Effects of Moving Cupping Therapy for Plaque Psoriasis: A Protocol for a Randomised Multicentre Clinical Trial

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Study protocol

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Abstract

ABSTRACT Background: The clinical treatment of plaque psoriasis is based on comprehensive therapy, which is expensive and unsatisfactory, and some of the drugs currently used have serious side effects. Moving cupping therapy has been used clinically for thousands of years in China and has the advantage of being inexpensive and easy to perform. It is now widely used in public hospitals in China for the treatment of psoriasis. However, at present, a comprehensive evaluation of the current clinical evidence regarding its use is lacking. This study aims to evaluate the efficacy and safety of moving cupping in the treatment of plaque psoriasis. Methods and analysis: A multicentre, two-arm parallel group, single-blind randomised controlled trial will be conducted in six academic and non-academic hospitals in China. A total of 110 adult patients (aged 18-65 years) who meet the inclusion criteria are now being recruited. Participants will receive (1) basic treatment combined with moving cupping therapy or (2) basic treatment combined with moving cupping placebo. The treatment cycle will be 4 weeks, and the treatment efficacy will be assessed weekly using the Psoriasis Area and Severity Index during the treatment period and the follow-up visits at weeks 6 and 8. The body surface area, physician's global assessment, Dermatology Life Quality Index, patient-reported quality of life, visual analogy scale, traditional Chinese medication syndrome scoring scale, combined medication, and adverse events will also be recorded and compared to the baseline values. Discussion: The results of this trial may help make better decisions in the treatment of plaque psoriasis. If the results are considered to be favorable, this ancient Chinese medicine therapy may be worthier of promotion because of its convenience and cheap advantages to benefit patients. Trial registration: This study has been registered at ClinicalTrials.gov under the identifier number NCT03952676. Registered on 15 May 2019.

Background

Psoriasis is a chronic inflammatory disease of the skin affecting approximately 2-3% of the global population. [1,2] Psoriasis is characterised by epidermal hyperproliferation, abnormal keratinocyte differentiation, angiogenesis with blood vessel dilatation, and excess T-helper cell type 1 (Th1) and type 17 (Th17) inflammation. [3] Plaque type is the most common form of psoriasis, accounting for 85-90% of psoriasis cases, [1] and leads to detrimental physical effects and reduced psychological wellbeing. [4,5] It is also closely related to metabolic syndrome and cardiovascular and chronic obstructive pulmonary disease. [6] For most patients, psoriasis results in decades-long restriction of various aspects of everyday life, issuing in enormous personal costs and mental stress. [7]

At present, the treatment of psoriasis consists primarily of local and systemic treatment. Local treatment mainly comprises hormonal drugs and calcineurin inhibitors, and systemic treatment comprises etretin, immunosuppressants, and biological agents. [8] The varying degrees of side effects and high economic costs limit the clinical application of these treatments. [9] Therefore, developing or identifying safe and effective treatments for psoriasis has broad social and economic benefits.

In recent years, complementary and alternative medicine (CAM) therapies have become an increasingly important area of dermatology. Cupping is becoming an important therapy in CAM. Cupping is an ancient method that has been used around the world. From ancient Egypt to the Han Dynasty in China, [10,11] from Hippocrates in Greece to the early Islamic period, [12,13] there are numerous descriptions of cupping treatments for various diseases. Cupping is also currently used to treat a wide range of medical conditions. There are two types of cupping methods: dry and wet. Moving cupping

therapy is a unique dry cupping therapy that has been used as a traditional treatment for thousands of years. This method involves the application of lubricant to the body part or to the mouth of the cup and using the flashing method or the cotton sticking method to adsorb the cup to the treatment area. The doctor pushes the cup by hand to move it up and down and left and right, causing flushing, congestion, and even ecchymosis of the skin at the treatment area. [14] Thus, moving cupping therapy integrates the functions of warm moxibustion, cupping, scraping, massage, and drug therapy, and it has a wide range of clinical applications. The warmth and negative pressure suction produced by this therapy can increase the permeability of blood vessels, expand the capillaries, and promote the phagocytic ability of white blood cells and reticulocytes, [15] thereby improving skin tolerance. In addition, the mechanical stimulation of pulling is beneficial to the secretion of sebaceous glands and sweat glands, and the use of lubricants can significantly improve skin barrier function. Psoriasis is also known to be closely related to mental factors. The warmth and negative pressure suction generated by moving cupping therapy can regulate the excitation and inhibition processes of the cerebral cortex via blood vessels and skin receptors, thereby resulting in balance. [16]

Although moving cupping therapy has been widely used in the treatment of plaque psoriasis and has been recognised by a large number of peers and patients, high-quality medical evidence is lacking. Therefore, the project team intends to provide supporting evidence for the efficacy and safety of moving cupping therapy for the treatment of plaque psoriasis through clinical studies.

