• Methodology

Extending the CONSORT Statement to moxibustion

Chung-wah Cheng[1], Shu-fei Fu[1], Qing-hui Zhou[2], Tai-xiang Wu[3], Hong-cai Shang[4], Xu-dong Tang[5], Zhi-shun Liu[6], Jia Liu[6], Zhi-xiu Lin[7], Lixing Lao[8], Ai-ping Lü[1,9], Bo-li Zhang[10], Bao-yan Liu[11], Zhao-xiang Bian[1]

1. School of Chinese Medicine, Hong Kong Baptist University, Hong Kong SAR, China
2. Changhai Hospital of Traditional Chinese Medicine, Secondary Military Medical University, Shanghai 200433, China
3. Chinese Evidence-based Medicine Center, Chengdu 610041, China
4. Evidence-based Medicine Certer, Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China
5. Department of Gastroenterology, Xiyuan Hospital, China Academy of Chinese Medical Sciences, Beijing 100091, China
6. Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China
7. School of Chinese Medicine, the Chinese University of Hong Kong, Hong Kong SAR, China
8. Center for Integrative Medicine, University of Maryland School of Medicine, Baltimore, MD 21207, USA
9. Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing 100700, China
10. Academy of TCM, Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China
11. Clinial Evaluation Center, China Academy of Chinese Medical Sciences, Beijing 100091, China

ABSTRACT: The STandards for Reporting Interventions in Clinical Trials Of Moxibustion (STRICTOM), in the form of a checklist and descriptions of checklist items, were designed to improve reporting of moxibustion trials, and thereby facilitating their interpretation and replication. The STRICTOM checklist included 7 items and 16 sub-items. These set out reporting guidelines for the moxibustion rationale, details of moxibustion, treatment regimen, other components of treatment, treatment provider background, control and comparator interventions, and precaution measures. In addition, there were descriptions of each item and examples of good reporting. It is intended that the STRICTOM can be used in conjunction with the main CONSORT Statement, extensions for nonpharmacologic treatment and pragmatic trials, and thereby raise the quality of reporting of clinical trials of moxibustion. Further comments will be solicited from the experts of the CONSORT Group, the STRICTA Group, acupuncture and moxibustion societies, and clinical trial authors for optimizing the STRICTOM.

KEYWORDS: moxibustion; randomized controlled trials; guidelines

DOI: 10.3736/jintegrmed2013009
Cheng CW, Fu SF, Zhou QH, Wu TX, Shang HC, Tang XD, Liu ZS, Liu J, Lin ZX, Lao L, Lü AP, Zhang BL, Liu BY, Bian ZX. Extending the CONSORT Statement to moxibustion. *J Integr Med*. 2013; 11(1): 54-63.
Received December 5, 2012; accepted December 19, 2012.

Correspondence: Zhao-xiang Bian, MD, PhD, Professor; Tel: +852-34112905; E-mail: bzxiang@hkbu.edu.hk. Bao-yan Liu, MD, Professor; Tel: +86-10-6401444-2401; E-mail: liuby@cintcm.ac.cn

1 Introduction

Moxibustion is a traditional therapeutic remedy by utilizing cauterization or heating with ignited flammable material applied to acupoints[1]. With the functions of warming the meridians, relieving the obstruction of collateral vessels, and regulating the zang-fu organs, it has been used to treat and prevent diseases for more than 2 500 years[2-4]. To date, there are different types

of moxibustion regarding to the materials used and procedures executed. Mugwort leaves (*Artemisia vulgaris*, moxa) are the most commonly used in moxibustion which are purified and prepared into fine and soft moxa floss. Moxa can be also combined with other herbs to form moxa cone and moxa stick. Direct moxibustion is for those ignited materials which are put directly on the skin, while indirect moxibustion is for those ignited materials which are suspended over the skin or put over a medium, such as ginger, garlic, salt, monkshood cake and paper. Besides, some forms of moxibustion are implemented by using special designated apparatuses, such as moxa burner moxibustion and electro-moxibustion. Natural moxibustion (Tianjiu) is another form of moxibustion in which irritant herbal patches are applied on acupoints every Geng Day after summer solstice (Sanfu Tianjiu) or every nine days after winter solstice (Sanjiu Tianjiu) three times consecutively according to the lunar calendar[2-4].

Recently, there is an increasing number of studies about the theory, underlying mechanism and clinical application on moxibustion, from basic research to clinical trials. Laboratory studies suggest that moxibustion has anti-inflammatory, anti-free radical, hypolipidemic, immunomodulatory, antiaging, antidepressant and anti-precancer effects, and effects of promoting blood circulation and enhancing the functions of internal organs[5]. However, its effectiveness cannot be fully elucidated from current available clinical evidence. According to a current review of 47 randomized controlled trials (RCTs) on moxibustion in PubMed between January 1998 and July 2008, definite clinical recommendation could not be made in specific diseases due to the limited number and low quality of the studies, and inadequate use of controls[6]. From another study of Lee *et al*[1] overviewing 10 systematic reviews on moxibustion, effectiveness had been demonstrated for breech presentation, supportive cancer care, stroke rehabilitation and pain conditions; however, there remained considerable uncertainty due to the poor quality of the primary studies.

