Scalp acupuncture treatment for motor dysfunction in children with cerebral palsy: study protocol for a multicenter randomized controlled Trial

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Abstract

Abstract Background: Scalp acupuncture has shown a remarkable treatment efficacy on motor dysfunction in children with cerebral palsy, especially when performed on the motor area of Jiao’s scalp acupuncture, which is the most widely used treatment. However, previous studies have summarized that the clinical curative effect of acupuncture treatment for children with cerebral palsy remains uncertain. Meanwhile, no randomized controlled trials on scalp acupuncture have been performed. The aim of this study is to evaluate the efficacy and safety of scalp acupuncture for motor dysfunction in children with cerebral palsy.

Methods/design: This is an assessor and analyst blinded, randomized controlled trial. One hundred cerebral palsy patients with motor dysfunction meeting the inclusion criteria will be allocated by a 1:1 ratio into either an acupuncture treatment group or a control group. Cerebral palsy in the control group will receive conventional rehabilitation treatment, whereas a combination of scalp acupuncture and conventional rehabilitation treatment will be applied to the acupuncture group. Thirty-six treatment sessions will be performed over a 12-week period. The Gross Motor Function Measure and the Fine Motor Function Measure Scale will be assessed as the primary outcome measure. The Pediatric Evaluation of Disability Inventory, and the Cerebral Palsy Quality of Life Questionnaire for Children will be selected as secondary outcome measurements. All assessments will be conducted at baseline, week 4 (treatment 12), week 8 (treatment 24), week 12 (treatment 36), and week 24 (follow-up).

Discussion: This is the first trial evaluating the efficacy and safety of scalp acupuncture for motor dysfunction in children with cerebral palsy. The results of this trial are expected to provide relevant evidence demonstrating that scalp acupuncture can be used as an effective rehabilitation treatment method for improving motor dysfunction in children with cerebral palsy.
cerebral palsy.

Background

Cerebral palsy (CP) is a well-recognized neurodevelopmental disorder beginning in the early childhood and persisting throughout the patient's lifetime. Motor disorders are often accompanied by disturbances of sensation, cognition, communication, perception, behavior, and seizures [1-3]. CP is the most common physical disability in childhood with a prevalence of 1.5 to 3.8 per 1000 live births in Europe, Australia, and the United States [4-6]. In 2004, the lifetime cost of health care for cerebral palsy in the USA was estimated at $921,000 [7,8]. In China, an epidemiologic study published in 2016 indicates a prevalence of 2.48 per 1000 children aged 1 to 6 years old based on a survey of 12 cities. According to this estimate, there are about 5 million children with CP among children under 14 years old and about 40,000 new cases will be diagnosed every year based on the estimated number of 16 million newborns per year in China [9]. Due to motor dysfunction in children with CP, the activities of daily living (ADL) and social participation are restricted, which greatly influences the quality of life (QOL) and their ability to adapt to society. In addition, this places a heavy burden on families and society as a whole and becomes a significant public health issue [10].

Western standard conventional treatment is multi-professional rehabilitation in children with CP, which including physical therapy (PT), occupational therapy (OT), and speech therapy (ST) is added in some children [8,11]. This approach is a complex procedure and multi-disciplinary designed to minimize complications and improve function [10]. In China, CP rehabilitation treatment framework mainly develops the clinical program mode of combining western medicine and traditional Chinese medicine. Acupuncture is used as a complementary and alternative treatment, which has increased worldwide and has become widely applied to CP rehabilitation treatment. Clinical trials have demonstrated
that acupuncture combined with rehabilitation therapy can reduce spasm, improve motor function, and enhanced daily life activities in children with CP [12-16].

Many studies [17] have shown that scalp acupuncture treatment has significant clinical effects on motor dysfunction in children with CP in China, and at present, there are many scalp acupuncture schools have been used to treat motor dysfunction for CP in hospitals. These include schools such as Jiao’s, Lin’s, Jin’s, Tang’s and other different scalp acupuncture schools and the China scalp-point program of the international Standardization [18]. Among them, the anterior oblique line of vertex-tempora of the international standardization scalp partition or the motor area of Jiao’s scalp acupuncture is usually chosen as the scalp acupuncture stimulatory region to treat motor dysfunction in CP. Jiao’s scalp acupuncture combines a modern understanding of neuroanatomy and neurophysiology with traditional techniques of Chinese acupuncture to develop a radical new tool for affecting the functions of the central nervous system and accepts a central theory that incorporates brain functions into Chinese medicine principles[10]. The motor area of Jiao’s scalp acupuncture that is specifically used for treatment of motor dysfunction in CP is the equivalent of the precentral gyrus of the cerebral cortex, on scalp projection [18]. In a preliminary study, we demonstrated the effect of Jiao’s scalp acupuncture combined with rehabilitation treatment on cerebral palsy [19]. However, there haven’t been any RCTs done to demonstrate the clinical curative effect of the motor area of Jiao’s scalp acupuncture treatment on motor dysfunction in children with CP.

Moreover, although acupuncture has become widely accepted as a treatment for CP and showed better clinical curative effect compared with conventional treatments in China, a new Meta-Analysis published in 2018 [20] based on clinical randomized controlled trials concluded that the clinical curative effect of acupuncture treatment in children with CP
remains uncertain due to the small number of randomized controlled trials available and the small sample sizes. More power and strong evidences shall be verified by high-quality and large-scale studies. Furthermore, another Meta-Analysis [17] based on scalp acupuncture treatment of motor dysfunction in CP summarized that the evidence was insufficient to warrant a clinical recommendation due to the generally low methodological quality of the included studies. In addition, there was no evidence available on the safety of this treatment because none of the trials reported adverse effects [10]. Based on above viewpoints, the purpose of this study is to evaluate the clinical efficacy and safety of scalp acupuncture treatment for motor dysfunction in children with CP.

