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Shiatsu for chronic lower back pain: Randomized controlled study

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ABSTRACT

Background: Although Shiatsu, a kind of complementary alternative medicine, was developed in Japan and is practiced around the world, no experimental studies on Shiatsu have been conducted. The aim of this study is to investigate the efficacy of Shiatsu therapy for chronic lower back pain.

Method: We conducted a prospective, randomized, open, blinded-endpoint design study at St. Luke's International Hospital, Tokyo, Japan from 2015 to 2017. Patients with lower back pain for more than 12 weeks and a score of four or more on the Roland-Morris Disability Questionnaire (RMDQ) at baseline were included in this study. We excluded patients with severe conditions, such as bone metastasis, or dementia. Patients were randomly allocated to either Shiatsu therapy in addition to standard care or standard care only by computer randomization. Those allocated to Shiatsu received one-hour Shiatsu every week for four weeks. Our primary outcome was improvement of RMDQ, and secondary outcomes were improvement of Short-Form McGill Pain Questionnaire (SF-MPQ), Oswestry Disability Index (ODI) and EQ-5D after 4 weeks and 8 weeks. Bivariate analyses were applied for assessing statistical significance.

Result: Fifty-nine patients were included; 30 were allocated to Shiatsu, and 29 to the control group. None of the baseline characteristics were significantly different between groups. Twenty seven patients (90%) in the Shiatsu group and 24 patients (83%) in the control group completed the study. At week 4, Shiatsu group tended to show greater improvement only in EQ-5D (difference 0.068, $p = 0.07$), but not statistically significant, compared to control group, wheres other outcome measures were similar between the groups. At week 8, those in the Shiatsu group tended to have greater improvement in RMDQ (difference 1.7, $p = 0.08$) compared to the control group. The Shiatsu group showed greater improvement in present pain scale of SF-MPQ (difference 0.5, $p < 0.05$), ODI (difference 4.0, $p < 0.01$) and EQ-5D (difference 0.099, $p = 0.01$) compared to control group.

Conclusion: In our limited sample trail, Shiatsu therapy combined with standard care for lower back pain improves some symptoms and QOL shortly after Shiatsu therapy.

1. Introduction

Shiatsu is a form of Japanese body work that was developed in the 1920s by Tokujiro Namikoshi.[1] Shiatsu activates natural healing power to alleviate symptoms by pressing Shiatsu points on the whole body with thumbs and palms, according to the concept of oriental medicine.[2] A Shiatsu license is a national certification obtained through at least three years of training in colleges in Japan.[3] In 2016, the total number of massage and Shiatsu practitioners was more than 110,000 and 21 colleges offered Shiatsu training courses in Japan.[4] Shiatsu therapy is now covered by governmental health insurance for certain conditions. As a result, it is estimated that more than 115.3 million patients have received Shiatsu or massage in Japan.[5] Now, Shiatsu is widely accepted and practiced in many Western countries.[6] The European Shiatsu Federation, with representatives from nine European countries, reported that many people, especially women in their 40 s, receive Shiatsu to maintain or improve their health.[7] The Canadian Shiatsu Society provides a certificate course to expand Shiatsu practice.[8] Therefore, Shiatsu has become one of the most popular complementary alternative medicines in the world.

Shiatsu may have numerous favourable effects to improve patients' health. One of the most common indications for Shiatsu is neck and back pain.[9,10] Shoulders and legs are also commonly treated with Shiatsu therapy. In addition, Shiatsu may be effective for angina,[11]

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burns,[12] and post-term pregnancy.[13] Moreover, internal medicine problems, such as worsening cardiac conditions or hypertension, might be mitigated by Shiatsu therapy.[1] In addition to the physical effects of Shiatsu, psychological improvements have been reported.[14] One study reported that adjunct treatment with Shiatsu may clinically improve schizophrenia.[15]

However, evidence for the efficacy of Shiatsu on any symptoms or conditions has not been reported.[6,16] A systematic review found only one randomized controlled trial (RCT), three nonrandomized trials and five observational studies.[6] The RCT evaluated the efficacy of Shiatsu on neck and back pain.[17] Although the study had a fair sample size, the authors did not evaluate improvement of pain but instead only evaluated quality of life (QOL) by using the SF-36, which did not yield significantly different results between the Shiatsu and control groups.[17] Three nonrandomized trails that evaluated efficacy of Shiatsu for chronic stress,[18] severe angina,[11] and post-term pregnancy[13] did not produce strong evidence. Therefore, high-quality studies of Shiatsu therapy are required to support the practice of Shiatsu practice.

