Immediate effect of an acupressure strap simulating wrist-ankle acupuncture on menstrual pain in young women: study protocol for a randomized controlled trial

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Study protocol

Keywords: Wrist-ankle acupuncture; Primary dysmenorrhea; Acupressure wrist-ankle strap; Randomized controlled trial; Study protocol

Posted Date: August 22nd, 2019

DOI: <https://doi.org/10.21203/rs.2.13360/v1>

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Abstract

Background: Dysmenorrhea seriously affects the ability to perform normal social activities and decreases quality of life. Primary dysmenorrhea can be effectively treated with acupuncture. Based on the wrist-ankle acupuncture (WAA) theory, we designed a portable WAA point compression treatment strap that treats diseases by automatically applying pressure to acupuncture points. The proposed study aims to evaluate the analgesic effect of the acupressure wrist-ankle strap in patients with primary dysmenorrhea.

Methods: The study will be a randomized controlled trial conducted from 1 May 2019 to 30 May 2020 that includes 78 students from Shanghai University of Traditional Chinese Medicine who have primary dysmenorrhea and meet the eligibility criteria. Participants will be randomly divided into two groups in a 1:1 allocation ratio. The intervention group will use the acupressure wrist-ankle strap equipped with tip compression component parts on the internal side; the control group will use the non-acupressure wrist-ankle strap with the tip compression parts removed. All participants will be treated for 30 min on the first day of menstruation. The main outcome measures are the pain intensity score measured by the visual analogue scale, and the onset time of analgesia. The secondary outcome measures are the pain threshold at Yinlingquan (SP 9), skin temperature at Guanyuan (CV 4), and expectations and satisfaction of patients as investigated via the Expectation and Treatment Credibility Scale.

Discussion: This trial will be the first study to evaluate the analgesic effect of the acupressure wrist-ankle strap in patients with primary dysmenorrhea. The quality of this study is ensured by the strict randomization, non-acupressure control, and blinded design. The results may provide a potential alternative treatment for primary dysmenorrhea and evidence-based proof of the analgesic effect of WAA.

Trial registration: Chinese Clinical Trial Registry, ID: ChiCTR1900021727. Registered on 7 March 2019.
<http://www.chictr.org.cn/listbycreator.aspx>

Background

Dysmenorrhea is a condition in which pain is experienced in the lower abdomen and lumbosacral area during menstruation. Patients with severe dysmenorrhea have associated nausea, vomiting, diarrhea, and even syncope [1]. Primary dysmenorrhea is more common in unmarried women, as they typically have no organic lesions in the reproductive organs; primary dysmenorrheic pain is mainly caused by uterine muscle spasm or tonic contraction. Secondary dysmenorrhea mainly prevails in married people, mostly due to pelvic inflammation, uterine fibroids, endometriosis, and other diseases [2]. Because of differences in the definition of dysmenorrhea and/or the methods used to measure dysmenorrheic pain, the prevalence of dysmenorrhea varies widely between countries, but generally ranges from 50–90% [3]. Primary dysmenorrhea not only causes the abovementioned symptoms, but can also be associated with diseases such as interstitial cystitis, arrhythmia, and irritable bowel syndrome, which seriously affect normal social activities, quality of life, and increase the mental and psychological burden of patients [4]. Furthermore, dysmenorrheic patients may be unable to attend work and school, which has an impact on social economy and education [5,6]. Previous studies report that 25–51% of dysmenorrheic patients are

unable to study, work, and live normally [7,8]. Therefore, it is important to investigate ways to reduce the labor loss caused by primary dysmenorrhea and improve the quality of life of patients.

In Western medicine, the symptoms of primary dysmenorrhea are treated or controlled using analgesics, non-steroidal anti-inflammatory drugs, and oral contraceptives. However, these drugs may trigger gastrointestinal reactions and/or affect the central nervous system and metabolism, leading to poor long-term efficacy, drug resistance, and adverse effects [9].