Objectives and hypotheses

The main goal of the current randomised controlled trial (RCT) is to evaluate the efficacy of moving cupping in the treatment of plaque psoriasis. The main hypothesis is that the Psoriasis Area and Severity Index (PASI), used as the primary endpoint, will indicate that moving cupping treatment of plaque psoriasis has significant clinical efficacy compared to the placebo. The body surface area (BSA), physician's global assessment (PGA), traditional Chinese medicine syndrome scoring scale (TCMSSS), and patient-reported outcomes (Dermatology Life Quality Index [DLQI], patient-reported quality-of-life [PR-QoL], and visual analogy scale [VAS]) for the evaluation of post-treatment clinical efficacy, psychology, quality of life, and degree of pruritus will also be considered. This study complies with the relevant Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist (Supplementary File 1). [17]

Methods

Study design

The proposed study was designed as a prospective multicentre, two-arm parallel group, single-blind RCT with patients with plaque psoriasis randomly assigned to either the treatment group (moving cupping) or the placebo group (sham moving cupping). Eligible participants will receive 4 weeks of treatment and a total of 8 weeks of follow-up (Figure 1).

Patient and public involvement

Neither patients nor the public were involved in the design of the RCT.

Recruitment

We plan to recruit 110 patients with plaque psoriasis for the present study. Recruitment will take place in the Yueyang Hospital of Integrated Traditional Chinese and Western Medicine (Shanghai, China), Shaanxi Traditional Chinese Medicine Hospital (Shaanxi, China), First Affiliated Hospital of Heilongjiang University of Traditional Chinese Medicine (Heilongjiang, China), The Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine (Jiangxi, China), Hospital of Traditional Chinese Medicine, Xinjiang Medicine University (Xinjiang, China), and Shijiazhuang Hospital of Traditional Chinese Medicine (Shijiazhuang, China). Eligible recipients will be recruited via social media, word of mouth, and dermatology out-patient clinics at local hospitals. Patients who are willing to join the clinical trial will receive study information and consent forms. The consent forms must be signed before the patients are included in the study. Figure 1 presents a flowchart of participant enrolment and analysis through the course of the trial. All consent and/or assent will be obtained by the researchers prior to the recipients' participation in the trial. All potential and enrolled recipients' personal information will be recorded and kept in a secure folder and made accessible only to the researchers to protect their privacy.

Participant screening

All patients who are diagnosed with plaque psoriasis will undergo laboratory blood testing before inclusion, including a complete blood cell count, liver function test, renal function test, and pregnancy test. Additionally, routine urine tests, vital sign monitoring, and physical examination will be performed (Figure 2).

Criteria

Inclusion criteria

1. Meet the diagnostic criteria for plaque psoriasis; 2. Skin lesions involve ≤10% BSA (the lesions are mainly located on the torso/limbs, palm/sole, or face/scalp, with the vulva area being unaffected); 3. Aged 18-65 years; and 4. Provide consent to participate in the study and sign the informed consent form.

Exclusion criteria

1. Any clinically active skin diseases other than moderate to severe psoriasis vulgaris that might confound or influence the study aim; 2. Patients who received any systemic treatments within 4 weeks before the baseline visit (e.g. drugs for other studies, immuno-suppressive drugs, biologics); 3. Patients who received topical treatment within 2 weeks before the baseline visit (e.g. corticosteroids, ultraviolet-light therapy including sunbathing); 4. Patients with an active infectious disease that is difficult to control; 5. Patients with a history of severe systemic disease, an alanine aminotransferase or aspartate transaminase level greater than 1.5 times that of the average; any of the main routine blood indices (white blood cell count, red blood cell count, haemoglobin level, platelet count) lower

than the normal limit, or other laboratory abnormalities; 6. Family history of cancer-prone patients; 7. Immunocompromised patients who may experience skin allergies or infection with moving cupping therapy; 8. Pregnant or lactating women; 9. Patients with a history of alcohol or drug abuse; 10. Patients with a history or family history of serious mental illness.