The aim of this study is to evaluate the efficacy of Shiatsu therapy on chronic back pain by conducting a randomized controlled trial.

2. Methods

We conducted a prospective, randomized, open, blinded-endpoint design study at St. Luke's International Hospital, Tokyo, Japan from 2015 to 2017. This study was approved by the ethical committee at the hospital (14-R157) and registered in the UMIN Clinical Trials Registry (UMIN000017146). Ambulatory patients with lower back pain were included in this study. Patients were randomly allocated to Shiatsu in addition to standard therapy or standard therapy only based on computer randomization. Our primary outcome was improvement of Roland-Morris Disability Questionnaire (RMDQ)[19] and secondary outcomes were improvement of Short-Form McGill Pain Questionnaire (SF-MPQ),[20] Oswestry Disability Index (ODI)[21] and EQ-5D at week 4 and week 8.

2.1. Study participants

Ambulatory adult patients with lower back pain for more than 3 months and four or more score in RMDQ[19] at baseline were included in this study. We excluded those with bacterial spondylitis, malignancy or metastasis on vertebra, acute compression fracture and collagen disease, such as ankylosing spondylitis.[22] All potential participants were evaluated by physical examination, blood test and X-rays to identify any exclusion factors. Board certificated radiologists interpreted the X-rays. In addition, patients who had prior diagnosis of dementia were excluded. All potential participants underwent Mini Mental State Examination (MMSE)[23,24] and those with a score of less than 24 were excluded. Written consent forms were obtained from all participants. Those who received complementary alternative medicine, including Shiatsu, within one year of the study were also excluded.

Potential participants were evaluated whether to be included to the study according to the following process. Potential participants were explained about the study and both history about back pain and medical history were taken by investigators at their first visit. If the potential participants were willing to participate in the study and didn't meet any exclusion criteria on histories, they completed all above questionnaires. When patients had four or more score in RMDQ, then, participants underwent blood test and X-ray. Participants were finally included to the study when results of blood test and X-ray had no evidence for exclusion criteria.

2.2. Intervention

We randomly assigned participants to Shiatsu therapy group or standard care group. Participants in both the Shiatsu therapy group and the standard care group received conventional pain relief by compress or oral medicine based on the World Health Organization (WHO) pain relief ladder.[25] Patients assigned to the Shiatsu therapy group also received one-hour of Shiatsu therapy once a week for four weeks, followed by four weeks of standard care only. Shiatsu therapy was administered by a national licensed Shiatsu providers with at least three years of experience. To provide generalized therapies for all participants in the Shiatsu therapy group, all Shiatsu providers completed a standardized training course for this study and were evaluated for their performance. The protocol for standardized Shiatsu therapy was uploaded elsewhere (supplemental file). Those assigned to standard care received only conventional pain relief for eight weeks. They received two free vouchers for Shiatsu when they completed the study.

2.3. Outcomes

Our primary outcome was improvement of RMDQ, and secondary outcomes were improvement of SF-MPQ, ODI and EQ-5D. Investigators for each questionnaire were blinded to allocations of interventions. Outcomes were measured at week 4 to evaluate immediate effects of intervention and at week 8 to evaluate the long-term effects of intervention.