Methods/design

Objectives

The objective of this proposed study is to investigate whether scalp acupuncture treatment could significantly improve motor function in children with CP.

Study design

This is an outcome assessor and data analyst-blinded, randomized, controlled superiority trial. The study is planned to be conducted from the 1\textsuperscript{st} of January 2019 to the 31\textsuperscript{st} of December 2021 in the Children's Hospital of Fudan University. CP patients with motor dysfunction meeting the inclusion criteria will be allocated in a 1:1 ratio into either an acupuncture treatment group or a control group. CP patients in the control group will receive routine rehabilitation treatment, whereas a combination of routine rehabilitation treatment and scalp acupuncture will be applied to the acupuncture group. The Gross Motor Function Measure (GMFM) and the Fine Motor Function Measure (FMFM) will be assessed as primary outcome measures. The Pediatric Evaluation of Disability Inventory
(PEDI) and the CP-Specific Quality of Life Scale (CP-QOL) will be selected as secondary outcome measurements. All assessments will be conducted at baseline, week 4 (treatment 12), week 8 (treatment 24), week 12 (treatment 36) and week 24 (follow-up). Figure 1 summarizes the flow of the entire trial. Figure 2 shows the study timeline, according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram. Additional file 1 presents the SPIRIT checklist.

**Inclusion criteria**

Participants meeting the following inclusion criteria will be included: (1) cerebral palsy patients between 12 and 72 months old; (2) cerebral palsy was diagnosed according to the diagnostic criteria of CP found in international guidelines; (3) cerebral palsy of the spastic type; (4) voluntary participation and informed consent signed.

**Exclusion criteria**

Participants with any of the following exclusion criteria will be excluded: (1) visual, auditory and mental disorders, affecting the rehabilitation assessment; (2) the child with epilepsy who is not under control with medication; (3) bleeding tendencies; (4) being oversensitive to acupuncture; (5) use of muscle relaxants or herbal therapies during the study period; (6) participation in another clinical trial.

**Informed consent**

Prior to the study, the general study process will be explained to potential participants and their legal guardian. Participants and their legal guardian will be informed that participation in the trial is completely voluntary and that they can withdraw from the trial at any time. In the event of their withdrawal, study data collected on the participant will not be deleted and will be used in the final analyses. Written informed consent should be obtained from each participant and his/her legal guardian before they undergo any interventions related to the study.
Interventions

The study is a randomized clinical trial carried out in outpatient rehabilitation departments of four hospitals. A total of 100 children with CP will be recruited. The patients will be randomly assigned to two different groups: 1) the treatment group and 2) the control group. The treatment group (n=50) will receive routine rehabilitation treatment combined with scalp acupuncture for 3 times per week and last for 12 weeks, and the control group (n=50) will receive routine rehabilitation treatment for 3 times per week and last for 12 weeks. Both groups will be evaluated at baseline, week 4 (treatment 12), week 8 (treatment 24), week 12 (treatment 36) and week 24 (follow-up). Both groups will receive CP routine rehabilitation treatment during the whole 12-week study period. The routine rehabilitation program was designed according to the Chinese CP rehabilitation treatment guidelines, which include physical therapy (PT) and occupational therapy (OT) for 3 days a week [21]. Chinese herbal medicine and Chinese patent drugs will be prohibited during the trial.

Scalp acupuncture treatment

The acupuncture intervention complies with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines. Moreover, all the acupuncturists will attend special training to achieve a sound understanding of the scalp acupuncture intervention program and to standardize the practices procedures across different acupuncturists. The trial adheres to the STRICTA guidelines [22, 23]. The parameters for scalp acupuncture are set as follows:

(1) Scalp acupoint selection: Primary acupoint: The Motor Area of Jiao's Scalp acupuncture; Secondary acupoint: Si shencong (EX-HN1).

(2) Scalp acupoint location:

Location of the Motor Area of Jiao's Scalp acupuncture: It is located over the anterior
central convolution of the cerebral cortex, it is a line starting from a point (known as the upper point of the Motor Area) 0.5cm posterior to the midpoint of the anterior-posterior midline of the head and stretching diagonally to the juncture between the eyebrow-occipital line and the anterior border of the corner of the temporal hairline, which is indistinct. Draw a vertical line upwards from the middle point of the zygomatic arch to the eyebrow-occipital line, the intersection of the two lines is the projection of the Motor Area. The Motor Area is divided into five equal parts: the upper one-fifth being the Motor Area of the lower limbs and the trunk, the middle two-fifths being the Motor Area of the upper limbs, the lower two fifths, the Motor Area of the face [10] (figure. 3 shows the motor area of Jiao’s scalp acupuncture). According to the type of cerebral palsy base on the limb affected by motor dysfunction, the motor area on the opposite side of the affected limb is selected as the site for acupuncture treatment for monoplegic and hemiplegic CP, and the bilateral motor areas were selected as the site for acupuncture treatment for diplegic and quadriplegic CP.

Location of the Si shencong (EX-HN1): It is located 1 cun from the Baihui acupoint (Governing vessel; GV20) in front, behind, left and right, with a total of 4 acupoints (figure. 4 shows the Si shencong). Baihui acupoint (GV20) is located 5 cun posterior to the front of the anterior-posterior midline of the head.

