



Protocol

Safety and risks of shiatsu: Protocol for a systematic review

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ABSTRACT

Introduction: People use shiatsu for health maintenance and help with illness. Shiatsu is often considered safe, but there has been no published systematic review of its possible risks. The review aims to assess the evidence of safety and risk of harm from shiatsu.

Methods: All types of studies, independent of control and with any style of shiatsu will be eligible. Reports in any language will be included. Peer-reviewed studies and non-peer-reviewed literature will be handled in separate parts of the review. Electronic databases (including among others MEDLINE, AMED, Alt HealthWatch, Web of Science, CiNii) will be searched for identification of peer-reviewed publications. Hand-search will be used for non-peer-reviewed literature. Risk of bias will be assessed using RoB 2.0 in conjunction with McHarm (randomised trials), ROBINS:I in conjunction with McHarm (non-randomised studies), a modified PHARMA checklist (adverse reports). When appropriate, reporting bias will be assessed using ORBIT. The relevance of the described intervention to shiatsu will be based on clinical experience, using CARE for massage and bodywork and TIDieR. Root cause analysis of adverse events will consider Bradford Hill's criteria in the light of clinical experience.

Results: Meta-analysis is not planned. Results for each study will be presented in tables. Relationships within and between studies will be explored. A theory about the safety profile of shiatsu will be developed. Identified incidents will be presented in a narrative way and tabular categories.

Conclusion: The relevance to various stakeholders will be highlighted and the issues occurring from the review will be explored.

1. Introduction

1.1. Background

1.1.1. What is Shiatsu?

Shiatsu is a form of East Asian bodywork. It is originated in Japan and translates to “finger pressure”. The first book using the term published by Tamai Tempaku in 1915 [1]. Its prehistory can be traced to the common Chinese root of many oriental medicine practices [2]. During its development, it has gained unique characteristics by integrating the Japanese culture of the past and present [3]. Outside of Japan, it is taught and practised in a significantly different way [4], with practitioners using many different styles of shiatsu [5,6]. Those styles, vary in their philosophical approaches and theoretical bases [5], but usually share some fundamental principles related to the way of application of pressure and stretch [7]. Also, they usually have the following characteristics: (a) diagnosis and therapy are combined, (b) the body is the only tool used, no mechanical devices, (c) treat the whole body [8].

Most known styles of shiatsu have been developed by experienced

Japanese practitioners who label their approach with a specific name. The differences in the styles have been debated vigorously in the past [2]. The two most known styles are:

- The Namikoshi shiatsu. It is the only officially recognised in Japan as has been defined by the Japanese Ministry of Health and Welfare: “...use of fingers and palms of one's hands to apply pressure to particular sections on the surface of the body for the purpose of correcting the body's imbalances, and for maintaining and promoting health. It is also a method contributing to the healing of specific illnesses (aches, pains, stress, nervous conditions and so on), thereby stimulating the body's ability to self-heal.” [9]. Namikoshi shiatsu does not use meridians or other Chinese medicine concepts.
- The Zen (or Masunaga) shiatsu. It is the most commonly practised in Europe [6]. It gives more emphasis on balancing the meridians (Kyo-Jitsu theory) that are recognised beyond the traditional acupuncture meridians as extended meridians. Uses the abdominal (Hara) diagnosis, the two-hand connection [10] and consider a lot the psychological aspects [11].

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Further styles include, among others, the barefoot (or macrobiotic) shiatsu, meridian shiatsu, tao shiatsu, tsubo shiatsu, quantum shiatsu, ohashiatsu [12,13]. The diversity of styles cannot be limited to the most commonly used approaches identified above. Due to the experiential aspect of shiatsu, it could be proposed that each practitioner practise its own, unique style [12], something that causes difficulties when trying to define shiatsu in a concise and comprehensive way [2]. There are at least 20 different definitions of shiatsu according to professional associations in different countries [14].

In Europe shiatsu is considered part of the Complementary and Alternative Medicine (CAM) [15], representing a therapy that is:

“{...} used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. {...} has been mainly used outside conventional health care, but in some countries certain treatments are being adopted or adapted by conventional health care.” [16].

