

Shiatsu, the Evidence Base

a critical review of a webinar

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1.1. Introduction

The webinar with Andrea Kleinau PhD was hosted by Cliff Andrews MRSS (T) for the New Energy Work Project, 4th of June 2019. It was part of a series of free webinars titled “Shiatsu: The Scientific Basis” while an online course on the same topic is planned by the organisers. While a full review of the whole series is possible to come at some time in the future, here the focus will be on the specific webinar.

The webinar was promoted with the text that is also available to its recording:

Did you know that there is very good research evidence that shows Shiatsu is not only safe and effective - but also that it is a more effective treatment than conventional medicine for some conditions? In this live Webinar Cliff will be talking with Andrea Kleinau who is the author of a PhD meta analysis of the research evidence on Shiatsu. This Webinar is essential viewing for all professional Shiatsu teachers, practitioners and students. (Kleinau and Andrews, 2019)

After the live webinar, the description of it on the website of the organisers reads as:

Andrea Kleinau is a Shiatsu practitioner and the director of the ESI Berlin Shiatsu School. She has recently completed a PhD level meta-analysis of the existing research into the effectiveness of Shiatsu. In this webinar Andrea shared the results of her work. This is essential information for all of us Shiatsu practitioners who are looking for evidence of the effectiveness of

what we do. The Webinar was a great success with 77% of attendees polled saying they will now reference research on Shiatsu's effectiveness in their publicity in the future. *You can download Andrea's PhD and the slides from the webinar from the links under the video.* (Shiatsu: The Scientific Basis, 2019)

1.2. Advertising?

The webinar began by openly claiming the focus of it: advertising! After a very brief introduction of the participants, the question that came was something like “do you cite research in your publications and advertising material?”. That might come as a big surprise but it shouldn't be so since both Cliff has excellent communication and advertising skills and Andrea is a communication scientist. In addition, that is often the focus of shiatsu practitioners on many occasions of discussions related to professionalization or research. Yet, it is very questionable if such an approach has anything to do with evidence based methods. It worth to mention that at the beginning of the webinar 75% of the participants indicated that they do not cite research in their publications, while 77% per cent of them answer to the closing poll that they will begin citing after that one-hour webinar! In that perspective, while the initiative for a webinar on the issue of the evidence base for shiatsu is praiseworthy, it is quite questionable if it has helped or made worst the relationship of shiatsu to the evidence based world and shiatsu aim for a professional status overall. It is more expected that such an approach will further deteriorate the advertising practice of the shiatsu practitioners with misleading and unsubstantiated claims, similar to what is often the situation in other manual therapies (Marcon, Klostermann and Caulfield, 2016; Hanna and Honeychurch, 2016).

1.3. What is research from an evidence based approach?

Andrea correctly made the distinction between the clinical experience about shiatsu and research under the evidence based approach, claiming that in the evidence based approach data should be collected systematically something that is usually not the case for the experience accumulated by clinical practice. Her interest in her PhD work (which she partly presented in the webinar) came by her observation that the experience of the practitioners in the clinic is not present in the evidence. Going further and questioning why people visit shiatsu practitioners (a question in which 62% of the participants of the webinar answered “for specific medical problems”), she made the – neutral but still surprising - claim that there has been research about specific health problems that tried to show the effectiveness of shiatsu. Neutral, since indeed there is a very limited amount of evidence for shiatsu in specific health issues, surprising since the lack of evidence in the area of shiatsu is well-known in those active in research and her own work shows exactly this lack of evidence. This introduces a poll questioning “what is evidence based research?”, in which about half of the participants of the webinar answer “any type of formal research” while about 40% answer “only double-blind control studies”. Now, this is quite worrying if we think existing misconceptions of the shiatsu community (but not only) regarding the evidence based approach. Unfortunately, the way that the webinar continues did not help on that perspective.

Without directly answering the question “what is evidence based research”, Andrea said that in order to investigate a clinical field you cannot rely on experience but you need statistical data. She supported her claim saying that this is due to the need to

avoid bias and ensure traceability of the evidence, making sure that it is not about the opinion of a practitioner or a teacher but about data that can be measured and counted. All those are very interesting but... what is the evidence based approach?