Randomisation, allocation, and blinding

After obtaining informed consent, patients will be randomised in a 1:1 ratio to either the moving cupping group or the placebo group. To ensure allocation concealment, central randomisation will be applied, and the random allocation sequence will remain concealed from the recruiting dermatologist. Due to the nature of moving cupping, it is not possible to blind the operating doctor involved in applying the treatment. To ensure blinding, we will use a placebo-cup to simulate the treatment of moving cupping and shield the patient's eyes with a black opaque eye mask. The treatment device will be of the same size and material, and the treatment method will maintain a consistent treatment frequency and intensity, but with no adsorption force. The operating doctor will not participate in the statistical analysis, and the treatment plan and grouping will be known only by the statistical analyst.

Intervention

Moving cupping intervention

Cup: Transparent glass texture. Different types of cups will be selected according to the patient’s skin lesions and related conditions (Figure 3).

Standardised manipulations of moving cupping: (1) First, apply Vaseline to the skin lesion area. (2) Hold a 95% ethanol-soaked cotton ball with tweezers, and hold the cup with the face down. After the cotton ball is ignited, immediately move the ball down inside the cup and remove it, and then quickly place the cup on the skin lesion area. (3) After using the cup to absorb the skin lesion area, hold the cup body in one hand and push and pull the cup along the specified route while applying light force, such that the skin of the treatment area turns purple in colour. (4) Apply even force when pushing the cup to prevent the cup from falling off due to air leakage. (5) Repeat on the skin lesion area 30 times, changing the cup five times per push and pull, with an interval of no more than 10 s, once every other day for 4 weeks.

Moving cupping placebo

Take a special perforated cup, select the same material as the intervention group and use the same manipulation method. Because of the perforated design, the fire cannot burn the air in the cup, so it can't form a negative pressure adsorption force. Thus, it simulates the form of moving cupping therapy without the therapeutic effect of moving cupping (Figure 3).

Basic treatment

1. Increase moisturising of the skin: As a basic treatment, the use of a moisturiser at all times is a must. The moisturiser should mainly be applied to the skin areas that are free of erosion and exudation, as

well as the dry non-lesion areas. A soft, fragrance-free moisturiser should be used, and Yuze moisturiser will be recommended to patients for sensitive dry skin.

2. Standard bath: Generally, patients should rinse quickly with warm water (35–39 °C) for approximately 5 min, once per day. Moisturiser should be applied within 2 min of bathing to avoid dehydration of the epidermis. In addition, the use of alkaline detergents to clean the skin should be avoided.
3. Avoidance of induced and aggravated factors: Some patients may have food allergies. Once food allergies are identified, such foods should be avoided to prevent inducing or aggravating the condition.
4. Maintain a reasonably healthy lifestyle: Patients should avoid staying up late and becoming over-stressed. Spicy, irritating foods should be avoided, and appropriate exercise should be undertaken. Patients should try to maintain normal bowel movements.
5. Adherence to reasonable treatment: Doctors and patients should conduct full communication and establish good mutual trust. Patients should adhere to reasonable treatment and care to achieve long-term relief.

Measurement

Baseline measurement

Patient’s vital signs and disease severity will be monitored by means of physical examination, biochemical examination, and different evaluation indices before treatment. Data from the above measures will be used as baseline moving cupping therapy data.

Examination during the interview

Interview plan

All patients will be interviewed at weeks 1, 2, 3, and 4 during the treatment. During weeks 1, 2, 3, and 4 of treatment, the psoriatic lesions will be measured by the PASI, PGA, BSA, and TCMSSS, and self-evaluation using the DLQI, PR-QoL, and VAS will be used to assess quality of life, psychological status, and degree of pruritus, respectively. In addition, in weeks 6 and 8 of the follow-up period, the PASI, PGA, BSA, and VAS will be recorded again to evaluate the efficacy of moving cupping. Possible adverse events and combined medications should be accurately recorded at all of the above time points.

Examination during follow-up

Follow-up plan

All patients will be recalled for a follow-up session at weeks 6 and 8 after treatment. For each session, the treatment effects will be assessed using the PASI, PGA, BSA, and VAS.