(2) Acupuncture manipulation: Disposable stainless steel needles (size 0.3 mm×40 mm) will be manually inserted at an approximately 15-degree angle to a depth of 1.5-2.0 cm respectively along the upper point and middle point of the motor area on the scalp [10]. The acupuncture direction of Si shencong (EX-HN1) acupoint is toward the Baihui (GV20) acupoint. For treating motor dysfunction, the needles will be rotated for at least 200 revolutions per minute for 1 minute every 20 minutes for a total of 60 minutes. Scalp acupuncture treatment will be performed by an independent certified practitioner
(acupuncturist) with 5 years of clinical experience [10].

(3) Treatment course: The scalp acupuncture treatment will be implemented three times a week (once every other day), twelve times per treatment course, with each patient having three treatment courses in total.

**Rehabilitation Treatment**

The children with CP will receive the routine rehabilitation programs as mentioned above. The rehabilitation programs will be carried out three times a week (once every other day) for 12 weeks, and each session of the rehabilitation treatment (PT and OT) will last approximately for 1 hour. All rehabilitation treatments will be carried out by qualified therapists.

**Follow up**

After the 12-week treatment observation, all patients will start an additional 12-week follow-up period. CP patients from both groups will continue to attend rehabilitation treatment in the follow-up period. However, all patients from both groups are free to choose whether to receive scalp acupuncture or not with consent from his/her parents during the follow-up period. During the 12-week follow-up period, all of the CP patients from both groups will be reassessed by GMFM, FMFM, PEDI and CP-QOL at week 24 and asked to fill out forms to record their rehabilitation treatment attendance. All assessment scales and forms will be returned to the researchers for reviewing at the end of the trial.

**Outcome measures**

Data collection will be performed by a trained assessor who is blind to patients’ assignment at baseline, after the intervention (4 weeks, 8 weeks and 12 weeks) and at the end of follow up (24 weeks).

**Basic characteristic variables**

All of the participants’ general status demographic information, such as age, sex, clinical
type and GMFCS level (Gross Motor Function Classification System, GMCFs) will be attained from baseline questionnaires.

**Primary outcome measurement**

This study has two primary outcomes, Gross Motor Function Measure (GMFM) and Fine Motor Function Measure Scale (FMFM) will be assessed at baseline, the interventions period (at 4 weeks, 8 weeks, 12 weeks) and the follow-up period (at 24 weeks).

**Gross Motor Function Measure, GMFM**

The Gross Motor Function Measure-66 (GMFM-66) is a standardized observational instrument designed to assess the gross motor function of children with CP. It is frequently utilised in clinical and research practice to measure change over time or following interventions [24]. It allows the therapist or physician to evaluate a child’s gross motor functioning by observing the way a child performs a series of motor skills. It is divided into five sections: Lying and Rolling, Sitting, Crawling and Kneeling, Standing, and Walking, Running and Jumping. Each item has a very specific detailed description whereby the evaluator scores how capable the child is of completing that item on the basis of four levels: 0=does not initiate, 1=initiates, 2=partially completes, 3=completes or NT=not tested [25]. The total score is a summation of the scores in the five areas by the Gross Motor Ability Estimator software (GMAE Version 1.0.). In addition, the Gross Motor Ability Estimator (GMAE-2) Scoring Software for the GMFM-66 can be downloaded from the CanChild website (https://www.canchild.ca/). The greater the number of tasks attempted, the greater the accuracy of the evaluation [25].

**Fine Motor Function Measure Scale, FMFM**

The Fine Motor Function Measure (FMFM) assessment scale is used to evaluate the fine motor activities of children with CP, including the upper limb activities and sensory ability.
This scale includes five domains, namely audiovisual tracking ability (5 items), upper limb joint’s ability (9 items), grasping ability (10 items), operation ability (13 items) and hand-eye coordination (24 items), which reflect the fine motor function by a total percentage of ability. Each item has a very specific detailed description whereby the evaluator scores how capable the child is of completing that item on the basis of four levels: 0=does not initiate, 1=initiates, 2=partially completes, 3=completes. The total score(0-100 points) is a summation of the scores in the five areas. The higher the score, the stronger the fine motor ability [25-27].

Secondary outcome measures

This study has two Secondary outcomes, Pediatric Evaluation of Disability Inventory (PEDI) and Cerebral Palsy Quality of Life Questionnaire for Children (CPQOL) will be assessed at baseline, the interventions period (at 4 weeks, 8 weeks, 12 weeks) and the follow-up period (at 24 weeks).

Pediatric Evaluation of Disability Inventory, PEDI

Pediatric Evaluation of Disability Inventory (PEDI) is an instrument for evaluating function in children with disabilities aged 6 months to 7.5 years. The PEDI measures both functional performance and capability within three domains of (1) self-care, (2) mobility, and (3) social function in two categories, that is, the Functional Skills Scale (FSS), Caregiver Assistance Scale (CAS), and Modifications Scale. It can be administered as an interview with parents/caregivers or through observation by professionals familiar with the child. The raw scores from each domain can be converted to both normative and scaled scores. FSS covers 40 diverse content areas assessed using 197 items scored unable (0) or capable (1). The self-care domain comprises 73 items covering use of utensils, personal hygiene, grooming, toileting tasks, and so forth. The mobility domain has 59 items covering transfers, such as normal use of toilet/potty, getting into/out of a bed or chair,
and indoor and outdoor locomotion. The social function domain has 65 items covering word comprehension, communication, problem solving, playing with adults and peers, and so forth [28-30]. CAS covers 20 diverse content areas scored on the following escalating 6-point scale: independent, supervision, minimal help, moderate help, maximum help, and total help. The items cover the self-care domain (n = 8), mobility domain (n = 7), and social function domain (n = 5). Modifications Scale measures any environmental or technical modifications needed to enhance the child’s function [31].