The modern evidence based approach in medicine (EBM) appear in the early 1990s (Sur and Dahm, 2011; Claridge and Fabian, 2005). Since then, health care has been extensively transformed in a way that the need for scientific research is a fundamental requirement of medicine (Kamath and Guyatt, 2016). EBM came to take the place of what could be called “expert based medicine” (Smith and Rennie, 2014). On that perspective, we can say that the EBM approach has not touched yet the world of shiatsu. But shiatsu is not alone on that. The EBM approach was resisted by the medical profession too (Grahame-Smith, 1995). While CAM practitioners and researchers overall get engaged with delay in the relevant debate (Wilson and Mills, 2002). But what is EBM? Is it really foreign and incompatible to shiatsu practice as many practitioners believe?

According to what some pioneers of the EBM paradigm wrote in an editorial for the British Medical Journal back in 1996, it is about “integrating individual clinical expertise and the best external evidence” (Sackett et al., 1996). In that editorial titled “Evidence based medicine: what it is and what it isn't” (a highly suggested read) they wrote, besides others:

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and

clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. {...}

Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients. (Sackett et al., 1996)

The misconceptions about EBM are many and often are well-justified. EBM today faces many challenges, and it needs to develop a lot further to bypass them (Ioannidis, 2016). However, it is clear that EBM is the paradigm of health care that dominates current and future practice (Sheridan, 2016).

Evidence based research methods are not easy to directly get adopted by all CAM modalities which in many cases are of a complex nature, involving a combination of multiple traditional or novel interventions (Veziari, Leach and Kumar, 2017; Walker et al., 2014; Coulter et al., 2014). A detailed discussion of the issues of the EBM approach in shiatsu and CAM overall while very useful, exceeds a lot the scope of this review.

In addition, the commonly perceived focus of EBM on the “gold standard” RCTs (especially the placebo-controlled ones) which is a research method designed to answer questions about the efficacy and safety of pharmaceuticals (Bothwell et al., 2016), can cause problems when researching clinical medical fields (Jones and Podolsky, 2015) including CAM (Vickers, 1996). But RCTs are not what EBM is about. Statistical data is not either. EBM research includes evidence of many types and from many sources. Sources of evidence are often put in hierarchical order according to their internal validity (ie. whether the study results are valid for the patients of the study). A version of the “standard” evidence hierarchy pyramid puts at the top the

- Systematic reviews and meta-analyses, followed by
- RCTs
- Cohort studies
- Case-control studies
- Cross-sectional surveys, and at the base
- Case reports (Greenhalgh, 1997).

Yet there are plenty of versions of that pyramid and, even more important, there are alternatives that seem to be more relevant to complex interventions, such as the Evidence House (Jonas, 2001) or the circular approach (Walach et al., 2006). Those consider not only the internal validity but external validity (ie. whether the study results can be used for patients other than the study patients) and model (or ecological) validity (ie. whether the study results can be used in real-life situations, with different practitioners, facilities, context etc.). Even the traditional pyramid has been recently modified by the EBM Working Group by putting at the top of it the randomised n-of-1

trials (experimental cross-over trials where the single patient is the control of itself) (Guyatt et al., 2000).

Another misconception goes even further. As described above, EBM is not about RCTs. It is not about quantitative evidence only either. The quantitative approach of inquiry has indeed dominated clinical health research for decades (Britten, 2005). Quantitative RCTs are usually considered the gold standard of medical knowledge because they can control efficiently confounding variables isolating the effect of the tested treatment, achieving high levels of internal validity and implying causality. Unfortunately, this is often at the cost of the external and model validity of the study (Khorsan and Crawford, 2014), making this approach not favourable for assessing the efficacy of CAM (Verhoef, Casebeer and Hilsden, 2002) or patients with multiple comorbidities (Fortin, 2006).

But if not numbers and statistics, then what? Qualitative research methods aim to seek answers by asking non-quantifiable questions and are more appropriate for “what”, “how”, “why” types of questions (Green & Thorogood, 2004, p.5). Their relevance to EBM lies in their ability to examine questions that are not easily answerable by the quantitative approach (Green and Britten, 1998; Pope and Mays, 1995).

Besides, a third approach had also appeared and is developing, namely the mixed methods research approach. In the first issue of the Journal of Mixed Methods Research, it is defined as:

[...] research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry. A key concept in this definition is integration [...] Tashakkori & Creswell (2007, p.4)

More recently, the NIH's Office of Behavioural and Social Sciences Research released a "best practices" guide for mixed methods research in the health sciences where mixed method research is defined as:

[...] a research approach or methodology:

- focusing on research questions that call for real-life contextual understandings, multi-level perspectives, and cultural influences;
- employing rigorous quantitative research assessing magnitude and frequency of constructs and rigorous qualitative research exploring the meaning and understanding of constructs;
- utilizing multiple methods (e.g., intervention trials and in-depth interviews);
- intentionally integrating or combining these methods to draw on the strengths of each; and
- framing the investigation within philosophical and theoretical positions. (Creswell et al., 2011, p.4)

Mixed methods fit well with the Evidence House idea of Jonas (2001), being able to generate evidence containing both statistically causal inferences and more complex, non-reductive qualitative explanations.

