

1 **Title**

2 Safety and Risks of Shiatsu: Protocol for a Systematic Review

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4 **(Corresponding) Author**

5 Stergios Tsiormpatzis^a, MSc Candidate

6 Tuohilammentie 388, 03300, Otalampi, Finland

7 +358401650278

8 stergios.tsiormpatzis@gmail.com

9 stsio@orientalmedicine.eu

10 ^a Independent

11

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21 **Abstract**

22 ***Introduction***

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

26 ***Methods***

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

40 ***Results***

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

45 **Discussion**

46 The discussion will highlight the relevance to various stakeholders and will explore
47 issues that occurred from the review.

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49 **Keywords**

50 Shiatsu; CAM; safety; risk; systematic review; protocol

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67 Introduction

68 Background

69 *What is Shiatsu?*

70 Shiatsu is a form of East Asian bodywork. It is originated in Japan and translates to
71 “finger pressure”. The first book using the term published by Tamai Tempaku in 1915
72 [1]. Its prehistory can be traced to the common Chinese root of many oriental
73 medicine practices [2]. During its development, it has gained unique characteristics
74 by integrating the Japanese culture of the past and present [3]. Outside of Japan, it
75 is taught and practised in a significantly different way [4], with practitioners using
76 many different styles of shiatsu [5,6]. Those styles, even if varies in their
77 philosophical approaches and theoretical bases [5], usually share some fundamental
78 principles related to the way of application of pressure and stretch [7]. Also, they
79 usually have the following characteristics: a) diagnosis and therapy are combined, b)
80 the body is the only tool used, no mechanical devices, c) treat the whole body [8].

81 Most known styles of shiatsu have been developed by experienced Japanese
82 practitioners who label their approach with a specific name. The differences in the
83 styles have been debated vigorously in the past [2]. The two most known styles are:

- 84 • The Namikoshi shiatsu. It is the only officially recognised in Japan as has
85 been defined by the Japanese Ministry of Health and Welfare:

86 *“...use of fingers and palms of one’s hands to apply pressure to particular*
87 *sections on the surface of the body for the purpose of correcting the body’s*
88 *imbalances, and for maintaining and promoting health. It is also a method*
89 *contributing to the healing of specific illnesses (aches, pains, stress, nervous*
90 *conditions and so on), thereby stimulating the body’s ability to self-heal.” [9].*

91 Namikoshi shiatsu does not use meridians or other Chinese medicine
92 concepts.

- 93 • The Zen (or Masunaga) shiatsu. It is the most commonly practised in Europe
94 [6]. It gives more emphasis on balancing the meridians (Kyo - Jitsu theory)
95 that are recognised beyond the traditional acupuncture meridians as extended
96 meridians. Uses the abdominal (Hara) diagnosis, the two-hand connection
97 [10] and consider a lot the psychological aspects [11].

98 Further styles include, between others, the barefoot (or macrobiotic) shiatsu,
99 meridian shiatsu, tao shiatsu, tsubo shiatsu, quantum shiatsu, ohashiatsu [12,13].

100 The diversity of styles cannot be limited to the most commonly used approaches
101 identified above. Due to the experiential aspect of shiatsu, it could be proposed that
102 each practitioner practise its own, unique style [12], something that causes
103 difficulties when trying to define shiatsu [2] in a concise and comprehensive way.

104 There are at least 20 different definitions of shiatsu by professional associations in
105 different countries [14].

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

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

112 It is a personalised treatment that recognises the interconnected physical, emotional
113 and psychosocial aspects of the receiver [17]. People use shiatsu for various health
114 complains and for health maintenance [5,18]. There is limited evidence for shiatsu's

115 effects in various health conditions [5,19]. Besides, some studies from Japan shows
116 physiological effects of shiatsu in humans, including modulation of the autonomic
117 nervous system [20] as well as effects on the cardiovascular system, blood pressure,
118 peripheral circulation, muscle pliability, spinal mobility and muscle stiffness,
119 electrogastrogram results, skin temperature, pelvic angle, pupil diameter and pulse
120 rate [21].

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

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

133 Massage has been defined as:

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

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

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

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

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

148 Moreover, the common characteristics shared by different shiatsu styles (principles
149 of application of pressure and stretch, a combination of diagnosis and therapy, no
150 use of tools and treatment of the whole body) are not necessary characteristics
151 neither of massage nor acupressure.