It is a personalised treatment that recognises the interconnected physical, emotional and psychosocial aspects of the receiver [17]. People use shiatsu for various health complaints and for health maintenance [5,18]. There is limited evidence for shiatsu's effects in various health conditions [5,19]. Besides, some studies from Japan shows physiological effects of shiatsu in humans, including modulation of the autonomic nervous system [20] as well as effects on the cardiovascular system, blood pressure, peripheral circulation, muscle pliability, spinal mobility and muscle stiffness, electrogastrogram results, skin temperature, pelvic angle, pupil diameter and pulse rate [21].

Although shiatsu is usually delivered on a futon, it is very adaptable, and can also be given to people in wheelchairs, on beds, and on massage couches [1]. The receiver lies fully clothed. The practitioner applies pressure to the body using fingers, palms, elbows, knees and other parts of the limbs, with minimum physical effort [22]. Other bodywork techniques such as acupressure, stretches, joint mobilisations, as well as much gentler touch, can be included. A typical session lasts about an hour, and the practitioner might also suggest exercise or dietary and lifestyle changes [23].

Due to the sharing of techniques with other forms of bodywork [24], shiatsu is often considered as a form of massage or acupressure [5,25–27]. Practitioners claim that this is not correct [28,29]. For this review, the distinction of shiatsu both from massage and acupressure is adopted. Even if a detailed assessment of the issue exceeds the limits of this paper, it worth to briefly explore it.

Massage has been defined as:

“the manipulation of the soft tissue of the body through stroking, rubbing, kneading, or tapping, to increase circulation, to improve muscle tone, and to relax the patient. {...} is performed either with the bare hands or through some mechanical means, such as a vibrator. The most common sites for massage are the back, knees, elbows, and heels” [26].

Thus it can be argued that differs from shiatsu at least in (a) the techniques of manipulation, (b) the tools used, (c) its possible partiality.

Similarly, it has been successfully proposed recently that the differences between shiatsu and acupressure are significant [28]. In addition, defining acupressure as:

“a form of touch therapy that utilizes the principles of acupuncture and Chinese medicine {...} the same points on the body are used as in acupuncture, but are stimulated with finger pressure instead of with the insertion of needles” [30]

it can be argued that it is a treatment modality much more limited technically compared to shiatsu and unable to be inclusive of the two main shiatsu styles.

Moreover, the common characteristics shared by different shiatsu styles (principles of application of pressure and stretch, a combination of diagnosis and therapy, no use of tools and treatment of the whole

body) are not necessary characteristics neither of massage nor acupressure.

Aiming to understand shiatsu as a whole and following a dialectical approach [31–33], for this review, all different styles will be considered as different presentations of shiatsu. Thus the given complexity is “reduced” in a specific unity, yet a unity in its difference. Each style of shiatsu is just a specific presentation of shiatsu shaped by multiple determinations but to remain shiatsu should be possible to produce it by a basic defining principle. That way shiatsu could be considered as a specific developing whole no matter the existing differences between styles and not diffused into different modalities. There is no “side” characteristic of any shiatsu style that can define shiatsu because no “side” characteristic is unique to it. The basic defining principle does not exist by itself either. Shiatsu as a whole is what develops from the multiple determinations that characterise each style/practice, as long as the basic defining principle constitute it.

While finding the basic defining principle of shiatsu is by itself a whole research programme that exceeds the purpose of this paper, there has been a recent attempt to define shiatsu [28] that, even if differs methodologically, could be compatible to such an approach. The definition of shiatsu resulted by that attempt is adopted as the minimum characteristic of shiatsu, which can be modified specifically by the characteristics of each different style following the above-described approach:

“Shiatsu is a manual therapy applied by leaning forward in a relaxed manner with the weight of one's body to an optimum point, and the correct use of fingers, palms, etc., in order to apply sustained, stationary pressure on different parts of the body for the purpose of correcting the imbalances of the body, and for maintaining and promoting health. It is a holistic therapy that aims to treat most of the body in each session.” [28].