The Consolidated Standards of Reporting Trials (CONSORT) Statement represents a comprehensive guideline for reporting the details of RCTs and is also associated with the improvement of trial design and implementation[7]. To cover various reporting requirement for different types of trials and interventions, several extensions and elaborations have been made from the first publication in 1996[8], such as reporting of harms[9], herbal interventions[10], non-pharmacological treatment[11], traditional Chinese medicine (TCM) interventions[12], non-inferiority and equivalence trials[13] and pragmatic trials[14]. The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) is also newly revised as an official extension of CONSORT in 2010[15]. We believe that a proper guideline is important for improving the overall quality of clinical trials on moxibustion. As there are some moxibustion-specific items not covered by the available CONSORT Statement, we have prepared a checklist of information to include when reporting interventions in a clinical trial of moxibustion by reference to that of STRICTA (Table 1). After that, comments will be solicited from the experts of the CONSORT Group, the STRICTA Group, acupuncture and moxibustion societies, and clinical trial authors. We hope that this extension of CONSORT for moxibustion can be widely disseminated and further optimized in future.

2 Methods

Authors had first thoroughly reviewed the clinical trials on moxibustion and nominated items of CONSORT and STRICTA checklists which needed to be modified on the basis of the specificities of moxibustion. Cheng CW and Bian ZX summarized the comments from the working group and edited for the draft of STandard for Reporting Interventions in Clinical Trials Of Moxibustion (STRICTOM). The working group then devoted an extensive discussion about the modifications and the descriptions of each item. After four rounds of circulation, the STRICTOM checklist was finalized.

3 Results

There was an agreement that the extension to moxibustion should be presented as a supplementary checklist with reference to that of STRICTA and could also be embedded within the two-group parallel trial CONSORT checklist[7], extensions for non-pharmacological treatment[11] and pragmatic trials[14]. The proposed checklist comprised 7 items broken out into 16 sub-items. The checklist texts for each of the items and their sub-items, together with descriptions and the examples of good reporting from the published literature were listed below.

Note: The examples which were quoted directly from the original studies were embedded with quotation marks, while limited editing was allowed for those examples without quotation marks. Furthermore, the references that were reported in the original published studies were not provided in this article for reasons of brevity.

STRICTOM Item 1: Moxibustion rationale

Item 1a

Type of moxibustion (e.g., direct moxibustion, indirect moxibustion, heat-sensitive moxibustion, moxa burner moxibustion, natural moxibustion).

Description

There are different types of moxibustion regarding to

Table 1 Checklist of information to include when reporting intervention in a clinical trial of moxibustion

No	Item	Detail
1	Moxibustion rationale	1a) Type of moxibustion (e.g., direct moxibustion, indirect moxibustion, heat-sensitive moxibustion, moxa burner moxibustion, natural moxibustion)
		1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate
		1c) Extent to which treatment was varied
2	Details of moxibustion	2a) Materials used for moxibustion (e.g., moxa floss, moxa cone, moxa stick, herbal patches, and their sizes and manufacturers)
		2b) Names of acupoints (or location if no standard name) for moxibustion (uni/bilateral)
		2c) Number of moxibustion units and/or moxibustion time per point (mean and range where relevant)
		2d) Procedure and technique for moxibustion (e.g., direct/indirect, warming/sparrow-pecking technique, warming needle, moxa box, heat-sensitive moxibustion)
		2e) Responses sought (e.g., warm feeling, skin reddening, burning pain, heat-sensitization phenomenon)
		2f) Patient posture and treatment environment
3	Treatment regimen	3) Number, frequency and duration of treatment sessions
4	Other components of treatment	4a) Details of other interventions administered to the moxibustion group (e.g., acupuncture, cupping, herbs, exercises, lifestyle advice)
		4b) Setting and context of treatment protocol, and information and explanations to patients
5	Treatment provider background	5) Description of treatment provider (qualification or professional affiliation, years in moxibustion practice and other relevant experience for professional, or any special training in advance for layman)
6	Control and comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify the choice
		6b) Precise description of the control or comparator. If another form of moxibustion or moxibustion-like control is used, provide details as for Items 1 to 3 above
7	Precaution measures	7) Precise description of the precaution measures, if any

the materials used and the details of procedures. Researchers should state the overall style and approach on which they have based the treatments. For classification based on materials used, whether moxibustion with moxa floss, moxa cone or other medicinal herbs should be clearly stated. For moxibustion not directly applied on the skin (indirect moxibustion), whether materials are ignited and suspended over the skin or put over a medium, such as ginger, garlic, salt, monkshood cake, paper, moxa tube and moxa burner, should be given. For classification based on the degree of responsiveness sought, whether gentle moxibustion or scarring moxibustion should be declared. If the treatment material or procedure is newly established by the researcher, this should be clearly mentioned.