152 Aiming to understand shiatsu as a whole and following a dialectical approach [31–
153 33], for this review, all different styles will be considered as different presentations of
154 shiatsu. Thus the given complexity is “reduced” in a specific unity, yet a unity in its
155 difference. Each style of shiatsu is just a specific presentation of shiatsu shaped by
156 multiple determinations but to remain shiatsu should be possible to produce it by a
157 basic defining principle. That way shiatsu could be considered as a specific
158 developing whole no matter the existing differences between styles and not diffused
159 into different modalities. There is no “side” characteristic of any shiatsu style that can
160 define shiatsu because no “side” characteristic is unique to it. The basic defining
161 principle does not exist by itself either. Shiatsu as a whole is what develops from the

162 multiple determinations that characterise each style/practice, as long as the basic
163 defining principle constitute it.

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

170 “Shiatsu is a manual therapy applied by leaning forward in a relaxed manner with the
171 weight of one’s body to an optimum point, and the correct use of fingers, palms, etc.,
172 in order to apply sustained, stationary pressure on different parts of the body for the
173 purpose of correcting the imbalances of the body, and for maintaining and promoting
174 health. It is a holistic therapy that aims to treat most of the body in each session.”
175 [28].

176 *Safety and Risks*

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

185 indications that the advertising strategy of professional associations and practitioners
186 positively feedback the misconception of safety [45–47].

187 From a research perspective, the findings of the CAMbrella project highlight the
188 safety of CAM as a key issue that should be addressed by research not later than
189 2020 [48]. During recent years, there have been serious attempts by researchers to
190 assess the safety profile of different CAM modalities and explore ways of
191 improvement [41]. Yet the lack of regulatory setting for CAM practice in many
192 countries, with the accompanying inadequate safety mechanisms and reporting
193 systems, are factors that impede research projects in CAM safety [49]. Besides, it
194 has been found that when CAM professions get statutory regulated occur safety-
195 related improvements, including raising of education and practice standards as well
196 as more efficient and transparent processing of complains [50].

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

202 In Switzerland, after many years of work by the Swiss Shiatsu Association [51], the
203 shiatsu practitioners can reach statutorily regulated professional status. The highest
204 qualification is that of a “Complementary Therapist with Advanced Federal Diploma
205 of Higher Education Professional Organization CT Method Shiatsu”, after completing
206 at least three years of studies (2660/909 learning/contact hours, of which at least
207 1250/500 hours of shiatsu [52]), a required amount of supervised professional
208 practice, case studies and federal exams [53].

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

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

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

225 One of the conclusions of the biggest shiatsu study ever conducted, which included
226 948 participants in three European countries [18], was that when performed by
227 qualified practitioners, shiatsu is a safe therapy with no enduring adverse effects
228 [61]. Even so, there has been no published systematic review of its possible risks.
229 Due to the existing bewilderment regarding the relevance of shiatsu to other
230 modalities, existing adverse event reports for shiatsu have been identified by reviews
231 evaluating the safety of massage [62–64].

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

242 **Aim and Objectives**

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

245 Objectives are

246 a) the categorisation of the general risk of harm for shiatsu. The categorisation will
247 be based on the definitions provided in Table 1.

248 b) the root cause analysis of incidents associated with shiatsu and identification of
249 specific risk factors that could lead to potential harm.

250 c) the categorisation of shiatsu related adverse events according to the 11th Revision
251 of the International Classification of Diseases (ICD-11) [66].

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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 Effect	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.

254 *Table 1: Definition of terms (adapted from [61,67,68])*

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266 **Methods**

267 ***Study Design***

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

273 ***Study Registration***

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

279 ***Reviewer's Team***

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

285 **Eligibility Criteria**

286 ***Criteria for considering studies for this review***

287 *Types of studies*

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

293 *Types of participants*

294 Studies examining adults or children, without any sex or age limitation, will be
295 included.

296 *Types of interventions*

297 Of interest are any shiatsu style when the term “shiatsu” is used for its description.
298 The reviewers will evaluate the relevance of the described intervention to shiatsu.
299 Studies related to mechanical instruments that include the term “shiatsu” in their
300 name will be excluded. There will be no restriction of studies for any setting of
301 delivery.