1.1.2. Safety and risks

Being part of CAM therapies, shiatsu shares safety issues associated with CAM, and especially the manipulative CAM modalities [34], while more shiatsu-specific issues might exist too. CAM are usually described as natural and thus considered safe by the patients using them [35–39]. Yet, natural does not necessarily mean safe [40], and it is reasonable to expect that if some therapy has a positive effect, it can cause harms too [41]. While some CAM leaders and practitioners recognise safety concerns for their modalities [42], it is often uncomfortable to accept the reality of adverse events [43] and safety awareness is often limited [44]. Additionally, there are indications that the advertising strategy of professional associations and practitioners positively feedback the misconception of safety [45–47].

From a research perspective, the findings of the CAMbrella project highlighted that the safety of CAM as a key issue should be addressed by research no later than 2020 [48]. During recent years, there have been serious attempts by researchers to assess the safety profile of different CAM modalities and explore ways of improvement [41]. Yet the lack of regulatory setting for CAM practice in many countries, with the accompanying inadequate safety mechanisms and reporting systems, are factors that impede research projects in CAM safety [49]. Besides, it has been found that when CAM professions become statutory regulated safety-related improvements occur, including raising of education and practice standards as well as more efficient and transparent processing of complaints [50].

Especially for shiatsu, the differences in regulatory status and training standards between countries, even inside Europe, varies considerably. The regulation and training spectrum ranges from statutorily recognised profession with vocational training to complete lack of professional standards or training requirements. Three indicative examples are Switzerland, the UK and Finland.

In Switzerland, after many years of work by the Swiss Shiatsu Association [51], the shiatsu practitioners can reach statutorily

regulated professional status. The highest qualification is that of a “Complementary Therapist with Advanced Federal Diploma of Higher Education Professional Organisation CT Method Shiatsu”, after completing at least three years of studies (2660/909 learning/contact hours, of which at least 1250/500 h of shiatsu [52]), a required amount of supervised professional practice, case studies and federal exams [53].

In the UK, while shiatsu is not statutory regulated there is the government supported UK register of complementary health practitioners (Complementary and Natural Healthcare Council – CNHC) [54] with its own Code of Conduct, Ethics and Performance. Registration demand professionally defined training standards at a minimum level 4 of the European Qualifications Framework (EQF) and 1000 notional hours [55]. The UK Shiatsu Society's ratified schools follow a minimum of three years learning outcomes based core curriculum providing at least 500 contact hours and 500 distance hours of shiatsu training [56].

In Finland, there is a complete lack of professionalisation, missing even a code of ethics and conduct. Recent efforts towards professionalisation from the newly founded Finnish Shiatsu Association [57] were resisted both from practitioners and the schools providing shiatsu training. Currently, just 100 h of training are enough in order for someone to become a member of a practitioner register [58].

This diversity in regulatory status and training standards is a safety concern [59] and associated with possible indirect or non-health risks too [60]. Thus any attempt to assess safety issues of shiatsu will have to consider this diversity.

One of the conclusions of the biggest shiatsu study ever conducted, which included 948 participants in three European countries [18], was that when performed by qualified practitioners, shiatsu is a safe therapy with no enduring adverse effects [61]. Even so, there has been no published systematic review of its possible risks. Due to the existing bewilderment regarding the relevance of shiatsu to other modalities, existing adverse event reports for shiatsu have been identified by reviews evaluating the safety of massage [62–64].

Given the existing adverse event reports as well as the variability in standards of training and practising styles of shiatsu, it is considered essential to assess potential areas of concern related to the safety of shiatsu. Thus patients can become aware of possible risks while practitioners, educational and regulatory organisations can work towards addressing those concerns and establishing a safe practice. Besides, there are worries that the gap in the evidence of its safety, is a factor that makes it difficult for shiatsu to be integrated into the healthcare systems of many countries or to become statutorily regulated [34]. Additionally, possible exaggerations of adverse events might discourage medical practitioners from seeking its inclusion in an integrated model of healthcare [65].

1.2. Aim and objectives

The review aims to assess the evidence of safety and risk of harm for shiatsu (exploratory review).

Objectives are

(a) the categorisation of the general risk of harm for shiatsu. The

- categorisation will be based on the definitions provided in Table 1.
- (b) the root cause analysis of incidents associated with shiatsu and identification of specific risk factors that could lead to potential harm.
- (c) the categorisation of shiatsu related adverse events according to the 11th Revision of the International Classification of Diseases (ICD-11) [66].