Acupuncture therapy plays an important role in the clinical treatment of primary dysmenorrhea [10] due to its safety, rapid onset of analgesic effect, low cost, and low incidence of adverse effects [11]. Wrist-ankle acupuncture (WAA) is more readily accepted by patients than traditional acupuncture and electroacupuncture, as WAA is easy to operate and causes very minimal pain and discomfort during the implementation process [12]. A systematic review of WAA for the treatment of pain showed that WAA alone and WAA as an adjuvant therapy were more effective than Western medicine, sham acupuncture, or body acupuncture, with few adverse effects [13]. A series of studies conducted by our research group also showed that WAA has a good analgesic effect [14–21]. However, WAA requires the operator to master specific techniques and thus needs to be performed by acupuncturists. Hence, our research team developed the acupressure wrist-ankle strap, which is a new portable WAA point compression treatment device [22] that aims to replace the need for acupuncture needles and enable the patients to operate it themselves to obtain pain relief.

Numerous studies have proved that WAA significantly reduces pain in patients with primary dysmenorrhea [23–26]. Our hypothesis is that the acupressure wrist-ankle strap, which stimulates the WAA points, will also produce analgesic effects in patients with dysmenorrhea. Thus, we designed the randomized controlled trial (RCT) described in this study protocol to evaluate the immediate analgesic efficacy of the acupressure wrist-ankle strap in patients with primary dysmenorrhea.

Methods And Design

2.1. Objectives

The proposed study has three objectives: (1) to determine whether the acupressure wrist-ankle strap has an immediate analgesic effect in patients with primary dysmenorrhea; (2) to explore the possible anti-dysmenorrheic mechanism of the acupressure wrist-ankle strap; (3) to explore the factors potentially affecting the therapeutic effect of the acupressure wrist-ankle strap.

2.2. Trial design

This RCT is designed to compare the efficacy of the acupressure wrist-ankle strap versus a non-acupressure wrist-ankle strap in the treatment of primary dysmenorrhea. Participants with primary dysmenorrhea will be randomly divided into two groups in a 1:1 ratio.

2.3. Participants

2.3.1. Inclusion criteria

The inclusion criteria are: (1) women aged 18–30 years; (2) meeting the criteria for the diagnosis of primary dysmenorrhea based on the Primary Dysmenorrhea Consensus Guidelines [27]; (3) basic regularity of the menstrual cycle (28 ± 7 days); (4) no ongoing treatment for dysmenorrhea; (5) provision of written informed consent; (6) mean pain intensity score evaluated by the visual analogue scale (VAS) of > 2 for three consecutive menstrual cycles.

2.3.2. Exclusion criteria

The exclusion criteria are: (1) pregnancy, pre-pregnancy, or lactation; (2) cardiovascular, hepatic, renal, hematopoietic, and other serious primary diseases or mental disorders (patients suspected of having other diseases based on the medical history and other examinations will be included); (3) patients who have never received acupuncture and moxibustion treatments; (4) patients who have taken any analgesic medications within 24 h before the intervention.

2.3.3. Recruitment

The recruitment targets are undergraduate and graduate students at Shanghai University of Traditional Chinese Medicine. Recruitment posters will be put up on campus.

2.3.4. Patient safety

The acupressure wrist-ankle strap is non-invasive, painless, non-toxic, and poses no safety risk to participants. If the participants are still in severe pain after treatment with the acupressure wrist-ankle strap, a variety of follow-up treatments will be provided, including acupuncture, moxibustion, and analgesic medications.

2.4. Intervention

All participants will go through a standardized interview in which the details of the study will be explained. The details of treatment will be fully documented in accordance with the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) [28]. During treatment, subjects will be in the sitting or supine position. All treatments will be performed by the same registered acupuncturist.

2.4.1. Portable WAA point compression treatment device

In accordance with the basic principles of WAA therapy, each side of the body is divided into six vertical zones, and one acupuncture point is set at the wrist and ankle in each vertical zone. The name of the acupuncture point is the same as that of the corresponding vertical zone. A circular horizontal line is drawn at the position of the diaphragm to divide the body into upper and lower halves. Acupuncture points at the wrist are used to treat pain in the upper body, while acupuncture points at the ankle are used to treat pain in the lower body. The acupuncture point selected for treatment is that with the same numbered name that corresponds to the vertical zone where the pain is located [12] (Fig. 1).