2.4. Randomization and statistical analysis

Participants were allocated to the Shiatsu therapy group or standard care group according to a computer-generated randomization list. The computer-generated randomization list was developed with STATA by the randomization manager, who was independent from any investigators. Only the manager could access the randomization list. A simple randomization procedure was applied. After completing inclusion evaluations, research assistants directly contacted the randomization manager in order to conceal allocation from investigators and analysts, but patients were not blinded. Implementation of Shiatsu therapy was confirmed by Shiatsu practitioners and investigators were informed at the end of the study. Sample size was determined based on 2.5 of difference and 4.7 of standard deviation in RMDQ with $\alpha = 0.05$ and $\beta = 0.90$. [26] Eighty-five samples were required for each arm, allowing for 10% dropout. The Fisher's exact test and Mann-Whitney U test were applied to compare baseline characteristics and improvement of outcome measures at weeks four and eight. Both per-protocol analysis and intention-to-treat analysis were performed to confirm the result. In intention-to-treat analysis, for those lost to follow-up, outcomes were imputed by carrying the last known outcome status [27]

3. Results

This study was terminated with limited number of participants due to the expiration of funding before recruitment was completed. Fifty-nine patients were included; 30 were allocated to the Shiatsu therapy, and 29 were allocated to the standard care group (Fig. 1). The mean age was 67.8 (standard deviation (SD):13.5), and 21 patients (35.6%) were male. Table 1 shows the comparison of the baseline characteristics between those in the Shiatsu therapy group and the standard care group. All characteristics, including demographic data and the condition of back pain, were similar between the two groups.

At week 4, 27 patients (90%) in the Shiatsu group and 24 patients (83%) in the standard care group presented for follow-ups. Table 2 shows the comparison of outcome improvements between the two groups. In terms of severity of back pain and disability questionnaires, improvements were similar between Shiatsu therapy and standard care groups. In contrast, those in the Shiatsu therapy group tended to have greater improvement of EQ-5D scores, but not statistically significant, compared to those in the standard care group according to both the per-protocol analysis (0.091 vs. 0.023, $p = 0.07$) or intention-to-treat analysis (0.076 vs. 0.018, $p = 0.08$).