Examples

(1) Every subject received both the two kinds of heat stimulation therapies, i.e., electrothermal Bian-stone moxibustion and traditional box-moxibustion at Guanyuan (CV6) and Qihai (CV4) on hypogastrium, with an interval of one day between the two methods (keeping away from the menstrual period)[16].

(2) "The procedure is to suspend the ignited moxa roll over the acupoint for 10 to 15 min until there is local skin blush, but no pain[17]."

(3) "Sanfujiu is a method of applying Chinese herbal medicine paste onto selected acupoints during the three hottest days (or dog days) of the summer[18]."

Item 1b

Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate.

Description

The underlying rationales for the chosen treatment

should be provided. For treatment based on traditional practice, the historical context should be supplied. Where consensus methods, expert clinical panels, practitioner surveys or some combination of sources have been used to define the treatment protocol, full details of the methodology with relevant literature and/or other sources should be given. For fully individualized trials as practitioners normally do, it is appropriate to specify the qualification of practitioners and provide details of how they provide treatment. Generally, references should have been published and are easy to obtain. If the reference is not a published work or only available in language different from the journal article, further information should be provided as an appendix or supplementary summary.

Examples

(1) "In Chinese traditional medicine, the stimulation of acupuncture point number 67 of the bladder meridian (acupoint BL67), located on the outer corner of the fifth toe, is recommended to favor cephalic version in the case of breech presentation[19]."

(2) All moxibustion treatments were applied to acupuncture points at bilateral ST23 (Taiyi) and ST27 (Daju), as those sites were included in the Stomach Meridian of Foot Yangmyeong (Korean, equivalent to the Chinese pinyin "Yangming") and have been shown to improve gastrointestinal function such as dyspepsia, abdominal pain and constipation. Four oriental medical doctors, each having a national license and practical experience of more than five years, selected the acupuncture points, frequency of moxibustion, number of sessions through consensus among them after reviewing the major textbook of acupuncture and moxibustion[20].

Item 1c

Extent to which treatment was varied.

Description

The extent to which the treatment is varied, if any, should be described. Basically, variations may include the point or treatment area selected, number of treatment sessions, number of moxibustion units per point and responsiveness sought, ranging from standardized treatment, partially individualized treatment, to fully individualized treatment. The underlying rationale of such study design should also be clearly stated.

Examples

(1) The therapists began to treat patients from the acupoint with the most heat-sensitive intensity. Treatment sessions ended when patients felt that the acupoint heat-sensitization phenomenon disappeared. Generally speaking, we found the time range from 30 to 60 min[21].

(2) "The points selected in both groups were as follows. Main points: Zhongwan (RN12), Qihai (RN6), Tianshu (ST25, bilateral), and Zusanli (ST36, bilateral); auxiliary points: Dachangshu (BL25, bilateral) and Shuifen (RN9) for the type of accumulation of damp-heat, Taichong (LR3, bilateral) and Pishu (BL20, bilateral) for the type of stagnancy of the liver-qi and deficiency of the spleen, Shenshu (BL23, bilateral) and Guanyuan (RN4) for the type of deficiency of the spleen-yang and the kidney-yang. The other points for the different symptoms were selected[22]."

STRICTOM Item 2: Details of moxibustion

Item 2a

Materials used for moxibustion (e.g., moxa floss, moxa cone, moxa stick, herbal patches, and their sizes and manufacturers).

Description

The most ordinary moxibustion materials include moxa floss (white, soft, cotton-like fibers prepared from moxa leaves), moxa cone (cone-like shape made of moxa wool and commonly with three different sizes) and moxa stick (strick wrapping moxa floss and some other herbs, such as *Cortex Cinnamomi*, *Rhizoma Zingiberis* and *Flos Caryophylli*, in a piece of paper)[4]. Details should be given of the types of moxibustion materials used, including the size (e.g., diameter and length), quality as well as the product name and manufacturer, if applicable. For indirect moxibustion, the insulating material, including ginger, garlic, salt, monkshood cake, medicinal herbs and paper, between the moxa and the skin, or special apparatuses, including moxa burner, should be clearly described. For special form of moxibustion using herbs other than moxa (e.g., natural moxibustion—Tianjiu), the formula, dosage of each ingredients and the processing method should be fully reported.

Examples

(1) The herbal regimen employed in the experimental group was according to *Zhang Shi Yi Tong* (*Comprehensive Medicine According to Master Zhang*) and included five herbs. The four herbs (*Sinapis Semen, Corydalis Rhizoma, Euphorbiae Kansui Radix and Asari Herba Cum Radice*) were ground into powder (mesh aperture number 80, Japanese standard 0.175 mm aperture sieve), and mixed thoroughly at the ratio of 7∶7∶4∶4, and the mixed powder was later mixed with fresh ginger juice in the ratio of 22 g to 30 mL before use[23].