302 *Types of comparator / control*

303 Studies with any kind or without any comparator/control will be eligible for inclusion.

304 *Types of outcome measures*

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

308 ***Criteria for considering reports for this review***

309 *Year of Publication*

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

311 *Language of Report*

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

318 *Geographical Location*

319 No geographical limitation will be included in the eligibility criteria.

320 *Publication Status*

321 Articles and abstracts published in peer-reviewed journals will be eligible for
322 inclusion and will be the main part of the review. Due to the minimal evidence base
323 for shiatsu and following the approach “the more you search, the more you find”
324 [77,78] as well as relevant suggestions available by Cochrane Training [79], grey
325 and non-peer-reviewed literature will also be eligible for inclusion and will be
326 examined in a separate part of the review.

327 **Search methods for identification of studies**

328 *Electronic searches*

329 For the identification of the studies, at least the following electronic databases and/or
330 interfaces will be used: MEDLINE (PubMed interface), Allied and Complementary
331 Medicine Database - AMED (EBSCOhost interface), Alt HealthWatch (EBSCOhost
332 interface), Web of Science Core Collection (Web of Science interface), Korean

333 Journal Database - KCI (Web of Science interface), Russian Science Citation Index
334 (Web of Science interface), SciELO Citation Index (Web of Science interface),
335 1findR (1science interface), Science Direct, SpringerLink, Japanese Academic
336 Libraries - CiNii, Directory of Open Access Journals - DOAJ, PubPsych, JSTOR,
337 Scopus, Wiley Online Library. All databases and interfaces will be searched from
338 conception. The term used for the searches will be “shiatsu”. The term will be applied
339 in titles and abstracts or equivalent depending to the structure of each of the
340 databases.

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

347 *Searching other resources*

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

350 **Data collection and analysis**

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

355 ***Selection of studies***

356 *Peer-reviewed literature*

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

364 *Grey and non-peer-reviewed literature*

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

367 ***Data extraction and management***

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

376 *Data items*

377 Items to be extracted include the in-text citation of the study, the design of the study,
378 the treated condition, the number of the patients, the sex and age of the patient(s),

379 the background of the practitioners, the country where the event took place,
380 characteristics of the intervention, characteristics of each event as per author(s) of
381 each study, number of total events and number of events experienced by each
382 participant, number of participants experiencing each event, factors associated with
383 each event (such as underlying condition of the patient or years of experience and
384 level of training of the practitioner), length of intervention, drop-outs with reasons for
385 them, active (by asking the patient) or passive (by waiting the patient to report them)
386 method of measuring the events, timing of measuring the events. Missing data will
387 be indicated.

388 ***Assessment of risk of bias in included studies***

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

392 *Randomised trials*

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

401 *Non-randomised trials*

402 The ROBINS:I tool for assessing risk of bias in non-randomised studies of
403 interventions [85] will be used to assess the pre-intervention domain (confounding
404 bias, selection bias), the at-intervention domain (interventions classification bias) and
405 the post-intervention domain (bias due to deviations from intended interventions,
406 bias due to missing data, measurement of outcome bias, selective reporting bias). In
407 conjunction, the McHarm tool will be used for assessing the internal validity of
408 capturing and reporting harms [82–84].

409 *Adverse reports*

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

416 *Assessment of reporting biases*

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

422 *Dealing with missing data*

423 In case of missing data, the author(s) will be contacted once by email to provide
424 clarifications. In case that there were no further details during two weeks since the
425 attempted contact, the lack of data will be documented. Studies failing to address the

426 risk of harm for which no further details become available with the earlier described
427 methods will be considered as containing reporting bias and will not be considered
428 as evidence of safety.

429 *Relevance of intervention assessment*

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

438 **Data Synthesis**

439 The wide variety of study populations, examined conditions and study designs is
440 expected to bring a highly heterogeneous collection of studies. Thus meta-analysis is
441 not planned for this review. Root cause analysis of the adverse events will attempt to
442 explore why the events happen [92] by pooling relevant studies, a process that will
443 include an investigation of causal inferences considering the Bradford Hill Criteria
444 [93] under the light of the clinical experience of the reviewers. Each reviewer will
445 present the results from their area of responsibility to the reviewer's team. This will
446 then be commented on by the members of the team. All reviewers will participate in
447 doing a narrative synthesis of the collected data.

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450 **Results**

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

456 Peer-reviewed studies and non-peer-reviewed literature will be presented in
457 separate sections of the results and will then be synthesised (see below). Results
458 will be reported for all included studies, independent of the quality assessment.
459 Results for each study will be summarised in a tabular format.

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

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

471 A synthetic table will present each of the identified adverse events, with
472 categorisation according to Table 1 and the ICD-11, as per the objectives of the
473 review.

