relationships that could influence the work reported in this study.

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**Authors' contributions**

Qian Liu and Xiuying Hu conceived the study. Qian Liu, Zuoyan Liu, Hong Cheng, Yang Xu and Xiuying Hu contributed to the design of this study. Qian Liu drafted the manuscript. Zuoyan Liu, Fang Wang, Li Liu and Xiuying Hu critically reviewed the manuscript for important intellectual content. All authors read and approved the final manuscript.

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**References**


Figures
Figure 1

CONSORT flow diagram of this study