**Cerebral Palsy Quality of Life Questionnaire for Children, CPQOL**

The quality of life of children with CP was measured with the Chinese version of the Cerebral Palsy Quality of Life for Children (CP QOL-Child). The cerebral palsy quality of life questionnaire for children contains 66 items in seven domains: Social well-being and acceptance (SWB), Functioning (FUN), Participation and physical health (PART), Emotional well-being (EWB), Access to services (ACCESS), Pain and feeling about disability (PAIN), and Family health (FAMILY). Almost all of the items have the following item stem: ‘How do you think your child feels about..?’ and a 9-point rating scale, where 1 = very unhappy, 3 = unhappy, 5 = neither happy nor unhappy, 7 = happy, and 9 = very happy. A few items where this stem or rating scale is not appropriate, such as items in the domain of pain and feeling about disability, have the following stem and rating scale: ‘How does your child feel about the amount of pain that they have’, where 1 = not upset at all to 9 = very upset [32,33]. The reliability and validity of the Chinese version of the CP QOL-Child have been established.

**Safety**

We will conduct the following tests on all participants at the screening stage to exclude
patients with serious organic lesions: white blood cell count, platelet count, hemoglobin, coagulation function, creatinine, blood urea nitrogen, alanine aminotransferase/aspartate aminotransferase, gamma-glutamyl transpeptidase and electroencephalogram examination.

The subjects will be requested to report information about adverse events (AEs). All AEs that occur during the trial period will be recorded, such as dizziness, sweating, fainting, pallor, perturbed or chest congestion during scalp acupuncture treatment, local anaphylaxis, bleeding, unbearable prickling, local hematoma, retained needle after treatment, and continuous severe local pain for more than one hour after acupuncture. The researcher will confirm the occurrence of AEs and record all details such as the time of occurrence, date, degree, measurement related to the acupuncture treatment, and causal relationship with the acupuncture treatment. Serious AEs must be reported to the principal investigator immediately [10].

**Quality control**

Before the trial, all staff members are required to attend a series of training sessions. These sessions will ensure that the personnel involved fully understand the research protocol and standard operating procedures for the study. In order to maintain the clinical trial at a consistently high quality, the Clinical Trail Unit of Children's hospital affiliated to Fudan university will monitor the study documents, case report forms (CRFs), informed consent forms, serious AEs, and data records regularly [10].

**Data collection, management, and monitoring**

The CRF, Treatment Form, and Adverse Events Form will be first completed and then double-entered into the electronic data capture (EDC) system electronically by two independent investigators to act as the first level of control to ensure the accuracy of the data. The second level of data integrity will include data monitoring and validation, which
will be performed periodically throughout the study. The original CRFs and all other forms (including the consent forms) will be archived securely in the Clinical Trail Unit (CTU) of the Children's hospital affiliated to Fudan university for 5 years following publication of the last paper or report from the study [10].

The safety of the study will be monitored by a Data and Safety Monitoring Board (DSMB) of the CTU of the Children's hospital affiliated to Fudan university, which consists of independent clinical experts and statisticians with access to unblinded data. The DSMB is independent from the sponsor, the competing interests, and the investigational site and will review the performance and safety of the trial monthly [10].

The criteria for unblinding and discontinuing allocated interventions for a given trial participant include getting severe diseases, having serious complications of CP or experiencing serious acupuncture-related AEs (if any), which have been described previously. The DSMB will reveal a participant’s allocated intervention and make the final decision to terminate the trial [10].

The final trial data set will be under the custody of Children's hospital affiliated to Fudan university. The data manager from the CTU of Children's hospital affiliated to Fudan university will have access to the complete, anonymous final data set. Access to the final data set or identifiable data by others will require written requests to be approved by the DSMB of the CTU of Children's hospital affiliated to Fudan university and all study investigators [10].

**Sample size calculation**

Sample size calculations were performed based on the two primary outcomes. According to our pilot trial, we assume that after 12 weeks of treatment the mean change of GMFM scores in the experimental group will be greater than the control group with the mean difference of 2.4, with standard deviation of 3.0. At alpha level of 0.025, 40 subjects will be
required for each group to ensure a statistical power of 0.9. Considering a 20% drop out, a total of 100 participants will be needed, each group is required to have 50 initial participants.

**Participant recruitment**

Participants will be recruited in four hospitals (Children's hospital of Fudan university, The 445th hospital of Chinese People's Liberation Army, Huajing Community health service center of Xuhui district and Jiangchuan Community health service center of Minhang district) in Shanghai, China. Prospective participants will be asked to meet with the study coordinator to discuss the study and provide information about the eligibility criteria. If children with CP are eligible and their parents/guardians are interested in participating, they will be invited for a series of rehabilitation assessments after diagnosis by neurologists. One hundred children with CP will be included in the study. When their informed consent has been obtained, children with CP will be randomized into two groups with different treatments [10].

**Randomization and allocation concealment**

The recruited patients were randomly assigned to experimental group or control group according to a randomization and allocation plan, which was computer-generated, block randomization (block size of 4 and 1:1 allocation) prepared by an independent epidemiologist not otherwise involved in the trial. A computer-generated block randomization process designed by the CTU is used to allocate participants to the treatment group or the control group in a 1:1 ratio (block size = 4). The randomization list is kept strictly confidential. Allocation concealment is ensured with the use of sequentially numbered (block number and sequence number), identical, opaque, sealed envelopes. Computerized randomization preserves allocation concealment and reduces the possibility of selection bias since the research assistant is kept unaware of the group assignments
until after the participants are allocated to groups.