(2) "One moxa corn (3.5 g of wormwood fiber on top of salt basement inside a bamboo container; 30 mm in diameter; 40 mm in length; KyeGoo Inc., Incheon, Korea) was burned in each 30-minute session[24]."

Item 2b

Names of acupoints (or location if no standard name) for moxibustion (uni/bilateral).

Description

The name and number of acupoints/locations (if no standard name) should be described as accurate as

possible. Accepted nomenclature should be used for standardized acupoints, while anatomical location should be used for specific location where there is no accepted name. Whether moxibustion is carried out unilaterally or bilaterally should also be stated. A total of acupoints with moxibustion per subject per session should be reported as much information given as possible. For individualized treatment, authors should consider the best way to report the points used, for example, by listing all the acupoints, identifying the most commonly used acupoints if the list is extensive, and/or reporting the mean and range of the numbers of acupoints used across all subjects.

Examples

(1) For the heat-sensitive moxibustion group, the moxa sticks are lit by the therapist and held over the rectangle area which consists of two outer lateral lines of dorsal Bladder Meridian of Foot-Taiyang, and two horizontal lines of BL13 (Feishu) and BL17 (Geshu), 6 inches outer from the first and second rib gap of anterior chest[21].

(2) "All moxibustion treatments were applied to acupuncture points at bilateral ST23 (Taiyi) and ST27 (Daju)[20]."

Item 2c

Number of moxibustion units and/or moxibustion time per point (mean and range where relevant).

Description

A total number of moxibustion units per acupoint should be reported as much information given as possible. If the regimen is measured by time, the moxibustion time per acupoint should be provided instead. It can be from lighting up of moxa to the removal of moxa, putting on and removal of herbal patches or the time elapsed for having electro-moxibustion. For individualized treatment, the mean and range of the numbers of moxibustion units per acupoint across all subjects should be reported instead.

Examples

(1) For the mild subjects, one moxa cone was used for every point, while for the severe ones, two moxa cones were used[22].

(2) "The smoldering stick was placed close to the BL67 acupoint, next to the outer corner of the fifth toenail, for a total of 20 min (10 min on each side)[19]."

Item 2d

Procedure and technique for moxibustion (e.g., direct/indirect, warming/sparrow-pecking technique, warming needle, moxa box, heat-sensitive moxibustion).

Description

The procedure for delivering moxibustion should be described with details in advance. How the moxibustion materials are placed, for example, putting directly on the skin (direct moxibustion), putting over a medium or suspending over the skin (indirect moxibustion) should be reported. If special techniques are applied, for example, warming technique (moxa stick is put over the acupoints), sparrow-pecking technique (moxa stick is moved up and down over the skin), warming needle (moxa wool is placed on top of the needle handle), moxa box (a special box-like container with burning moxa inside), and heat-sensitive moxibustion (moxibustion on heat-sensitive acupoints), precise details of the treatment provided are also necessary.

Examples

(1) Point stimulation involved a burning, cigar-shaped moxa pole held approximately 1 inch over the acupuncture points. The moxa pole was moved in a clockwise circular motion directly over each point, stimulating each for a period of 2 min or until the skin around the area of the point became pink[25].

(2) Cotton-sheet moxibustion: After routine sterilization with active iodine, an absorbent cotton sheet (without holes, 30 mm × 30 mm, 0.1 mm thick, and weighing about 20 mg) was applied to point Ah Shih and ignited using a match. As the cotton rapidly burned, the patients experienced only a slight burning sensation[26].

(3) The warming-suspended moxibustion about distance of 3 cm is used to search for the acupoint heat-sensitization phenomenon. The following patient sensations will suggest the special heat-sensitization acupoint: diathermanous sensation due to moxa heat, defined as the heat sensation conducting from the local skin surface into deep tissue; expanding heat sensation due to moxa heat, defined as the heat sensation spreading to the surrounding little by little around the moxa point; transferring heat sensation due to moxa heat, defined as the heat sensation transferring along some pathways or directions. When at least one of the below sensations exists at the acupoint, therapist marks the point as a heat-sensitive acupoint[27].

Item 2e

Responses sought (e.g., warm feeling, skin reddening, burning pain, heat-sensitization phenomenon).

Description

The intensity of stimulation sought should be described, for example, gentle moxibustion of which patients feel warmth without any burning pain and local area turns red. If the study protocol requires eliciting special sensation (e.g., heat-sensitive moxibustion) or forming of scars (scaring moxibustion), the procedure should be reported.

Examples

(1) "The woman (patient) was asked for her perception of heat to adapt the distance between the moxa stick and the skin. The technique requires a sensation of intense heat but no painful burning[19]."

(2) "The therapists begin to treat patients from the most heat-sensitive intensity acupoint. Treatment sessions end when patients feel the acupoint heat-sensitization phe-

nomenon has disappeared[27].”