2. Methods

2.1. Study design

This protocol was prepared following the PRISMA harms checklist and PRISMA-P recommendations [67,69] as well as the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 [70,71]. Deviations from those guidelines occur in order to improve the clarity and readability of the protocol, following peer-reviewers suggestions and journal author guidelines [72].

2.2. Study registration

Following the recommendation of the International Prospective Register of Systematic Reviews (PROSPERO) this protocol will be registered only after the peer-review process is completed and the article accepted for publication [73,74]. Any need for amendments and updates will be maintained to the registered record and explained in the report of the review [75].

2.3. Reviewer's team

Besides the author of this protocol, three more researchers with specialist knowledge of shiatsu practice will be part of the review team, since this has been suggested as a requirement to better address challenges in CAM safety research [49]. The researchers have diverse shiatsu background and practice different styles of shiatsu, residing in countries with varying regulatory status too.

2.4. Eligibility criteria

2.4.1. Criteria for considering studies for this review

2.4.1.1. *Types of studies.* All types of experimental, quasi-experimental or observational studies will be considered [76], including randomised control trials, cohort studies, case-control studies, case studies, case reports, case series, cross-over trials, independent of the follow-up period. Review articles will be used only for the identification of further studies through their references but will be excluded by the review process.

2.4.1.2. *Types of participants.* Studies examining adults or children, without any sex or age limitation, will be included.

2.4.1.3. *Types of interventions.* Of interest are any shiatsu style when the term “shiatsu” is used for its description. The reviewers will

Table 1

Definition of terms (adapted from [61,67,68]).

Term	Definition
Adverse Effect	An unfavourable outcome that occurs during or after the intervention and the causal relation between the intervention and the event is at least a reasonable possibility.
Adverse Event	An unfavourable outcome that occurs during or after the intervention but is not necessarily caused by it.
Risk of Harm	The totality of possible adverse consequences of an intervention; harms are the direct opposite of benefits.
Safety	Substantive evidence of an absence of harm. The term is often misused when there is a simple absence of evidence of harm.
Side Effects	Any unintended effect, adverse or beneficial, that occurs by the usual application of the intervention.
Transitional Side Effect	An effect described as changing from negative to positive by the patients and being consistent with the theory. Causing neither distress nor stopping the patients from doing their normal activities. It should not last more than a couple of days.

evaluate the relevance of the described intervention to shiatsu. Studies related to mechanical instruments that include the term “shiatsu” in their name will be excluded. There will be no restriction of studies for any setting of delivery.

2.4.1.4. Types of comparator/control. Studies with any kind or without any comparator/control will be eligible for inclusion.

2.4.1.5. Types of outcome measures. The outcome of interest is the risk of harm, including all categories defined in Table 1. Studies that are otherwise eligible but do not report the outcome of interest will be included, and their author(s) will be contacted to provide further clarifications.

2.4.2. Criteria for considering reports for this review

2.4.2.1. Year of publication. No limitation of publication year will be included in the eligibility criteria.

2.4.2.2. Language of report. There will be no language limitation. Articles reported in languages other than the accessible by the reviewers (English, Finnish, Greek, Spanish) will be accessed using machine translation (google translate or equivalent). The same applies to articles in the Japanese language which are expected to exist due to the historical roots of shiatsu and its developmental relevance to Japan. Articles accessed using machine translation will be indicated as such in the results.

2.4.2.3. Geographical location. No geographical limitation will be included in the eligibility criteria.

2.4.2.4. Publication status. Articles and abstracts published in peer-reviewed journals will be eligible for inclusion and will be the main part of the review. Due to the minimal evidence base for shiatsu and following the approach “the more you search, the more you find” [77,78] as well as relevant suggestions available by Cochrane Training [79], grey and non-peer-reviewed literature will also be eligible for inclusion and will be examined in a separate part of the review.

2.5. Search methods for identification of studies

2.5.1. Electronic searches

For the identification of the studies, at least the following electronic databases and/or interfaces will be used: MEDLINE (PubMed interface), Allied and Complementary Medicine Database – AMED (EBSCOhost interface), Alt HealthWatch (EBSCOhost interface), Web of Science Core Collection (Web of Science interface), Korean Journal Database – KCI (Web of Science interface), Russian Science Citation Index (Web of Science interface), SciELO Citation Index (Web of Science interface), 1findR (1science interface), Science Direct, SpringerLink, Japanese Academic Libraries – CiNii, Directory of Open Access Journals – DOAJ, PubPsych, JSTOR, Scopus, Wiley Online Library. All databases and interfaces will be searched from conception. The term used for the searches will be “shiatsu”. The term will be applied in titles and abstracts or equivalent depending to the structure of each of the databases.