**Statistical analysis**

The Statistical Product and Service Solutions (SPSS) statistical package program (version 20.0, SPSS Inc., Chicago, IL, USA) will be used to analyze data in the CTU of Children's hospital affiliated to Fudan university by statisticians. All analyses will be based on the intention-to-treat principle using the last observation carried forward rule. Baseline information will be collected before randomization and include the gender and age of patients, disease course, clinical type, GMFCS level, primary outcome (GMFM, FMFM), and secondary outcomes (PEDI, CP-QOL). Descriptive statistics will be used to detail baseline participant demographics and general status of patients, such as gender, age, disease course, clinical type and GMFCS level. Variables will be checked for normal distribution and presented as mean +/-standard deviation and compared by Student t test when normally distributed. For not-normally distributed variables, the data will be expressed as median +/-interquartile range, and non-parametric tests will be used. Categorical variables will be expressed as number (%) and analyzed by χ² tests or Fisher’s exact tests, when appropriate. Mixed effect model will be used to analyze the between-group difference in repeated measured two primary outcomes and other outcomes (GMFM, FMFM, PEDI, and CP-QOL scores) across five testing time points (weeks 0, 4, 8, 12 and 24). Mean group difference and 95% confidence intervals will be reported. Safety analyses will be compared with the incidence of AEs in the two groups using the χ² test. A p value of < 0.025 will be considered as statistically significant for the two primary outcomes.

**Discussion**

Chinese scalp acupuncture is a contemporary acupuncture technique integrating traditional Chinese needling methods with Western medical knowledge of representative
areas of the cerebral cortex. As acupuncture developed, various physicians began to introduce western neurophysiology into the field of acupuncture and explored correlations between the brain and human body. Dr. Jiao Shun-fa who is the founder of Jiao’s scalp acupuncture, a neurosurgeon in Shan Xi province, is also the recognized founder of Chinese scalp acupuncture. Dr. Jiao combined the modern understanding of neurophysiology and neuroanatomy with the traditional concept of acupuncture to develop the new scalp acupuncture to affect the functions of the central nervous system [10]. The motor area of Jiao’s scalp acupuncture is frequently used in rehabilitation of paralysis due to stroke, traumatic brain injury, spinal cord injury and multiple sclerosis. It has been demonstrated effective in treating any type of paralysis, especially for motor dysfunction after stroke [34-36]. Based on fMRI studies, it has also been shown that scalp acupuncture has effects on movement regulation and the curative effect of scalp acupuncture is correlated to cerebral activating reaction in motor dysfunction with stroke patients[37,38].The motor area of Jiao’s scalp acupuncture is divided into five equal parts: the upper one-fifth being the Motor Area of the lower limbs and the trunk, the middle two-fifths being the Motor Area of the upper limbs, the lower two fifths, the Motor Area of the face[10]. However, motor dysfunction is the most significant clinical symptom in children with CP. In view of the motor dysfunction of CP, the upper 1/5 and middle 2/5 regions of the Motor Area on the scalp were selected as the primary areas for scalp acupuncture stimulation region. On the other hand, based on the traditional Chinese medicine theory, the disease is classified into “five kinds of retardation, five kinds of flaccidity and five kinds of stiffness” categories of Chinese medicine according to the clinical manifestations of cerebral palsy. At the same time, the disease is caused by the deficiency of innate endowment and the internal organs’ vital essence, which is inadequate nutrition of the “fu-viscera of mental activity”. The scalp acupoints of Si shencong (EX-HN1) are widely
used in the treatment of brain-related diseases in traditional Chinese medicine, because of their effects on “activating the brain, regaining consciousness and soothing the nerves in the brain”. Therefore, the scalp acupoints of Si shencong (EX-HN1) were selected as the secondary area for scalp acupuncture stimulation region [39-42]. In brief, scalp acupuncture uses special techniques to harmonize and regulate the functional activities of the brain and body.

Based on the International Classification of Functioning, Disability, and Health (ICF), once the diagnosis of CP is ascertained or highly suspected, there are numerous tools to assess the impact of CP on different health-related domains, such as physical functioning, daily activities, quality of life, health-related quality of life, family well-being, education, and so on [43-46]. In cerebral palsy rehabilitation clinical studies, rehabilitation evaluation plays an important role. The GMFM scale was selected as the gold standard for the evaluation of a treatment’s curative effect in almost all rehabilitation treatment CP researches done both domestically and overseas. To administer the GMFM, a trained therapist observes the child completing a number of gross motor tasks in a standardised environment, and the child’s best ability is measured. The GMFM is a reliable, valid and responsive measure of gross motor function for children with cerebral palsy. It is frequently utilised in clinical and research practice to measure change over time or following interventions [24]. The FMFM assessment scale is used to evaluate the fine motor activities of children with CP, including the upper limb activities and sensory ability [47]. This scale includes five areas, namely audiovisual tracking ability, upper limb joint’s ability, grasping ability, and hand-eye coordination, which reflect the fine motor function by a total percentage of ability.

The PEDI was used as an individual level assessment scale to evaluate daily life activities of CP, it responds to the complex activity ability and necessary functional skills of patients in daily environments and is often used to assess the influence degree of motor
dysfunction in families and social environments [10,48]. The PEDI has also been recommended as a gold standard in paediatric rehabilitation [28,29]. Quality of life is a very relevant and important construct in the context of children with cerebral palsy because it can provide a broad subjective indication of their well-being across several life domains such as physical health and social and emotional well-being. Quality of life is considered a broad and multidimensional concept that includes subjective evaluations of both the positive and negative aspects of life. In the context of rehabilitation, quality of life has clinical utility as an important health-related outcome measure that can guide practice [33,49,50]. Based on the concept of ICF, this study will evaluate the clinical efficacy of scalp acupuncture treatment for motor dysfunction in children with cerebral palsy in a comprehensive and multidimensional view by using the international assessment scale.