1.4. The meta-analysis

So, how those misconceptions were perpetuated in the webinar? It is probably due to the nature of the specific study that Andrea undertook in her PhD. Here we just examine her study in the perspective of the issues identified above, not as a study itself. Andrea correctly describe aspects of the quality assessment (essentially assessment of the internal validity) she had to complete before she can consider a

study for inclusion in the meta-analysis. She considered 1785 papers (the search terms include “acupressure” which is why so many records returned) of which just six satisfy the eligibility criteria of the study. It is quite common for meta-analysis to consider only RCTs, yet this is not necessarily how things have to be done. Even in the meta-analysis level, the previously described diversity of study approaches inside the EBM approach is possible to successfully exploited as long as this help to answer the research question (Borenstein et al., 2009). Andrea’s study indeed does not include only RCT’s, while herself spoke for the need of different designs and a “mega-meta-analysis” as she called it. But unfortunately, that issue wasn’t developed in the webinar at a level that could make the non-specialised participants to question the quantitative-RCT-EBM misconception.

1.5. Case studies, case reports and normal practice

Andrea spoke about studies from Japan that cannot be used scientifically (implying the EBM misconception described above) but being good descriptions of cases. Yet here there is another misconception that is widespread in the shiatsu community as previous discussions in the mailing list of the Shiatsu Research Network indicate. The one between case studies and case reports, which was extended further during the webinar to include the practitioner’s clinical case records too. Thus a brief attempt to separate the meanings:

A case study is a research method of qualitative nature that is well suited for mixed methods research too (Yin, 2014, p.65). It demands a wide variety of research skills and multiple sources of data. It is a good approach when complex phenomena are to be understood (“how” and “why” questions), with the demand of an extensive, in-depth description of a “case”, retaining a holistic and real-world, naturalistic perspective (Yin,

2014, p.4). Case studies can nicely complement quantitative experimental designs (like RCTs), and inform pilot studies by forming a working hypothesis or better focusing new research (Yin, 2014, p.40). As all research involving humans, case studies require prior ethics approval in order to be done.

A case report is a way to describe and analyse events with previously unreported characteristics that occurred clinically, usually in one or two patients, as well as their management. They are retrospective descriptions and constitute the first level of evidence, over which all the research hierarchy is built. Case reports do not need prior ethics approval (naturally since they are just retrospective descriptions of events already occurred without research intention) yet the informed consent of the patient should be ensured for the manuscript prior to the submission to a journal. Writing case reports is probably the most appropriate way for practitioners to get familiar with the demands of scientific writing and reporting for peer-reviewed journals, require relatively short training and can have a very important influence on the evidence base for modalities with lack of evidence, such as shiatsu.

Clinical case records refer to the systematic documentation of the health history and care of a patient. They are extensively used by all kind of healthcare providers and depending on the local professional, regulatory and legal status of shiatsu they might be a requirement for professional practice. Usually, during the basic training of the practitioners, there is a requirement for record keeping but not so often training on its technique. Clinical case records are not research but they can be used in research or audits of clinical practice. They are not publishable as such and the legal requirements for the protection of the personal data should be followed. Well-kept clinical case records are not only an element of good professional practice and quality healthcare delivery but can support well-documented research too.

During the webinar and while wondering about how the effectiveness of shiatsu could be presented, Cliff suggested that the record keeping should become a requirement for the normal practice. Even if that does not answer to the question, since clinical case records are not part of the evidence as such, it is a step towards higher professional standards and it is something that professional associations should consider seriously as long as shiatsu is considered healthcare and shiatsu practitioners professionals.

1.6. Experience and STRISS

Continuing on the issue of the Japanese studies, Andrea made the observation that there were no useful details regarding the qualification of the practitioners or the treatment environment. Unfortunately, that is the case for most of the studies about shiatsu, independent of their origin. She recommended to associations (something to wonder about, why to recommend to associations? Research is not done by associations but by researchers) to include experienced and well-known practitioners in research while Cliff was wondering what role the experience of the practitioners might play in research and if related data could be used in research.