Item 2f

Patient posture and treatment environment.

Description

The posture of patient should be comfortable, natural and well fit to the needs of moxibustion. As moxibustion with the therapeutic components of heat (burning pain and heat stress), tar (extract), aroma (fume) and psychological stress[6], the environment may also be a factor to provide a standard treatment. If both front and back points are used, the posture of the patient of both sides of the treatment should be described. Whether the treatment is provided in clinics or at patients' home should also be clarified. Therefore, the details of patient posture and treatment environment should be reported for ensuring the repeatability of results.

Examples

(1) “Participants were asked to remove clothing from their upper bodies, lie on a table in a prone position and then rest for 10 min[28].”

(2) “The patient adopted a lying position to fully expose point Ah Shih[26].”

(3) The patient is usually in the comfortable supine position for treatment, with 24 to 30 ℃ temperature in the room. He should be wearing loose trousers, especially making his knee joints exposed[29].

STRICTOM Item 3: Treatment regimen

Item 3

Number, frequency and duration of treatment sessions.

Description

The planned number of sessions, frequency and durations of each treatment and the length of the entire treatment should be documented in the Methods section while the actual number of treatments patients received should be reported in the Results section. If there are variations between patients, the mean and range of number of sessions, frequency and durations of treatment across all subjects should be reported in Results section instead.

Examples

(1) Four weeks of treatment were given, with four treatments per week during the first two weeks and three treatments per week thereafter[30].

(2) All patients received 72 acupuncture sessions of 30 min each over a period of 13 weeks (the treatment was given once daily, 12 treatments constituting a therapeutic course with an interval of 3 d between each two courses, and after six courses of treatment, the results were analyzed)[22].

STRICTOM Item 4: Other components of treatment

Item 4a

Details of other interventions administered to the moxibustion group (e.g., acupuncture, cupping, herbs, exercises, lifestyle advice).

Description

It is common that moxibustion is integral or adjunctive to other treatments, such as having suspended moxibustion and acupuncture simultaneously or placing an ignited moxa stick on the handle of needles after insertion (warm needling). Any additional components on the moxibustion group including acupuncture, cupping, herbs, exercises or lifestyle advice, whether carried out by the practitioner or the patient, should be described clearly. If corresponding reporting standards are available, such as STRICTA for acupuncture, CONSORT for TCM or herbal interventions, the details of other interventions should be fully reported according to those checklist items. Besides, the frequency with which these interventions are given, and patients' compliance with these interventions, should also be mentioned.

Examples

(1) The comprehensive therapy of acupuncture-moxibustion and Chinese Tuina was adopted, with acupuncture applied first, followed by Chinese Tuina, once daily. A) The acupuncture-moxibstuion method: The points selected were ……, during which the needles were manipulated once. Moxibustion was added for points Xinshu (BL15) and Pishu (BL20). The moxibustion was operated like this: Upon the arrival of qi, a 2-cm moxa stick was put on the needle handle and burned. When the burning of moxa stick finished, the ash was cleaned and the needle taken out. B) The Chinese Tuina method: The patient was asked to take the sitting position …… 6 d constituting one therapeutic course, with a 2-day interval between courses[31].

(2) For a study of insomnia, the patient for the treatment group was asked to be in a good humor and moderate exercise[32].

Item 4b

Setting and context of treatment protocol, and information and explanations to patients.

Description

Studies on moxibustion may favor design choices that maximize applicability of the trial's results to usual care settings, rely on unarguably important outcomes such as mortality and severe morbidity, and include a wide range of participants[14]. Therefore, special instructions to practitioners and information about the trial to patients might be expected to modify outcomes. Hence, the setting and context of treatment can provide important additional components and should be clearly reported.

Examples

(1) “The pregnant women will be informed as follows: If you decide to take part in the study, in addition to being

given various postural recommendations, you will be included, at random, in one of the three treatment groups. In two of these, moxibustion techniques will be applied at a specific point on each foot, while in the third group the standard treatment procedures followed in the healthcare system will be applied, to see if spontaneous correction occurs. If you are assigned to one of the two groups in which moxibustion is applied, then, according to the random choice made, you may be given moxibustion at a point that has been proved to be effect, or on the contrary, at a point that has not proved to be of any value for the aims of our study[33]."

(2) "Every subject then met with a diagnostic acupuncturist (DA) for a TCM diagnosis and individual point prescription. The study facilitator (SF) collected point prescriptions for both experimental and control subjects but gave the point prescriptions for only experimental subjects to the treating acupuncturist (TA)[25]."

STRICTOM Item 5: Treatment provider background Item 5

Description of treatment provider (qualification or professional affiliation, years in moxibustion practice and other relevant experience for professional, or any special training in advance for layman).