Acupuncture is a frequently used therapy for CP rehabilitation in China, but the evidence of its effect from previous studies seems to be inconclusive. Some Meta-Analysis have been done to study the effect of acupuncture on CP rehabilitation [17,20]. These reviews have drawn consistent conclusions that acupuncture appears to be safe and effective for CP rehabilitation, but the benefits require further confirmation with larger, more transparent and well conducted randomized clinical trials [10]. Thus, the purpose of this research is to observe the therapeutic effect of scalp acupuncture using Jiao's motor area and Si shencong (EX-HN1) acupoint for motor dysfunction in children with CP by international general evaluation scales. Under strict quality control, this study could potentially confirm whether or not scalp acupuncture is an effective adjunct to the standard rehabilitation treatment on motor dysfunction for children with CP.

**Trial status**

The treatment protocol version number currently in use is NO. 2019.2.15. The date
recruitment began on 1 March 2019 and the approximate date recruitment will be completed on 31 December 2021.

**Abbreviations**

ADL: Activities of Daily Living; CAS: Caregiver assistance scale; CG: Control group; CP: Cerebral Palsy; QOL: Quality of Life ;CPQOL: Cerebral Palsy Quality of Life Questionnaire; CTU: Clinical Trail Unit; CRF: Case report form; DSMB: Data and Safety Monitoring Board; EDC: Electronic data capture; FMFM: Fine Motor Function Measure; FSS: Functional Skills Scale; ST: Speech Therapy; GMFM: Gross Motor Function Measure; ICF: International Classification of Functioning, Disability, and Health; OT: Occupational therapy; PEDI: Pediatric Evaluation of Disability Inventory; PT: Physical therapy; RCT: Randomized Controlled Trial; TG: treatment group.

**Declarations**

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authenticity of the data from the research results in this subject and whether the
assessment indicators have been fulfilled.

**Availability of data and materials**

Not applicable.

**Authors’ contributions**

JW, WS and HY conceived and designed the study, collected the data, and wrote the
manuscript. DK revised the manuscript. WLY and YW analyzed and interpreted the data.
BPS, XJS, DDL, RCD, HYH, and JL collected the data and coordinated recruitment and
treatment of patients. All authors read and approved the final manuscript.

**Competing interests**

The authors declare that they have no competing interests.

**Consent for publication**

Not applicable.

**Ethics approval and consent to participate**

The central ethical approval has been confirmed from the Research Ethical Board of
Children’s Hospital of Fudan University (ref approval no. 2019(NO.024)) and we will not
begin recruiting at other centres in the trial until local ethical approval has been obtained.
In the case of any changes to the study protocol, we will submit a written application form
to the Research Ethics Board. They will decide whether or not it is necessary to change
the study protocol. The Research Ethics Board will supervise all procedures of the study.
The purpose and risks of the trial will be explained in detail to the participants, who will
be required to write informed consent to indicate that they agree with the protocol and
would participate in the trial. The participants will be able to quit at any time during the
study period.

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References

1. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for Gross Motor Function in Cerebral Palsy: Creation of Motor Development Curves. JAMA. 2002; 288(11):1357-1363.

2. Bax M, Goldstein M, Rosenbaum P, et al. Proposed definition and classification of cerebral palsy, April 2005. Developmental Medicine & Child Neurology. 2005; 47(8):571-576.

3. Emine EK. Definition, Epidemiology, and Etiological Factors of Cerebral Palsy. 2016. publication at: https://www.researchgate.net/publication/308401297.

4. Ryan JM, Allen E, Gormley J, et al. The risk, burden, and management of non-communicable diseases in cerebral palsy: a scoping review. Developmental Medicine & Child Neurology. 2018; 60(8): 753-764.

5. Kirby RS, Wingate MS, Van Naarden Braun K, et al. Prevalence and functioning of children with cerebral palsy in four areas of the United States in 2006: a report from
the Autism and Developmental Disabilities Monitoring Network. Res Dev Disabil. 2011; 32(2): 462-469.

6. Cans C, Guillem P, Baille F, et al. Surveillance of cerebral palsy in Europe: A collaboration of cerebral palsy surveys and registers. Developmental Medicine & Child Neurology, 2000; 42(12):816-824.

7. Honeycutt A, Dunlap L, Chen H, et al. Economic costs associated with mental retardation, cerebral palsy, hearing loss, and vision impairment—United States, 2003. MMWR Morb Mortal Wkly Rep. 2004; 53(3):57-59.

8. Duncan B, Shen K, Zou LP, et al. Evaluating Intense Rehabilitative Therapies with and without Acupuncture for Children with Cerebral Palsy: A Randomized Controlled Trial. Archives of Physical Medicine & Rehabilitation. 2012;93(5):808-815.

9. Li XJ. Current situation, challenges and development strategies of cerebral palsy rehabilitation in China. Chinese journal of rehabilitation medicine. 2016;31 (1):6-8.

10. Jun W, Jian P, Dhiaedin K, et al. Acupuncture treatment on the motor area of the scalp for motor dysfunction in patients with ischemic stroke: study protocol for a randomized controlled trial. Trials. 2017; 18:287.

11. Bower E, Michell D, Burnett M, et al. Randomized controlled trial of physiotherapy in 56 children with cerebral palsy followed for 18 months. Developmental Medicine & Child Neurology, 2010, 43(1):4-15.

12. Liao HH, Yen HR, Muo CH, et al. Complementary traditional Chinese medicine use in Children with cerebral palsy: a nationwide retrospective cohort study in Taiwan. BMC Complementary and Alternative Medicine. 2017;17(1):155.