The portable WAA point compression treatment device [22], the acupressure wrist-ankle strap, is an instrument developed based on WAA therapy that is used instead of invasive acupuncture treatment (Fig. 2). The wrist-ankle strap has removable compression parts that exert pressure and stimulate the corresponding WAA points (compression points). The wrist-ankle strap is equipped with installation bases for six fixed compression parts, corresponding to the positions of six compression points on the wrist and ankle. Before being worn by the patient, one to two compression parts are installed in accordance with the individual acupuncture needs of the patient. When the acupressure wrist-ankle strap is being worn, the tips of the compression parts are located at the compression points. For treatment, compression points in the Upper 1–Upper 6 and Lower 1–Lower 6 zones will be selected when the corresponding zones are identified as the therapeutic zones in accordance with the theory of WAA. Compression of different wrist-ankle compression points relieves various symptoms, and is mainly used to relieve pain, insomnia, carsickness, seasickness, and vomiting.

2.4.2. Acupressure wrist-ankle strap group (intervention group)

The therapeutic WAA zones for abdominal pain in patients with primary dysmenorrhea are the Lower 1 and Lower 2 zones. Thus, the bilateral Lower 1 and Lower 2 acupuncture points will be stimulated. The Lower 1 point is located at the medial border of the calcaneus tendon, while the Lower 2 point is located 3 inches above the tip of the medial malleolus and the posterior border of the humerus. The acupressure wrist-ankle strap will be used to replace the stimulation achieved with acupuncture needles. Two compression parts will be installed inside the wrist-ankle strap for each patient (Fig. 3). Patients will wear a wrist-ankle strap on both sides, so that both the Lower 1 and Lower 2 compression points are simultaneously pressed for 30 min (Fig. 4).

2.4.3. Non-acupressure wrist-ankle strap group (control group)

Patients will wear a wrist-ankle strap on both sides for 30 min, but the compression parts will not be installed on the inside of the straps (Fig. 3, 4).

2.5. Outcome measures

2.5.1. Main evaluation indexes

The main evaluation indexes are the pain intensity score measured by the VAS and the onset time of analgesia. The pain intensity score will be scored 3 min before treatment, and at 5, 10, and 30 min after the removal of the wrist-ankle strap. The analgesic onset time is defined as the time taken for the dysmenorrheic pain to be significantly relieved.

2.5.2. Secondary evaluation indexes

2.5.2.1. Pain threshold measurement

The pain threshold will be measured at the Yinlingquan acupoint (SP 9) using a pressure pain detector (YISIDA, Hongkong, China). Measurements will be made 3 min before treatment and at the end of treatment (after the acupressure wrist-ankle strap is removed).

2.5.2.2. Skin temperature at Guanyuan acupoint (CV 4)

The skin temperature at Guanyuan (CV 4) will be measured using an infrared thermal imager (FLIR ONE, FLIR System, America). Measurements will be made 3 min before treatment, at the analgesic onset time, and at the end of treatment (after the acupressure wrist-ankle strap is removed).

2.5.2.3. Patient expectations and satisfaction with outcomes

Patient expectation and satisfaction with the curative effect will be investigated using the Expectation and Treatment Credibility Scale (ETCS) [29]. The ETCS includes four statements with a yes/no response: (1) ETCS1: I am sure this treatment will relieve my pain; (2) ETCS2: I think this treatment is reasonable; (3) ETCS3: I will recommend this therapy to my friends; (4) ETCS4: I believe this therapy can cure other diseases. Both groups will complete the ETCS questionnaire 3 min before treatment and 3 min after treatment.

2.6. Study procedure

Before study commencement, participants will complete a general information form, the Cox Menstrual Symptom Scale (CMSS) [30], the traditional Chinese medicine (TCM) syndrome differentiation form [31],

and provide written informed consent. Subjects who meet the eligibility criteria will be enrolled, grouped, and given corresponding interventions. The schedule of enrolments, allocation and assessments is given in Fig. 5. The study procedure is illustrated in Fig. 6.