Aiming for literature saturation, the reference lists of included studies will be scanned for identification of possible eligible studies not identified thru the databases. In addition, eligible study authors will be scanned using Google Scholar, ResearchGate and Academia for identification of possible further details related to their study and they will be contacted in case that there are not enough details regarding the outcomes of interest.

2.5.2. Searching other resources

For the identification of grey literature and non-peer-reviewed literature, hand-search in the archives and libraries of the reviewers and internet searches will be used.

2.6. Data collection

The results of the literature searches will be uploaded to the Evidence Synthesis Tool and Database CADIMA [80]. Duplicates will be removed while studies published in multiple papers will be linked as a single unit-record with all reports considered during the synthesis.

2.6.1. Selection of studies

2.6.1.1. Peer-reviewed literature. The reviewers will screen the titles and abstracts of the search results against the eligibility criteria and according to predefined responsibilities. Reasons for exclusion for each study will be documented. In case of uncertainty regarding the eligibility, the full text will be obtained, and the decision will be made based on the predefined eligibility criteria. If necessary, the authors of the controversial papers will be contacted. The full text of all eligible studies will be obtained and screened in order to select the studies for final inclusion.

2.6.1.2. Grey and non-peer-reviewed literature. The reviewers will screen relevant to the intervention grey and non-peer-reviewed literature against the eligibility criteria.

2.6.2. Data extraction and management

Using predesigned forms in the internet-based Evidence Synthesis Tool and Database CADIMA, the relevant data as described in the following paragraph “Data items” will be extracted manually from the eligible studies. In case there are not enough data for the interesting outcome of a study, the author(s) will be contacted. In case of identification of multiple reported studies at this stage, they will be linked as a single unit-record with all reports considered during the synthesis. In case of contradictions between the same study reports, the author(s) will be contacted to provide further clarifications.

2.6.2.1. Data items. Items to be extracted include the in-text citation of the study, the design of the study, the treated condition, the number of the patients, the sex and age of the patient(s), the background of the practitioners, the country where the event took place, characteristics of the intervention, characteristics of each event as per author(s) of each study, number of total events and number of events experienced by each participant, number of participants experiencing each event, factors associated with each event (such as underlying condition of the patient or years of experience and level of training of the practitioner), length of intervention, drop-outs with reasons for them, active (by asking the patient) or passive (by waiting the patient to report them) method of measuring the events, timing of measuring the events. Missing data will be indicated.

2.7. Assessment of risk of bias in included studies

Risk of bias for each study will be accessed using the following tools. Each item of the assessment will be presented independently in a table or graphic format within and across studies.

2.7.1. Randomised trials

The RoB 2.0 revised tool for assessing risk of bias in randomised trials by the Cochrane Collaboration [81] will be used to assess the domains of selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and practitioners), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting) and any other domain not previously identified. In conjunction, the McHarm tool will be used for assessing the internal validity of capturing and reporting harms [82–84].

2.7.2. Non-randomised trials

The ROBINS:I tool for assessing risk of bias in non-randomised

studies of interventions [85] will be used to assess the pre-intervention domain (confounding bias, selection bias), the at-intervention domain (interventions classification bias) and the post-intervention domain (bias due to deviations from intended interventions, bias due to missing data, measurement of outcome bias, selective reporting bias). In conjunction, the McHarm tool will be used for assessing the internal validity of capturing and reporting harms [82–84].

2.7.3. Adverse reports

The quality of the adverse event reports published anecdotally in journals will be assessed by using a modified version of the PHARMA checklist of items for inclusion in an anecdotal report of a suspected adverse event [86,87] which combine an adaptation of the causality assessment of case reports tool by WHO-UMC [88]. The modified tool as adapted for the needs of the current review can be found in [Appendix A](#).