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

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491 **Discussion**

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

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

496 a) the wide variability in styles of shiatsu and its relevance to safety issues.

497 b) the variability of professional and regulatory status between countries and their
498 relevance to safety issues.

499 c) the variability of training standards between countries and their relevance to safety
500 issues.

501 d) the relevance of the intervention described in the studies to shiatsu and desired
502 elements of description that could make future reports of shiatsu studies more
503 relevant.

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

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512 **Conclusion**

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

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533 **Appendix A**

534 Modified PHARMA [86,87] checklist of items for inclusion in an anecdotal report of a
 535 suspected adverse treatment event – bodywork and manual modalities adaptation
 536 including WHO-UMC [88] causality assessment.

Item	Comments
1) Title	Should be non-declarative (the term “associated with” should be used, rather than “caused by” or “due to”). Should mention: <ul style="list-style-type: none"> - the advert event - the modality suspected to have cause it - the age and sex of the patient - any important susceptibility factors
2) Abstract / Summary	Should include: <ul style="list-style-type: none"> - the adverse event - the suspected modality - details of the patient(s) - evidence that links the modality to the event - the management used - the mechanism (if known) - the implications for therapy - hypotheses that arise (if any)
3) Introduction	Should: <ul style="list-style-type: none"> - be brief - name the suspected modality - name the adverse event with which it was associated - briefly mention previous similar reports - state the purpose of the report
4a) The case report – Background	Should include: <ul style="list-style-type: none"> - <u>Patient data</u>: Including at least age and sex, preferably weight, height, ethnic background, occupation, obstetric status (if applicable) - <u>Premorbid condition</u>: Details of all the patient’s diagnoses, including duration and severity - <u>The suspected modality</u>: Description of the modality and style or technique used, the reasons of application, the frequency and duration of treatment, the qualifications and training of the practitioner(s) - <u>Concurrent treatments</u>: Details of all kind of therapeutic modalities and techniques used concurrently, including prescription or over-the-counter medicines, herbal or nutritional

	<p>supplements, recreational drugs, CAM or other bodywork and manual modalities</p> <ul style="list-style-type: none"> - <u>Other relevant history</u>: Relevant family history and lifestyle (e.g. smoking and drinking habits)
4b) The case report – The adverse event	<p>The event should be described in detail, including:</p> <ul style="list-style-type: none"> - Definition of the case (if available) - Assessment of the severity and seriousness of the event - A time-course in relation to the application of the modality - Diagnostic tests, both relevant to the diagnosis of the event and relevant to the link with the modality or technique - Known or postulated susceptibility factors - Measures taken to treat the adverse event - Final outcome - Diagram showing the time-course of the adverse event (if possible)
5) Discussion	<p>Should include:</p> <ul style="list-style-type: none"> - Causality assessment - <u>Classification of the event</u>: At least similar to A/B pharmacological classification[97]: A: result of an exaggerated, but otherwise normal action of a modality/technique applied in the usual therapeutic way B: totally aberrant effects that are not to be expected from the usual application of a modality/technique - Reasons for modality or technique implication - Reasons for non-implication of other treatments and/or other factors (including qualifications and training of the practitioner(s)) - Review of previous cases (published and unpublished) - Methods of diagnosis (if relevant) - Possible mechanisms - Possible form of management - Implications for clinical practice - Implications for training - Hypotheses generated by the report (if any)

537 *Table A1: Checklist*

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Term	Description
Certain	A clinical event occurring in a plausible time relationship to the application of the modality, and which cannot be explained by concurrent disease or treatments. The event must be definitive based in theory of the modality or based in the described clinical phenomena.
Probable / Likely	A clinical event with a reasonable time sequence to the application of the modality, unlikely to be attributed to concurrent disease or treatments.
Possible	A clinical event with a reasonable time sequence to the application of the modality, but which could also be explained by concurrent disease or treatments.
Unlikely	A clinical event with a temporal relationship to the application of the modality which makes a causal relationship improbable, and in which concurrent disease or treatments provide plausible explanations.
Conditional / Unclassified	A clinical event reported as adverse, about which more data is essential for a proper assessment or the additional data are under examination.
Non-accessible / Unclassifiable	A report suggesting an adverse event which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.

541 Table A2: Causality Assessment

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548 **Authors**

549 All research done by the author

550

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555 **Conflict of interest**

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

557

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