2.7. Sample size calculation

The participants will be randomly divided into the acupressure wrist-ankle strap group (intervention group) and the non-acupressure wrist-ankle strap group (control group) in a 1:1 allocation ratio. PASS 11 software (NCSS, Kaysville, Utah, USA) was used to calculate the required sample size. The VAS at each treatment time-point is the main evaluation index, and the difference in the VAS score between the two groups ($D1$) is about 10 mm. M indicates the number of repeated measurements. Preliminary experiments showed that the mean baseline VAS was 7.4 with a standard deviation of 1.4. The correlation between measurement points was 0.7. With the test levels set at $\alpha = 0.05$ (two-sided), $\beta = 0.1$, $D1 = 1$, $M = 4$, $\sigma = 1.4$, $\rho = 0.7$, and the module selected as “Tests for Two Means in A Repeated Measures Design”, at least 32 participants are required per group. Considering a 20% dropout rate, 39 participants will be enrolled in each group, giving a total of 78 participants.

2.8. Randomization and blinding procedures

Random numbers will be generated by a computerized random number table generator using the stratified block randomization method of the SAS package (SAS statistical software version 9.4; SAS Institute Inc., Cary, NC, USA) with a random block size. The random number table file will be password-protected and will be managed by an independent, blinded statistician who is not involved in participant recruitment, treatment, or assessment. Eligible subjects who provide written informed consent will be randomly assigned to a group. The participants and the researchers who evaluate the results will be unaware of which intervention group the participants have been assigned to. The wrist-ankle straps used in both groups will have the same packaging. As only one treatment will be given, the participants will not be aware of the differences between the products during the treatment.

2.9. Data collection and management

The CMSS and the TCM syndrome differentiation form will be used to assess the symptoms of primary dysmenorrhea before treatment, while the ETCS will be completed before and after the treatment in the current menstrual cycle. Participants will complete the general information questionnaire 3 min before treatment. Researchers will ensure the reliability and validity of the questionnaire by providing guidance for each item. Clinical observation results will be recorded on a uniformly printed and numbered clinical observation form. A corresponding computer database will be established and the data will be inputted into the computer on the day of observation.

2.10. Statistical analysis

SPSS for Windows 21.0 will be used for statistical processing. The normal distribution test and homogeneity test of variance will be used for measurement data. All analyses will be conducted in accordance with the intent-to-treat principle. Measurement data will be expressed as mean $\pm$ standard deviation, while count data will be described as number and percentage. All statistical tests will be performed on both sides, and the difference will be considered statistically significant when $P < 0.05$. The baseline characteristics of the two groups will be analyzed using the t -test or nonparametric test. Repeated measures analysis of variance will be adopted to analyze the outcome (analgesic effect). Pearson's correlation analysis will be used to assess the correlation between patient expectations and efficacy.

2.11. Ethics and dissemination

The trial protocol is in accordance with the principles of the Declaration of Helsinki [32] and was approved by the China Ethics Committee of Registering Clinical Trials (Ethics Reference: ChiECRCT20190037). This trial was registered in the Chinese Clinical Trial Registry on 7 March 2019 (ID: ChiCTR1900021727). Written informed consent will be obtained from each participant before enrollment.

Discussion

WAA is a unique kind of acupuncture, as the needling points are selected in accordance with body divisions and participants do not need to achieve the sensation of *de qi*, which is usually experienced as sourness, distention, and pain [33]. Acupuncture at the bilateral Lower 1 and Lower 2 points reportedly achieves a total effective rate of 96.43% in the treatment of primary dysmenorrhea [12]. WAA achieves a significant rapid reduction in the pain associated with primary dysmenorrhea.

Based on the theory of WAA, the pain caused by primary dysmenorrhea is located in the Lower 1 or Lower 2 areas, and so we chose Lower 1 and Lower 2 as the points for intervention. The needling points of WAA are distributed on the meridians; Lower 1 is on the Foot Shaoyin Kidney Channel, while Lower 2 is on the Foot Taiyin Spleen Channel [35,36]. The position of the Lower 2 needling point is at Sanyinjiao (SP 6), which is the intersecting point of the three yin channels of the foot, and connects with the uterus through channels and collaterals. SP 6 is one of the best acupoints with immediate analgesic effect for dysmenorrhea [37]. Therefore, the theory of WAA provides a theoretical basis for the ability of the acupressure wrist-ankle strap to alleviate the pain of primary dysmenorrhea.

Primary dysmenorrhea has a high incidence [38]. During the onset of dysmenorrhea, patients often cannot access a doctor due to the severity of symptoms, and patients themselves often use few analgesic approaches. Furthermore, an unhealthy lifestyle, lack of self-care awareness, and chronic recurrent menstrual pain may cause a fear of menstruation and produce anxiety, which aggravates the

symptoms of dysmenorrhea. Thus, there is a need for a physical intervention method that can be used to alleviate pain at any time and place.