13. Jindal V, Ge A, Mansky PJ. Safety and Efficacy of Acupuncture in Children. Journal of Pediatric Hematology/Oncology. 2008;30(6):431-442.

14. Duncan B, Barton L, Edmonds D, et al. Parental perceptions of the therapeutic effect
from osteopathic manipulation or acupuncture in children with spastic cerebral palsy. Clinical Pediatrics.2004;43(4):349-353.

15. Sun JG, Ko CH, Wong V. Randomized control trial of tongue acupuncture versus sham acupuncture in improving functional outcome in cerebral palsy. Journal of Neurology, Neurosurgery & Psychiatry.2004;75(7):1054-1057.

16. Dabbous OA, Mostafa YM, Noamany HAE, et al. Laser acupuncture as an adjunctive therapy for spastic cerebral palsy in children. Lasers in Medical Science.2016;31(6):1061-1067.

17. LI LY, LIU ZH, XIE QL. Meta-Analysis on scalp acupuncture based therapy in treating children cerebral palsy. World Journal of Acupuncture-Moxibustion (WJAM).2014;24(3):49-53.

18. Sun KX, Zhang HM. Review of Literature on the Treatment of Infantile Cerebral Palsy by Scalp Acupuncture. Shanghai journal acupuncture-moxibustion. 2004;23(8):38-41.

19. Wang J, Sun KX, Wu XB, et al. Preliminary Study of the Effect of Scalp Acupuncture on Motor Function in Infantile Cerebral Palsy. Shanghai journal acupuncture-moxibustion. 2009;11(28):634-636.

20. Li LX, Zhang MM, Zhang Y, et al. Acupuncture for cerebral palsy: a meta-analysis of randomized controlled trials. Neural Regen Res.2018; 13(6):1107-1117.

21. The children rehabilitation professional committee of the China rehabilitation medical association, The Rehabilitation committee of pediatric cerebral palsy of the China disabled persons rehabilitation association and the editorial board of China cerebral palsy rehabilitation guidelines. China cerebral palsy rehabilitation guidelines (2015): the sixth part. Chinese Journal of Rehabilitation Medicine. 2015;30(12): 1322-1330.

22. Macpherson H, Altman DG, Hammerschlag R, et al. Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT
statement. PLoS Med. 2010;7: e1000261.

23. Boutron I, Moher D, Altman DG. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008;148(4):295-309.

24. Harvey AR. The Gross Motor Function Measure (GMFM). Journal of Physiotherapy, 2017; 63(3):187.

25. Gray N, Vasquez MM, Duncan B. Comparison of the GMFM-66 and the PEDI Functional Skills Mobility domain in a group of Chinese children with cerebral palsy. Child Care Health Dev, 2011;37(3):398-403.

26. Xu DH, Shi W, Li H, et al. Validity and responsive of the fine motor function measure scale for children with cerebral palsy. Chinese Journal of Rehabilitation Medicine. 2008;23(11): 1010-1013.

27. Shi W, Li H, Yang H, et al. Study on reliability and unidimension of the Fine Motor Function Measure Scale for children with cerebral palsy. Chinese journal of evidence-based pediatrics. 2008;3(02):110-118.

28. Dumas H, Fragala-Pinkham M, Haley S, et al. Item Bank Development for a Revised Pediatric Evaluation of Disability Inventory (PEDI). Physical & Occupational Therapy in Pediatrics.2010; 30(3):168-184.

29. Li H, Shi W, Sun Y, et al. Association analysis between items of functional skills of pediatric evaluation of disability inventory and international classification of functioning disability and health-child and youth version category coding. Chinese Journal of Rehabilitation Medicine.2014;29(06):521-527.

30. Kakooza-Mwesige A, Tumwine JK, Forssberg H, et al. The Uganda version of the Pediatric Evaluation of Disability Inventory (PEDI). Part I: Cross-cultural adaptation. Child: Care, Health and Development.2018;44(4):552-561.
31. Amer A, Kakooza-Mwesige A, Jarl G, et al. The Ugandan version of the Pediatric Evaluation of Disability Inventory (PEDI-UG). Part II: Psychometric properties. Child Care Health & Development, 2018; 44(4):562-571.

32. Wang HY, Cheng CC, Hung JW, et al. Validating the Cerebral Palsy Quality of Life for Children (CP QOL-Child) questionnaire for use in Chinese populations. Neuropsychological Rehabilitation. 2010;20(6):883-898.

33. Chen KL, Wang HY, Tseng MH, et al. The Cerebral Palsy Quality of Life for Children (CP QOL-Child): Evidence of construct validity. Research in Developmental Disabilities, 2013; 34(3):994-1000.

34. Hao JJ, Hao LL. Review of Clinical Applications of Scalp Acupuncture for Paralysis: An Excerpt from Chinese Scalp Acupuncture. Global Advances in Health and Medicine. 2012;1(1):102-121.

35. Wang J, Sun KX, Wu XB, et al. Effects of Individualized Scalp Acupuncture on Mobility Ability of Children with Spastic Cerebral Palsy. Chin J Rehabil Theory Pract. 2010;16(01):50-51.

36. Wang J, Pei J, Cui X, et al. Individualized scalp acupuncture for motor dysfunction in stroke: a randomized controlled trial. Chinese Acupuncture & Moxibustion. 2017;37(09):918-924.

37. Romeo Z, Marta M, Barbara T. Modulation of hand motor-related area during motor imagery and motor execution before and after middle 2/5 of the MS6 line scalp acupuncture stimulation: An fMRI study. Brain and Cognition. 2016;103:1-11.