The idea of getting “the best” practitioners to be included in research should be debated vigorously. One of the participants mentions that in the research project for her bachelor there was no effect of the experience of the practitioner in the results. Currently, there is no evidence of such an effect in shiatsu studies. To the knowledge of the author, only an ongoing PhD study aims to explore specifically the therapist effect in the treatment with shiatsu of people with multiple sclerosis (Esmonde, van Wersch and Harland, 2014). Thus such a recommendation is partly unfounded, yet understandable. But good marketing intentions (“let’s get the best practitioners (if such

a thing exist) to show the best results) are not necessarily good research practice. What shiatsu need is not to present evidence of the “best” practitioners but evidence for the common practitioners. It is important for studies to have strong model validity for their results to be generalizable, since the average patient is not going to be treated by “the best” practitioner but by an average practitioner as most of us are.

Overall, the opening of those issues in the webinar is another indication of the need for the previously proposed in SRN discussions STandards for Reporting Interventions in Shiatsu Studies (STRISS). Even if it might not be good practice to include only very experienced practitioners in research projects, it is good practice to report details about the practitioners and the overarching setting of the treatment. With the results of the study about the therapist effect unpublished, we can only speculate by saying that the experience is not the only factor that might play a role. Much richer description of the elements that might play a role in the therapeutic setting would be good to be included in research publications and, even better, to be integral elements of rich study designs that go beyond pure statistics.

1.7. Slightly superior?

The results of the meta-analysis as presented in the webinar show that shiatsu was slightly superior either to placebo or to a comparator intervention. That was explained in terms of a notion that “if treatment was good, by adding shiatsu it was better”. The same approach continued by Cliff when he began saying that many medicines are also just slightly better than placebo in studies or overall that it is a myth that western medicine is clinically proven and related ideas in order to claim that as shiatsu community we are not alone on that, as well as that it is not true that shiatsu is not effective but it is just difficult to show its effectiveness using evidence-based methods,

bringing as example the blinding difficulties (lack of a proper sham type of shiatsu, an issue not discussed in that review).

The only thing that we can agree to is that it is difficult to show effectiveness using evidence based methods. Otherwise, the relevant arguments presented in the webinar are nothing more than logical fallacies and are not going to be discussed in detail in that review. To oversimplify, in RCTs it could always be expected that if shiatsu is added to a good treatment the result will be slightly better. This is true for interventions associated with important nonspecific effects (including, for example, the therapeutic relationship, the additional care or patient expectations) when subjective outcome measures are used. But does that mean something? In the opinion of the author means that there is a lot of work in front, to develop the right research methodologies and designs that will be better able to document robustly the effect of shiatsu, whatever that is. What does not mean for sure is that with the few hundred studies about shiatsu “we are at the same boat” with the dominant medical paradigm for which tens of millions of studies are available with some hundreds of thousands new studies produced each year.

1.8. On the presented studies

Even if the length of the present review already reaches the limits of lay readability, it worth to briefly comment on the studies that were presented as “Which conditions have been shown to be better treated by Shiatsu?” in the webinar. In the opinion of the author, their presentation was quite problematic, missing important elements of the studies and not properly referenced in the presentation slides. Yet a critical assessment of the studies themselves is not on the aims of the review.

The first two studies were about fibromyalgia.

The one by Field et al. (2002) describes the experimental trial procedure as “a combination of several types of massage including Swedish massage and shiatsu, consisted of moderate pressure stroking of the head, neck, shoulders, back, arms, hands, legs, and feet for 30 minutes”. In detail:

The massage began with lengthening and stretching of the neck and spine with the hands positioned under the head and neck, followed by stroking the forehead and face. Pressure was applied to the tender points, and the shoulders were gently depressed. The arms and legs were stretched, and the arms were lifted and moved in a circular motion as in a Trager massage. Finger pressure was applied to the palms of the hands and the soles of the feet, with extra pressure given to the tender points. Stroking was then continued from the top to the bottom of the limbs. Medium pressure squeezing was applied to the upper shoulder and neck area, and light, brisk rubbing movements were performed along the spine. The massage was concluded in each position with gentle rocking and more stroking from head to toe. (Field et al., 2002)

The relevance of the study to shiatsu as such is left to the judgment of the readers.