The purpose of this proposed RCT is to evaluate the clinical efficacy of the acupressure wrist-ankle strap in relieving pain caused by primary dysmenorrhea. The immediate analgesic effect of this acupressure wrist-ankle strap will be determined based on VAS scores, the onset time of dysmenorrheic pain, and the change in the pain threshold at Yinlingquan (SP 9) during treatment. The possible mechanism of the acupressure wrist-ankle strap will be investigated by recording and observing the temperature change in the Guanyuan (CV 4) area. The CMSS and TCM Syndrome Scale will be used to analyze the correlation between the analgesic effect of the acupressure wrist-ankle strap and the TCM syndrome and severity of the disease.

The acupressure wrist-ankle strap is a pure physical therapy method that is non-invasive, painless, non-toxic, has no adverse effects, and is easy to operate. Furthermore, the acupressure wrist-ankle strap benefits the environment due to its low-carbon characteristics and can be recycled.

If the proposed RCT verifies the analgesic effect of the acupressure wrist-ankle strap in primary dysmenorrhea, the strap can be used as an effective physical intervention method for primary dysmenorrheic pain that does not require a doctor's intervention and can be used at any time and place. The proposed RTC may also provide evidence for the analgesic effects of WAA and promote the application of WAA in clinical practice.

4. Trial status

Recruitment of participants started on 1 May 2019 and is anticipated to end on 30 May 2020. (The protocol is Version 1.0, dated 2019/4/10.)

Abbreviations

WAA: Wrist-ankle acupuncture

RCT: Randomized controlled trial

VAS: Visual Analogue Score

ETCS: Expectation and Treatment Credibility Scale

TCM: Traditional Chinese medicine

CMSS: Cox Menstrual Symptom Scale

SP 6: Sanyinjia

Declarations

Ethics approval and consent to participate: The proposed RCT has been approved by the China Ethics Committee of Registering Clinical Trials (Ethics Reference: ChiECRCT20190037). Written informed consent for study participation will be obtained from all participants before enrollment.

Consent for publication: Not applicable.

Availability of data and material: Not applicable.

Competing interests: The authors declare that they have no competing interests

Funding: Three-year Action Plan for Further Accelerating the Development of Traditional Chinese Medicine in Shanghai: ZY (2018–2020) - FWTX–3013.

Authors' contributions: The trial was designed and developed by SJZ and YR. The manuscript was drafted by QHZ. The protocol was carefully revised and edited by YR, CX,YL and FFF. SJZ and QHZ contributed to the discussion. All authors read and approved the final manuscript.

Acknowledgments: Fanfu Fang provided general support as the head of the Rehabilitation Department in Changhai Hospital and Qinghui Zhou was responsible for the design of this RCT and for communicating important protocol modifications to relevant parties.

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Figures

Figure 1

Wrist-ankle acupuncture zones and needling points. The body is divided into six vertical zones, numbered 1–6.

Figure 2

Acupressure wrist-ankle strap as the finished product. A) The product packaging, B) the product.

Figure 3

Parts of the acupressure wrist-ankle strap. A) The removable compression parts, B) wrist-ankle strap with the compression parts installed, C) wrist-ankle strap with the compression parts removed.

Figure 4

Application of the wrist-ankle strap to the Lower 1 and Lower 2 regions. Photographs show A) unilateral locations of the Lower 1 and Lower 2 regions, B) unilateral compressed wrist-ankle strap, C) unilateral non-compressed wrist-ankle strap.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
TIMEPOINT	$-t_I$	0	5min	10min	t^*	30min
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Acupressure wrist-ankle strap group
Non-acupressure wrist-ankle strap group
ASSESSMENTS:						
VAS		X	X	X		X
The skin temperature		X			X	X
The pain threshold		X				X
Patients' expectation and satisfaction		X				X

* primary dysmenorrhea analgesic onset time

Figure 5

The schedule of enrolments, allocation and assessments.

Figure 6

Flow diagram of the proposed study.

Supplementary Files

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

- [SPIRITChecklist.docx](#)