Primary parameters

PASI: Incorporates the extent of psoriasis at four anatomic sites by evaluating signs of erythema, scale, and elevation. PASI scores range from 0 to 72. The primary outcome of the RCT is the proportion of patients with a ≥75% reduction in PASI scores compared to baseline at the 4-week follow-up visit. [18]

Secondary parameters

The secondary parameters of this study include the following:

1. PGA: The PGA is scored on a five-point scale, reflecting the overall degree of erythema, infiltration, and desquamation across all psoriatic lesions. [18]
2. BSA: The BSA involved in psoriasis is estimated by fingerprinting, wherein the entire palm of the patient represents approximately 1% of the total BSA. The number of handprints on psoriatic skin on a body part is used to determine the extent to which the body part is affected by psoriasis (%). [18]
3. DLQI: The DLQI is a participant-reported questionnaire used to measure the health-related quality of life of adults with skin diseases. Scores range from 0 to 30, with a higher score indicating a greater impact on the participant's quality of life. [19]
4. PR-QoL: The PR-QoL is used to assess the impact of psoriasis on an individual's social life. Scores range from 0 to 25, with a higher score indicating a greater impact on the participant's social life. [20]
5. VAS: The VAS is used to measure lesion pruritus from 0 to 100 mm at each visit (with 0 indicating no pruritus and 100 indicating maximum pruritus). [21]
6. TCMSSS: According to the different TCM syndromes of patients, comprehensive evaluation will be carried out from tongue-condition, pulse-condition, and skin, etc. [22]

Safety monitoring

All participants will be advised to remain under supervision in the clinical research unit for 15 min after treatment. In addition, participants' data will be monitored by the research team throughout the study for any adverse events, in particular, skin damage or potential allergies. All potential adverse events will be recorded. If any participant experiences an adverse effect as a result of trial participation, they will receive free treatment and compensation accordingly. If any concerns are identified during screening or clinical assessment of the participants, further clinical evaluation and/or investigation will be immediately undertaken. If concerns are identified during the study, the participant will be withdrawn if this is believed to be in their best interest.

Sample size

The sample size of the current trial was calculated based on the formula: $N = 4\ (Z_{\alpha/2} + Z_{\beta}\ )^2\ (\ )\ /\ (P_0–P_1\ )^2$. [23] The inspection level (α) was set at 0.05, the test power was 0.8, then 1-β=1-0.1=0.8. According to the clinical trial results and data analysis of recently published articles, [24] the study group PASI-50

reached 75%, the control group reached 35.3%, 42 participants will be required for each group. Given a loss to follow-up rate of approximately 30%, we expect to require 55 participants for each group. As a result, this trial will require at least 110 participants in its current setup.

Timeline

The recruitment began in August 2019, and the intervention period will end in December 2020. Figure 2 provides the study schedule of enrolment, intervention, and assessment.

Data collection and management

Including data records, data recording requirements, medical record review, data reporting, data monitoring, data inspection, and blinded method implementation audits are entrusted to the Nanjing Ningqi Medical Technology Co., Ltd. Data Management Centre.

Statistical analysis

1. Statistical analysis plan and statistical software: After the test plan is determined, the statistical professional will be responsible for formulating a statistical analysis plan in consultation with the main investigator. Analysis will be performed using SAS statistical software.
2. Data management and statistical analysis: Data management, selection of analytical data sets, statistical analysis content, and statistical analysis methods will be based on the data network platform designed by Nanjing Ningqi Medical Technology Co., Ltd. Data Management Centre and will be commissioned by the centre for third-party statistics. The measurer will be blinded to the results.

Missing data

The possibility of loss to follow-up was considered and calculated as a part of the study’s sample size estimation. In addition, we will account for other types of randomly missing data by treating dropouts as non-success or non-survival using the intention-to-treat principle.