Description

Characteristics of the professional practitioners providing treatment should be reported, including qualification or affiliation, years in moxibustion practice, as well as any other experience that may be relevant to the trial. For multicenter studies, the measures, if any, used to standardize treatment procedures between practitioners in different centers should be reported. If the treatment is provided by laymen or patients themselves, authors should provide the details of any training in advance or any other measures used for standardizing the treatment regimens.

Examples

(1) "The intervention was performed by two midwives trained in acupuncture using moxa (the Japanese name for mugwort) sticks made from *Artemisia vulgaris* (Suzhou Shenlong Medical Apparatus Factory, Suzhou, China) that burn without smoke. We consulted with two acupuncturists and decided to increase the frequency of the intervention, asking women to perform moxibustion at home in addition to the hospital sessions. During the first session, women were trained by the midwife to perform the intervention at home on the days they did not receive it at the hospital. We also provided women with a leaflet explaining the technique to facilitate their partners' helping performing the sessions[19]."

(2) Moxibustion will be performed by certified acupuncture medical doctors at four centers. Qualified specialists of acupuncture in TCM with at least five years of clinical experience will perform the acupuncture in this study. All treatment regimens will be standardized between practitioners from the four centers via video, hand-on training and Internet workshops[29].

STRICTOM Item 6: Control and comparator interventions Item 6a

Rationale for the control or comparator in the context of the research question, with sources that justify the choice.

Description

The rationale for selection of control or comparator (e.g., placebo, usual care, different moxibustion regimens, active treatments, a waiting list, no treatment) should be presented and justified in relation to the research question and the methodology. If moxibustion-like placebo control (sham moxibustion) is used, whether it is burning away from traditional location or whether insulation is added below the moxa should be identified. Where co-interventions, including active interventions and usual care, are provided in both the moxibustion group and control group, the underlying rationales of those study designs should be justified. Sources that led to the choice, such as literature, expert opinion or prior work, should also be supplied and referenced.

Examples

(1) "Sham treatment was given by adding insulation below the moxa pillar to prevent the transfer of heat from the moxa pillar to the patient. The sham treatment looks similar to the real moxibustion treatment in its appearance and burning procedure; therefore, participants were able to smell the smoke or observe the burning moxa. The validity of this method was well established as blinded to the participants in a previous study[20]."

(2) Intra-articular hyaluronan (HA) or hylan is popular approved treatment for knee osteoarthritis (KOA). A number of systematic reviews have shown positive evidence on the efficacy and safety of intra-articular HA for KOA. For example, a recent review has showed that HA is an effective, safe, and tolerable treatment for symptomatic KOA. Therefore, this protocol selected Sodium Hyaluronate Injection Intra-articular as the conventional drug[29].

Item 6b

Precise description of the control or comparator. If another form of moxibustion or moxibustion-like control is used, provide details as for Items 1 to 3 above.

Description

A precise description of the components of the control or comparator should be presented. If corresponding reporting standards are available, such as CONSORT for pharmacologic treatment, STRICTA for acupuncture, CONSORT for TCM or for herbal interventions, the details of the active comparator should be fully reported

according to those checklist items. Where co-interventions are provided to both the experimental and control groups, how patients in different groups are treated should be reported in full detail. If the control treatment is another form of moxibustion or moxibustion-like control, it should be specified in the same way as stated in Items 1, 2 and 3 above. If it is a waiting list or no treatment arm, the setting of the treatment protocol and the information to patients might be expected to modify outcomes. Therefore, the information about the period of waiting or whether the patients will receive further treatment after the study needs to be provided.

Examples

(1) "Patients in the control group were given, in addition, the gastro-intestinal mucomembranous protector montmorillonite (trade name: Smecta; product of Tianjin Bofu-Yipusheng Pharmaceutical Co., Ltd., batch No. T0169, 3 g/packet), at a dosage of three times daily, 1-1.5 g for children below 1 year old and 1.5-2.0 g for 1-2 years old, with the dose doubled at the first intake of medication. The drug was mixed in warm water and administered orally[34]."

(2) Placebo moxibustion was performed by holding the burning moxa pole approximately 8 inches above and 2-3 cm away from traditional location for a period of 2 min. Special and meticulous attention was made on the part of the acupuncturist to not generate a heat sensation. Both true treatment and sham/placebo sessions were identical in duration. Those assigned to the sham/placebo group were offered true treatment at the end of the study at no charge[25].

(3) "Patients were treated conventionally, including fluid supplementation, water-electrolyte and acid-base disturbance correction, and other expectant treatments[34]."

STRICTOM Item 7: Precaution measures

Item 7

Precise description of the precaution measures, if any.

Description

As moxibustion produces heat, tar and aroma, it may increase the risk of adverse events such as burning, coughing and allergies relevant to the ingredients included in moxa pillar[35]. These adverse events directly affect the compliance of patients and also the rate of drop-out. Therefore, the precaution measures, if any, should be reported as full details, while all important harms or unintended effect should be reported according to the Item 19 Harms of the CONSORT checklist[7].