38. Cui FY, Zou YH, Tan ZJ, et al. Rehabilitation of motor function and curative effect of scalp acupuncture in patients with hemiplegia after stroke: studies on fMRI and DTI. Journal of Beijing University of Traditional Chinese Medicine (Clinical Medicine). 2013;20(4):34-38.
39. Chen ZH, Lai XS, Jiang GH. Influence of electroacupuncture on Sishencong on central cholinergic neurons of rat with experimental vascular dementia. Modern Journal of Integrated Traditional Chinese and Western Medicine. 2006;15(14):1184-1185.

40. Zhao LG, Ma L, Zheng ZY, et al. Effect of Acupuncture of “Baihui”(GV 20) and “Sishencong”(EX-HN 1) on Memory and Cerebral SOD Activity in Alzheimer’s Disease Rats. Acupuncture Research. 2005; 30(1):26-29.

41. Wang MJ, Wang F, Ye JF, et al. Effect of Wushen points in the Treatment of the cerebral palsy and Its Influence on Cerebral Hemodynamics. Journal of Nanjing University of traditional Chinese medicine. 2018;34(2): 132-135.

42. Wang J, Sun KX, Wu XB. Clinical Observations on the Effect of Scalp Acupuncture on Gross Motor Function in Cerebral Palsy Children. Shanghai journal acupuncture-moxibustion. 2010;29(07):442-445.

43. Waters E, Davis E, Ronen GM, et al. Quality of life instruments for children and adolescents with neuro disabilities: How to choose the appropriate instrument. Developmental Medicine & Child Neurology. 2009;51(8):660-669.

44. James S, Ziviani J, Boyd R. A systematic review of activities of daily living measures for children and adolescents with cerebral palsy. Developmental Medicine & Child Neurology. 2014;56(3):233-244.

45. Schiariti V, Klassen AF, Cieza A, et al. Comparing contents of outcome measures in cerebral palsy using the International Classification of Functioning (ICF-CY): a systematic review. European journal of paediatric neurology. 2013;18(1):1-12.

46. Schiariti V, Longo E, Shoshmin A, et al. Implementation of the International Classification of Functioning, Disability, and Health (ICF) Core Sets for Children and Youth with Cerebral Palsy: Global Initiatives Promoting Optimal Functioning. International Journal of Environmental Research and Public Health. 2018;15(9):1-19.
47. Chernykh ER, Kafanova MY, Shevela EY, et al. Clinical Experience with Autologous M2 Macrophages in Children with Severe Cerebral Palsy. Cell Transplantation. 2014;23 Suppl 1(1): S97-104.

48. Schulze C, Page J, Lilja M, et al. Cross-cultural validity of the German version of the Pediatric Evaluation of Disability Inventory (PEDI-G)-A Rasch model application. Child: Care, Health and Development. 2017;43(1): 48-58.

49. Ravens-Sieberer U, Auquier P, Erhart M, et al. The KIDSCREEN-27 Quality of Life measure for children and adolescents: Psychometric results from a cross-cultural survey in 13 European Countries. Quality of Life Research. 2007;16(8):1347-1356.

50. Gilson KM, Davis E, Reddihough D, et al. Quality of Life in Children with Cerebral Palsy. Journal of Child Neurology. 2014;29(8):1134-1140.

Additional Files

Additional file 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Additional file 2: SPIRIT Figure

Additional file 3: SPIRIT checklist

Additional file 4: the Motor Area of Jiao's Scalp acupuncture.

Additional file 5: the Sihencong Scalp acupuncture points

Figures
Figure 1

Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing subject allocation to the study conditions (TG, treatment group; CG, control group; GMFM, Gross Motor Function Measure; FMFM, Fine Motor Function Measure; PEDI, Pediatric Evaluation of Disability Inventory; CP-QOL, Cerebral Palsy Quality of Life)
| TIMEPOINT** | Enrolment | Allocation | Post-allocation | Follow up | Close-out |
|------------|-----------|------------|----------------|-----------|-----------|
| ENROLMENT: |           |            |                |           |           |
| Eligibility screen | X |            |                |           |           |
| Informed consent | X |            |                |           |           |
| Demographics | X |            |                |           |           |
| Clinical type | X |            |                |           |           |
| Disease course | X |            |                |           |           |
| History of disease | X |            |                |           |           |
| Allocation | X |            |                |           |           |
| INTERVENTIONS: |          |            |      |           |           |
| Acupuncture+ |            |            |      |           |           |
| Rehabilitation | |            |    |           |           |
| Rehabilitation | |            |  |           |           |
| ASSESSMENTS: |            |            |      |           |           |
| GMFCS | X |            | X |           |           |
| GMFM | X | X | X | X | X | X |
| FMFM | X | X | X | X | X | X |
| PEDI | X | X | X | X | X | X |
| CPQOL | X | X | X | X | X | X |
| Adverse events | X | X | X | X | X | X |

Figure 2 shows the study timeline, according to the Standard Protocol.

GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; FMFM, Fine Motor Function Measure; PEDI, Pediatric Evaluation of Disability Inventory; CP-QOL, Cerebral Palsy Quality of Life.

Figure 2 shows the study timeline, according to the Standard Protocol GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; FMFM, Fine Motor Function Measure; PEDI, Pediatric Evaluation of Disability Inventory; CP-QOL, Cerebral Palsy Quality of Life.
Figure 3

the Motor Area of Jiao’s Scalp acupuncture
Figure 4

the Si shencong acupoints (EX-HN1)

Supplementary Files

This is a list of supplementary files associated with the primary manuscript. Click to download.

Additional File 5 the Sihencong Scalp acupuncture points.jpg
Additional File 2 SPIRIT Figure.pdf
Additional File 4 the Motor Area of Jiao's Scalp acupuncture.jpg
Additional File 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.pdf
Additional File 3 SPIRIT Checklist.pdf