Discussion

Psoriasis often requires multiple methods of combination therapy in the clinic, and even this does not achieve satisfactory results. People are therefore becoming increasingly concerned with current combinations of CAMs in modern medical practice. Cupping is a form of CAM that has existed for thousands of years in various civilisations around the world. It plays a unique role in various disease areas, including dermatology. Studies have found that cupping can lower the level of superoxide dismutase in the blood and that it plays a role in reducing oxidative stress. [25,26] Cupping can also significantly reduce the haemoglobin level in the cupping area and increase the level of oxyhaemoglobin. In addition, it can also increase HSP-70 and β-endorphins to relieve pain. [27] Although the mechanism of moving

cupping treatment of psoriasis is not clear, there are indications that moving cupping can alleviate plaque psoriatic skin inflammation and excessive thickening of skin lesions, and conventional treatment combined with moving cupping has a better curative effect. However, its true therapeutic effect still requires further, rigorous scientific verification.

At present, the clinical research on moving cupping treatment of psoriasis is only small-scale. The relevant RCT study did not adopt blinding methods, lacked placebo control, did not follow the consort statement, and was published in languages other than English. Therefore, large-sized RCTs are needed to truly assess the role and possible adverse outcomes of moving cupping in the treatment of plaque psoriasis.

This study will be the first placebo-controlled study of moving cupping in the treatment of plaque psoriasis with multiple centres, double-arm parallel groups, and a single-blind RCT. The study has several advantages. The first is that it will use a placebo control to exclude the placebo effect, reduce the risk of bias, and define the clinical efficacy of moving cupping in the treatment of plaque psoriasis. The second advantage is that because of the large land area of China, the study will include a total of six hospitals in different regions, covering different ethnic and socio-economic populations; as such, its experimental design will increase the generalisability of its trial outcomes. However, there are some limitations to this study. Due to the particularity of moving cupping therapy, it is difficult for different operators to maintain the same strength when moving the cup. In addition, since different cup sizes are selected for the different treatment sites, adsorption forces are also inconsistent. All of the above limitations may lead to the risk of bias. In conclusion, this study aims to verify whether moving cupping therapy is effective in the treatment of plaque psoriasis. We also hope to provide safe and effective treatment of plaque psoriasis through this study.

Trial Status

The protocol version number is 2.0 and the version date is May 15, 2019. The study plans to start recruiting participants in August 2019 and complete the recruitment in December 2020.

Abbreviations

PASI: Psoriasis Area and Severity Index

PGA: Physician’s global assessment

BSA: Body surface area

DLQI: Dermatology Life Quality Index

PR-QoL: Patient-reported quality-of-life

VAS: Visual analogue scale

TCMSSS: Traditional Chinese medicine syndrome scoring scale

RCT: Randomised controlled trial

Declarations

- **Ethics approval and consent to participate**

  Central ethical approval has been confirmed from the Yueyang Hospital of Integrated Traditional Chinese and Western Medicine (ref approval no. 2019-003) and we will not begin recruiting at other centres in the trial until local ethical approval has been obtained. Informed consent will be obtained from all participants before study initiation.

- **Consent for publication**

  Not applicable.

- **Availability of data and material**

  We declared that materials described in the manuscript, including all relevant raw data, will be freely available to any scientist wishing to use them for non-commercial purposes, without breaching participant confidentiality.

- **Competing interests**

  None declared.

- **Funding**

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- **Authors' contributions**

  MX and XL conceived of the study, while XY, YL, XY, LL, and HL designed the study. The study protocol was drafted by MX and XL and was revised by BL. SY, LL, LG, HL, RX, JC, LY, YZ, YY, LH will implement the study. All authors approved the final manuscript of this study protocol.