Examples

(1) "Burning injury was carefully avoided in the process by the operator by focusing his attention and whisking away the burning ash in a timely manner[34]."

(2) "Smokeless and odourless moxibustion sticks were used. Advice on the intensity of stimulation was given advising the participant not to let the points become uncomfortably hot[36]."

4 Discussion

RCTs represent the gold standard in evaluating the efficacy of health care interventions[7]. However, the significance of evidence produced is eroded by data suppression, misrepresentation and manipulation in lack of methodological rigor[37]. To assess a trial accurately, a complete, clear and transparent report on its methodology and findings is absolutely essential. The CONSORT Statement stands up a good framework to improve the reporting of RCTs, in the meanwhile, it affects design and execution of a trial indirectly. By taking account of the different systems to interpret both diseases and therapies between traditional medicine, such as TCM and conventional medicine, the generalizability of the original CONSORT checklist is limited[12] and the improvement of general reporting quality is low[38]. The publications of extensions specified on herbal medicine, non-pharmacologic treatment, TCM and acupuncture (STRICTA) not only can make the reporting guidelines more practical and pragmatic to the aims of studies, but also can arouse the awareness among peers. It is undoubted that the reporting quality, as well as the overall quality of clinical research can be improved. Moxibustion is a traditional therapeutic modality with a series of technical procedures. A precise reporting standard is necessary and urged for providing more high-quality clinical evidence on its effectiveness and safety. The items of STRICTOM are specific for reporting interventions in clinical trials of moxibustion. We hope that it can be further optimized by soliciting comments from the experts of the CONSORT Group, the STRICTA Group, acupuncture and moxibustion societies and clinical trial authors, and become an official extension of CONSORT.

5 Competing interests

The authors declare that they have no competing interests.