2.7.4. Assessment of reporting biases

The assessment of possible biases due to non-study related processes (such as publication bias or outcome reporting bias) is included in the methods described earlier for the assessment of randomised and non-randomised studies. The Outcome Reporting Bias in Trials (ORBIT) classification system [89] will be used when appropriate.

2.7.5. Dealing with missing data

In case of missing data, the author(s) will be contacted once by email to provide clarifications. In case that there were no further details during two weeks since the attempted contact, the lack of data will be documented. Studies failing to address the risk of harm for which no further details become available with the earlier described methods will be considered as containing reporting bias and will not be considered as evidence of safety.

2.7.6. Relevance of intervention assessment

Given the lack of guideline for reporting interventions in shiatsu studies, the relevance of the interventions described in the papers to shiatsu will be assessed by the authors based on clinical experience. Non-specific guidelines such as the adaptation of the CARE guidelines for therapeutic massage and bodywork publications [90] and the template for intervention description and replication (TIDieR) as adopted for manual therapy interventions [91] will be considered. The assessment will include all study designs as well as the grey and non-peer reviewed literature.

2.8. Data synthesis

The wide variety of study populations, examined conditions and study designs is expected to bring a highly heterogeneous collection of studies. Thus meta-analysis is not planned for this review. Root cause analysis of the adverse events will attempt to explore why the events happen [92] by pooling relevant studies, a process that will include an investigation of causal inferences considering the Bradford Hill Criteria [93] under the light of the clinical experience of the reviewers. Each reviewer will present the results from their area of responsibility to the reviewer's team. This will then be commented on by the members of the team. All reviewers will participate in doing a narrative synthesis of the collected data.

3. Results

The results of the review will begin with an assessment of the quality of the studies as a whole and an audit trail of the excluded studies. A PRISMA consort flow diagram [94] showing the process of study selection will be accompanied by an explanation of exclusions according to the eligibility criteria as described in this protocol.

Peer-reviewed studies and non-peer-reviewed literature will be presented in separate sections of the results and will then be synthesised

(see below). Results will be reported for all included studies, independent of the quality assessment. Results for each study will be summarised in a tabular format.

Identified incidents will be presented in a narrative way beginning by using a detailed examination (analysis) of each incident and followed by pooling of the relevant studies (synthesis). The Conceptual Framework for the International Classification for Patient Safety (ICPS) [95,96] will inform the terminology used in the narrative synthesis for terms beyond those defined in [Table 1](#). This final synthesis will follow a framework consisted of the following elements:

- (1) Development of a synthesis of both the peer-reviewed studies and the non-peer-reviewed literature.
- (2) Exploration of relationships within and between studies.
- (3) Development of a theory about the safety profile of shiatsu, including the identification of specific risk factors that could lead to potential harm.

A synthetic table will present each of the identified adverse events, with categorisation according to [Table 1](#) and the ICD-11, as per the objectives of the review.

Data extraction forms and tables used during the review process will become available as supplements of the review.

4. Discussion

The results of the review are going to be discussed in order to highlight their relevance to various stakeholders, including among other patients, shiatsu practitioners, policymakers, integrative clinicians, educators, researchers.

Besides, issues anticipated to occur from the review and discussed include:

- (a) the wide variability in styles of shiatsu and its relevance to safety issues.
- (b) the variability of professional and regulatory status between countries and their relevance to safety issues.
- (c) the variability of training standards between countries and their relevance to safety issues.
- (d) the relevance of the intervention described in the studies to shiatsu and desired elements of description that could make future reports of shiatsu studies more relevant.

Since the review will consider Japanese studies it is expected all the anticipated issues to consider the differences between shiatsu in Japan and abroad too.

Conclusion

Shiatsu is a CAM modality that is used both in order to maintain health, as well as to treat illnesses. When applied by trained practitioners it is usually considered a safe therapy. However, a systematic review that will evaluate various types of available sources of literature to identify and describe the risks of shiatsu in various conditions is missing. This may lead either in exaggerations or understatement of those risks by various stakeholders. The results of this review could help inform better the stakeholders, and thus to contribute in a safer and more evidence-based practice.

Authors

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Conflict of interest

The author is himself a shiatsu practitioner. No further conflict of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.eujim.2019.03.006>.

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