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  None

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Figures

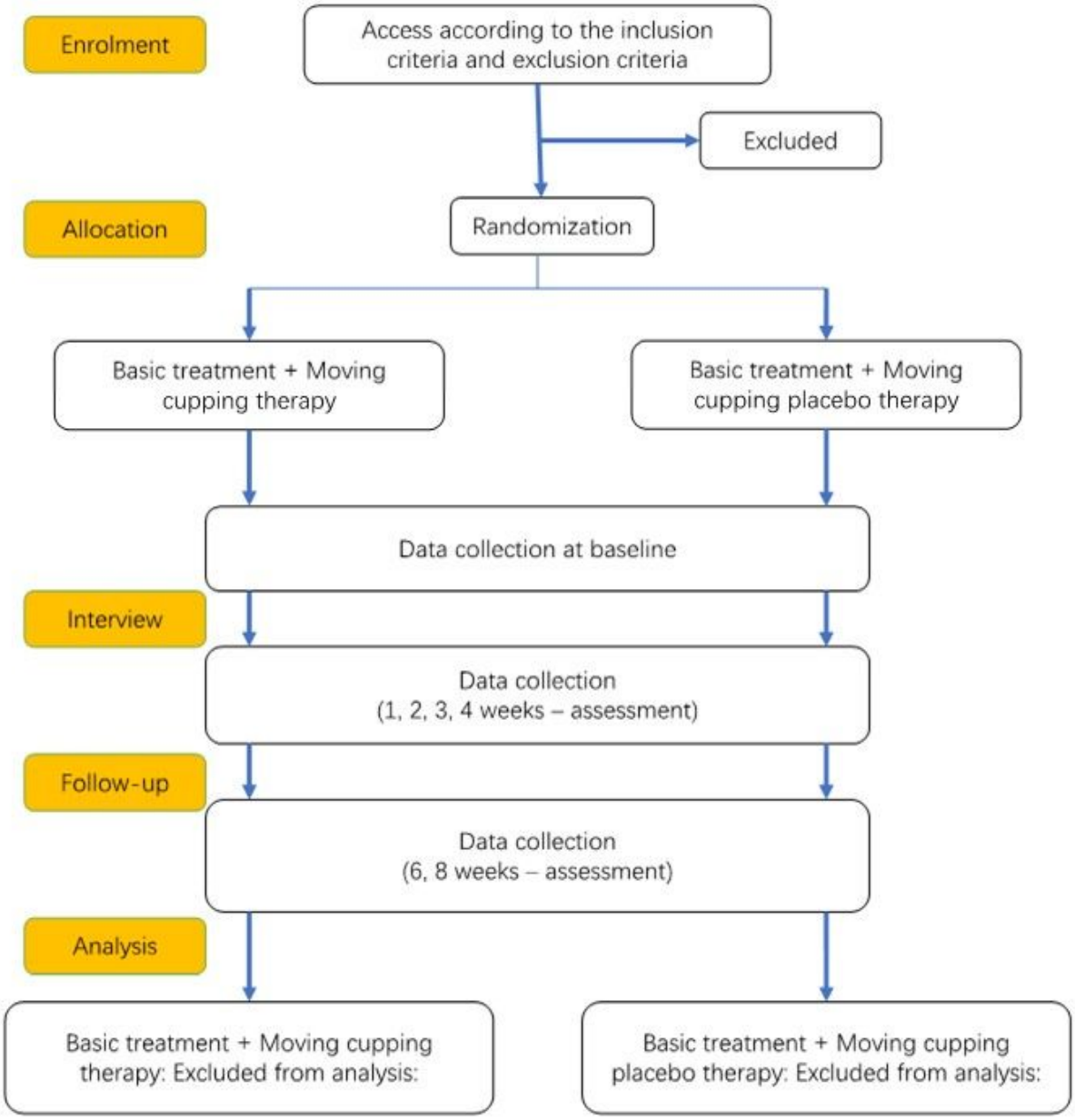

Figure 1

Consolidated Standards of Reporting Trials diagram of participant enrolment and analysis

	Study Period							
	Enrolment	Allocation	Treatment period				Follow-up period	
Time point	$-t_1$	0	t_1	t_2	t_3	t_4	t_5	t_6
Enrolment:								
Eligibility screen	×							
Informed consent	×							
[List other procedures]	×							
Allocation		×						
Interventions:								
Basic treatment+moving cupping therapy								
Basic treatment+moving cupping placebo								
Assessments:								
PASI	×	×	×	×	×	×	×	×
BSA	×	×	×	×	×	×	×	×
PGA	×	×	×	×	×	×	×	×
DLQI		×	×	×	×	×		
PR-QoL		×	×	×	×	×		
VAS		×	×	×	×	×	×	×
TCMSSS		×	×	×	×	×		
Vital signs	×	×	×	×	×	×		
Routine blood test	×					×		
Blood biochemical test	×					×		
Routine urine test	×					×		
Combined medication	×	×	×	×	×	×		
Pregnancy tests	×							
Physical examination	×					×		
Adverse event		×	×	×	×	×		
Serious adverse events		×	×	×	×	×		

Figure 2

Study schedules of enrolment, intervention, and assessment PASI, Psoriasis Area and Severity Index; PGA, physician's global assessment; BSA, body surface area; DLQI, Dermatology Life Quality Index; PR-QoL, patient-reported quality-of-life; VAS, visual analogue scale; TCMSSS, traditional Chinese medicine syndrome scoring scale.