The second by Yuan, Berssaneti and Marques (2013) was a non-randomized controlled pilot study following a standardized (and described in detail) shiatsu protocol. The intervention group receive the usual pharmaceutical treatment plus shiatsu while the control group receive the usual pharmaceutical treatment plus being in the waiting list for usual care. Even if the study as such is interesting clinically and relevant to shiatsu, as a pilot (or feasibility study) it does not evaluate effectiveness, something that should be left to the main study. Its aim is to help to design the main study by testing the feasibility, safety, acceptability, sample size and other elements

of it (Vogel and Draper-Rodi, 2017). To the knowledge of the author, the pilot study was not followed by the main study so far. Besides, it worth to mention that the registration of the trial (Yuan, 2012) did mention randomisation, yet the results published do specifically indicate in the limitations of the study that “the assignment of patients into the groups was not randomized, and the assessment was not blinded because of logistic difficulties” (Yuan, Berssaneti and Marques, 2013).

The next two studies were related to gynaecological complaints.

The one by Kul (2011) was a medical dissertation, yet it was possible to get access to its abstract only. Without being able to comment to its full content, the study has an interesting element since, besides patient-reported outcome measures such as the Menopause Rating Scale (MRS II), it uses objective measures too (cortisol values). The design was a wait list control randomised trial (ie. both groups receive treatment). Yet, once again, this was a feasibility study. Thus its conclusions cannot be related to the effectiveness of shiatsu but, as the abstract mention too, to the safety, acceptability and compliance with the design, which indicates the desirability of a main study with methodological adjustments in order to investigate the efficacy of shiatsu on menopausal symptoms. To the knowledge of the author, this pilot study was not followed by the main study so far.

The other study by Ingram, Domagala and Yates (2005) refers to self-application of stimulation in three acupoints by women in post-term labour. In detail

the shiatsu points taught to women were {...} GB-21 {...} LI-4 {...} and SP-6 {...}.

Each point has a slightly different effect, so all points were shown and held with thumb pressure as deep as the woman found to be comfortable until a reaction was felt. If a reaction was felt on the point, then the woman was

encouraged to work the point as deeply and firmly and for as long and often as was comfortable. If a woman experienced no reaction from a point, then she would probably not use that particular point. If her partner was present, they were also shown how to work the point with pressure.

The women were also taught simple breathing techniques and exercises on all fours (rocking, squats, cat arches). Each session took no more than 15 min and the women were then encouraged to use the shiatsu points at home as often as it felt comfortable using firm pressure. (Ingram, Domagala and Yates, 2005, p.12)

The relevance of the study to shiatsu as such is left to the judgment of the readers.

Regarding its design, the study was a pilot audit on the use of the techniques for post-term pregnancy. As a pilot no effectiveness conclusions are possible, yet due to the way it was discussed in the webinar, we will mention two aspects of the clinical results: the women who get trained to the techniques were more likely to go to spontaneous labour, while they had longer labours with the same usage of analgesia (including the Entonox gas which is one of the simplest and non-invasive analgesias in labour) as those who didn't get trained. The conclusions of the study cannot be something else than the fact that this pilot raise the hypothesis for the possible effect of the techniques used on post-term pregnancies.

Overall, the way those studies were presented in the webinar, especially considering the title used, is at least misleading with a bias in favour of shiatsu, when in fact what they indicate is exactly the lack of robust evidence for shiatsu.

1.9. Limitations and Conclusions

This critical review of the webinar has all the limitations of a rapid review which was completed in a short time after watching the webinar and took just about three working days to be completed. It tried to balance between a scholar and a plain language review, without always succeeding at it. The limited reference usage comes from literature already known to the author, with the aim to help the readers that wish to go deeper in some of the issues. The issues discussed are chosen with the idea of dissolving some misconceptions that the author had identify to exist in the shiatsu community and this webinar seems to perpetuate. The review does not aim to examine the scientific work of Andrea, the PhD dissertation of whom the author has only briefly read in the original German language some months before the webinar.

Overall, the examined webinar while probably successful from the perspective of the number of participants and the positive comments that have receive so far, lacks a lot behind if its aim was to present the evidence base for shiatsu. What it did succeed is to bring in the surface misconceptions that the shiatsu community has about research and the evidence based approach. Its critic is a warning against an "instrumental" use of evidence for advertising and publicity purposes. Communication and advertising skills are important in many perspectives. Shiatsu schools, teachers, associations, practitioners and researchers need them. The recent attempts with those webinars or the recent focus of the European Shiatsu Federation and other associations in publicizing research related topics are welcomed, yet without well-developed research literacy skills risk to blow-back and discredit shiatsu community as a whole.

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