REFERENCES

1 Lee MS, Kang JW, Ernst E. Does moxibustion work? An overview of systematic reviews. BMC Res Notes. 2010; 3: 284.

2 Cheng X, Deng L. Chinese acupuncture and moxibustion. Beijing: Foreign Languages Press. 1987.

3 Sun GJ. Science of acupuncture and moxibustion. Shanghai: Shanghai Scientific and Technical Publishers. 1997. Chinese.

4 Shi XM, Zhou JZ. Shi Xue-min's comprehensive textbook

of acupuncture and moxibustion. Beijing: People's Medical Publishing House. 2007.
5 Xie ZL, Chen YY. Laboratory studies on the effects of moxibustion. Fujian Zhong Yi Yao. 2012; 43(2): 56-58. Chinese.
6 Kim SY, Chae Y, Lee SM, Lee H, Park HJ. The effectiveness of moxibustion: an overview during 10 years. Evid Based Complement Alternat Med. 2011; 2011: 306515.
7 Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Ann Intern Med. 2010; 152(11): 726-732.
8 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA. 1996; 276(8): 637-639.
9 Ioannidis JP, Evans SJ, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D; CONSORT Group. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004; 141(10): 781-788.
10 Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C; CONSORT Group. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT statement. Ann Intern Med. 2006; 144(5): 364-367.
11 Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P; CONSORT Group. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008; 148(4): 295-309.
12 Wu TX, Li YP, Bian ZX, Li TQ, Li J, Dagenais S, Moher D, for CONSORT for TCM working group. Consolidated standards for reporting trials of traditional Chinese medicine (CONSORT for TCM) (for solicitation of comments). Zhongguo Xun Zheng Yi Xue Za Zhi. 2007; 7(8): 601-605. Chinese.
13 Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ; CONSORT Group. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. JAMA. 2006; 295(10): 1152-1160.
14 Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D; CONSORT group; Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008; 337: a2390.
15 MacPherson H, Altman DG, Hammerschlag R, Li YP, Wu TX, White A, Moher D, STRICTA Revision Group. Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): extending the CONSORT statement. J Evid Based Med. 2010; 3(3): 140-155.
16 Huang T, Wang RH, Huang X, Tian YY, Zhang WB, Ayali H, Wang GJ, Zhang YQ, Litscher G, Wang L. Comparison of the effects of traditional box-moxibustion and eletrothermal Bian-stone moxibustion on volume of blood flow in the skin. J Tradit Chin Med. 2011; 31(1): 44-45.
17 Shi Y, Cui YH, Wu HG, Zhang W, Zhao C, Liu HR, Guo LQ, Wu BL, Yu AZ, Zhang YY. Effects of mild-warming moxibustion on Bcl-2 and PKC expressions of peripheral blood in elderly people. J Tradit Chin Med. 2012; 32(1): 45-51.
18 Tai CJ, Chien LY. The treatment of allergies using Sanfujiu: A method of applying Chinese herbal medicine paste to acupoints on three peak summer days. Am J Chin Med. 2004; 32(6): 967-976.
19 Guittier MJ, Pichon M, Dong H, Irion O, Boulvain M. Moxibustion for breech version: a randomized controlled trial. Obstet Gynecol. 2009; 114(5): 1034-1040.
20 Park JE, Sul JU, Kang K, Shin BC, Hong KE, Choi SM. The effectiveness of moxibustion for the treatment of functional constipation: a randomized, sham-controlled, patient blinded, pilot clinical trial. BMC Complement Altern Med. 2011; 11: 124.
21 Chen R, Chen M, Xiong J, Yi F, Chi Z, Zhang B. Comparison of heat-sensitive moxibustion versus fluticasone/salmeterol (seretide) combination in the treatment of chronic persistent asthma: design of a multicenter randomized controlled trial. Trials. 2010; 11: 121.
22 Zhou EH, Liu HR, Wu HG, Shi Z, Zhang W, Zhu Y, Shi DR, Zhou S. Down-regulation of protein and mRNA expression of IL-8 and ICAM-1 in colon tissue of ulcerative colitis patients by partition-herb moxibustion. Dig Dis Sci. 2009; 54(10): 2198-2206.
23 Hsu WH, Ho TJ, Huang CY, Ho HC, Liu YL, Liu HJ, Lai NS, Lin JG. Chinese medicine acupoint herbal patching for allergic rhinitis: a randomized controlled clinical trial. Am J Chin Med. 2010; 38(4): 661-673.
24 Son CG. Safety of 4-week indirect-moxibustion therapy at CV4 and CV8. J Acupunct Meridian Stud. 2011; 4(4): 262-265.
25 Anastasi JK, McMahon DJ, Kim GH. Symptom management for irritable bowel syndrome: a pilot randomized controlled trial of acupuncture/moxibustion. Gastroenterol Nurs. 2009; 32(4): 243-255.
26 Li XW, Yang YK, Xie XM, Bai LN, Zhang XS. Economic evaluation of treating herpes zoster with various methods of acupuncture and moxibustion. J Tradit Chin Med. 2012; 32(1): 125-128.
27 Chen M, Chen R, Xiong J, Yi F, Chi Z, Zhang B. Effectiveness of heat-sensitive moxibustion in the treatment of lumbar disc herniation: study protocol for a randomized controlled trial. Trials. 2011; 12: 226.
28 Mori H, Kuge H, Tanaka TH, Taniwaki E, Ohsawa H. Is there a difference between the effects of single and triple indirect moxibustion stimulations on skin temperature changes of the posterior trunk surface? Acupunct Med. 2011; 29(2): 116-121.
29 Chen R, Chen M, Kang M, Xiong J, Chi Z, Zhang B, Fu Y. The design and protocol of heat-sensitive moxibustion for knee osteoarthritis: a multicenter randomized controlled trial on the rules of selecting moxibustion location. BMC Complement Altern Med. 2010; 10: 32.
30 Park JE, Lee MS, Jung S, Kim A, Kang K, Choi J, Park J, Choi SM. Moxibustion for treating menopausal hot flashes: a randomized clinical trial. Menopause. 2009; 16(4): 660-665.
31 Lu M, Liu X. Insomnia due to deficiency of both the heart

and spleen treated by acupuncture-moxibustion and Chinese tuina. J Tradit Chin Med. 2008; 28(1): 10-12.
32 Ju YL, Chi X, Liu JX. Forty cases of insomnia treated by suspended moxibustion at Baihui (GV 20). J Tradit Chin Med. 2009; 29(2): 95-96.
33 Vas J, Aranda JM, Barón M, Perea-Milla E, Méndez C, Ramírez C, Aguilar I, Modesto M, Lara AM, Martos F, García-Ruiz AJ. Correcting non-cephalic presentation with moxibustion: study protocol for a multi-centre randomised controlled trial in general practice. BMC Complement Altern Med. 2008; 8: 22.
34 Zhang HY, Lu SF, Xiao N. Effect of warming moxibustion on Shenque acupoint for the treatment of acute diarrhea in children with infantile cerebral palsy. Chin J Integr Med. 2009; 15(6): 454-457.
35 Park JE, Lee SS, Lee MS, Choi SM, Ernst E. Adverse events of moxibustion: a systematic review. Complement Ther Med. 2010; 18(5): 215-223.
36 Do CK, Smith CA, Dahlen H, Bisits A, Schmied V. Moxibustion for cephalic version: a feasibility randomised controlled trial. BMC Complement Altern Med. 2011; 11: 81.
37 Bian ZX, Wu TX. Legislation for trial registration and data transparency. Trials. 2010; 11(1): 64.
38 Wang G, Mao B, Xiong ZY, Fan T, Chen XD, Wang L, Liu GJ, Liu J, Guo J, Chang J, Wu TX, Li TQ; CONSORT Group for Traditional Chinese Medicine. The quality of reporting of randomized controlled trials of traditional Chinese medicine: a survey of 13 randomly selected journals from mainland China. Clin Ther. 2007; 29(7): 1456-1467.