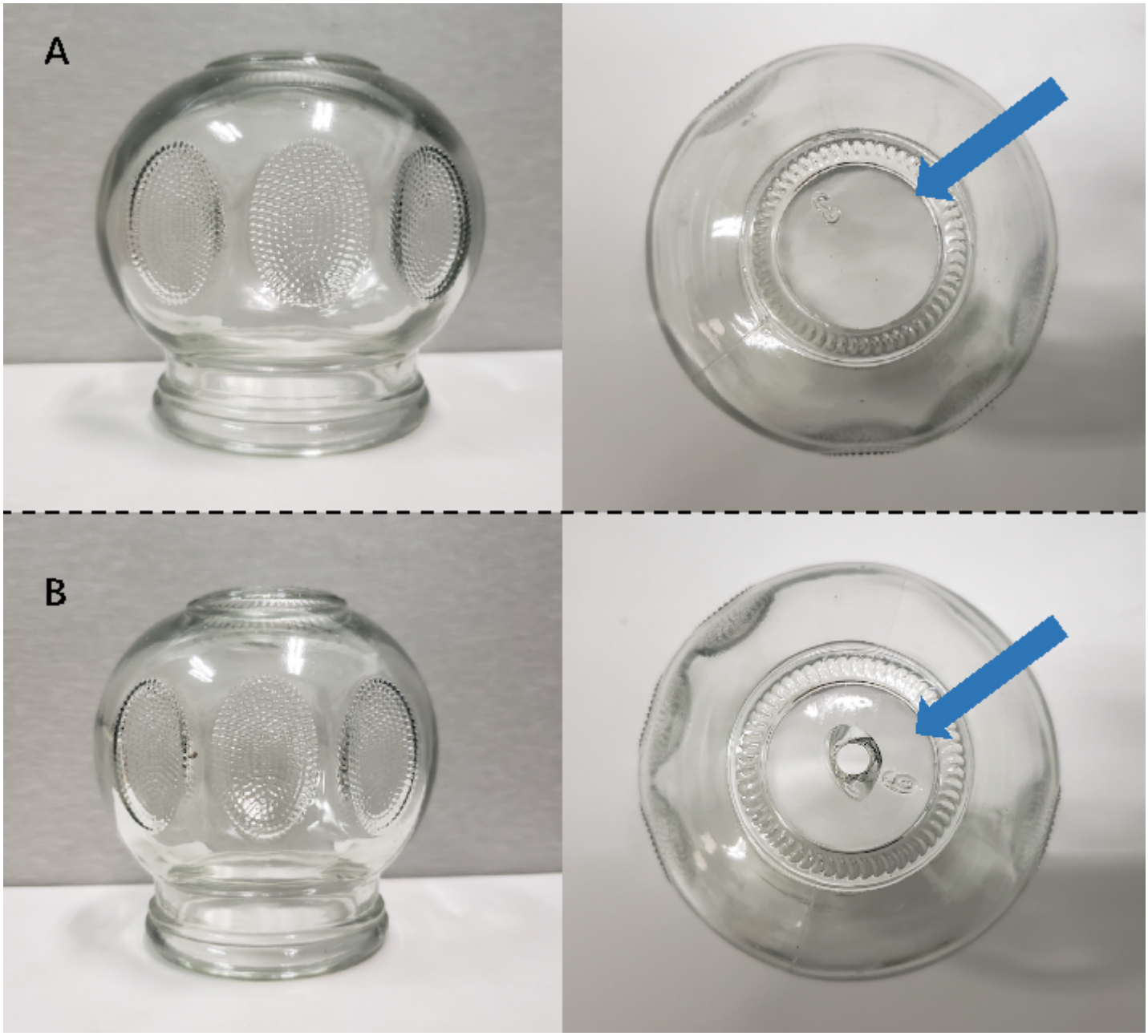

Figure 3

Different cups used in the intervention group and the control group when implementing moving cupping therapy A: Cups used in the intervention group can produce negative pressure adsorption force when the air in the cup is burned out; B: The cup used in the placebo group has a special perforation design, and no negative pressure adsorption was formed after combustion.

Supplementary Files

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