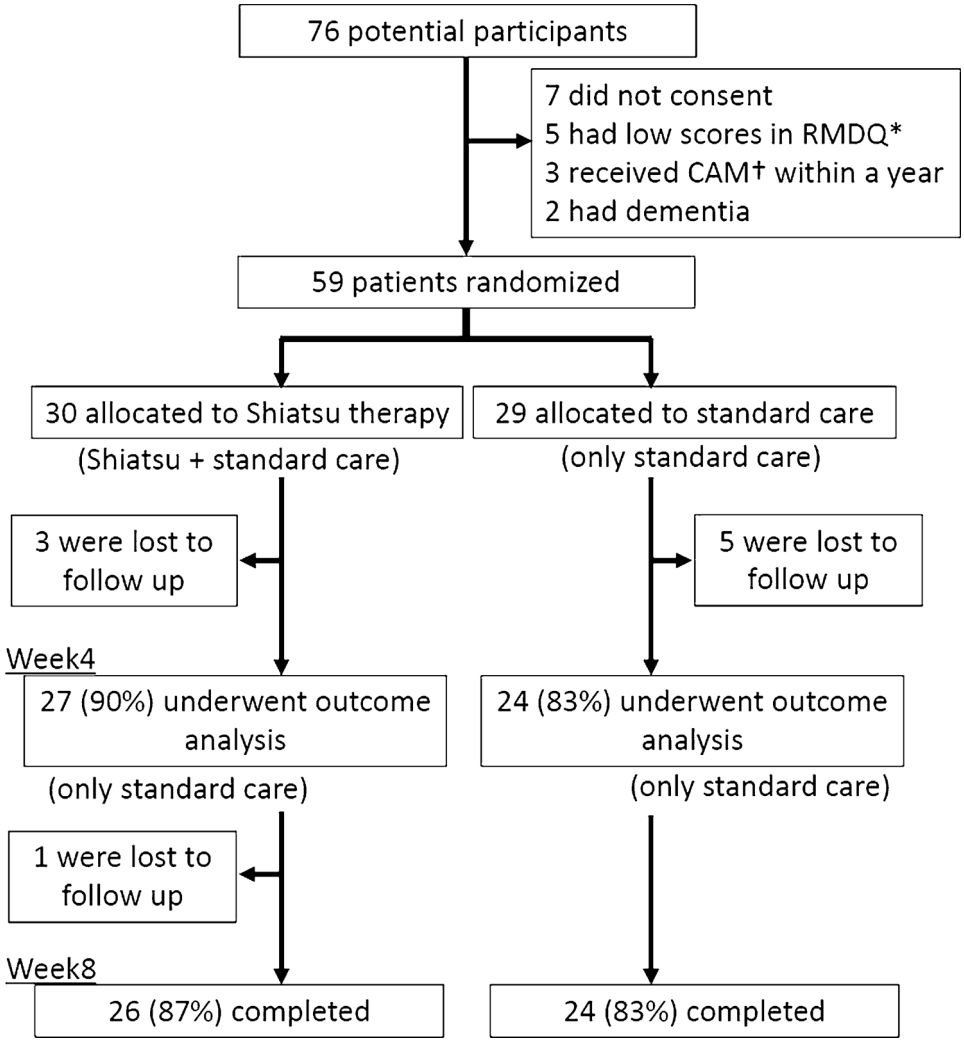

Fig. 1. CONSORT flowchart.
*RMDQ: Roland-Morris Disability Questionnaire, †CAM: Complementary alternative medicine.

At week 8, 26 (87%) in the Shiatsu group and 24 (83%) in the standard care group completed the study (Table 3). Those in the Shiatsu therapy group tended to have better improvement of RMDQ according to both the per-protocol analysis (3.4 vs. 1.7, difference 1.7, $p = 0.11$) and the intention-to-treat analysis (3.0 vs. 1.4, difference 1.6, $p = 0.06$), but not statistically significant. Total scores in SF-MPQ significantly improved according to the intention-to-treat analysis (3.9 vs. 1.3, difference 2.6, $p < 0.05$), but not to the per-protocol analysis (4.3 vs. 1.6, difference 2.7, $p = 0.06$). Statistically significant improvements were observed in present pain intensity in SF-MPQ (0.7 vs. 0.2, difference 0.5, $p = 0.04$ in intention-to-treat analysis), ODI (4.6 vs. 0.6, difference 4.0, $p < 0.01$ in per-protocol analysis; 4.1 vs. 0.5, difference 3.6, $p < 0.01$ in intention-to-treat analysis) and EQ-5D (0.110 vs. 0.011, difference 0.099, $p = 0.01$ in per-protocol analysis; 0.096 vs.

Table 1
Comparison of baseline characteristics between patients in the Shiatsu therapy and standard care groups.

	Shiatsu therapy ($n = 30$)	Standard care ($n = 29$)	p-value
Demographics			
Age, mean (SD)	67.4 (12.2)	68.3 (15.0)	0.55
Male, n (%)	10 (33.3)	11 (37.9)	0.79
Height, mean, cm (SD)	158.3 (6.9)	157.8 (8.2)	0.59
Weight, mean, kg (SD)	55.1 (10.9)	58.4 (9.8)	0.12
Body mass index, mean, kg/m^2 (SD)	21.8 (3.4)	23.4 (3.3)	0.07
Measurement for Back pain			
Duration of back pain, median, month (IQR)	180 (66-360)	240 (120-360)	0.61
Roland-Morris Disability Questionnaire, mean (SD)	8.6 (3.2)	9.1 (4.0)	0.80
Short-Form McGill Pain Questionnaire			
Total score of descriptors, mean (SD)	9.9 (6.5)	8.7 (5.5)	0.54
Visual analog scale, mean, cm (SD)	4.5 (2.2)	4.8 (2.0)	0.49
Present pain intensity, mean (SD)	2.4 (0.8)	2.3 (0.8)	0.83
Oswestry disability index, mean, % (SD)	15.5 (4.6)	14.6 (4.5)	0.26
EQ-5D, mean, % (SD)	0.673 (0.083)	0.685 (0.111)	0.53

Table 2
Improvement of outcomes at week 4 between Shiatsu group and standard care group.

	Per-protocol analysis			Intension-to-treat analysis		
	Shiatsu therapy (n = 27)	Standard care (n = 24)	p value	Shiatsu therapy (n = 30)	Standard care (n = 29)	p value
Improvement of RMDQ*, mean (SD)	2.2 (3.4)	2.2 (3.6)	0.73	2.0 (3.2)	1.7 (3.3)	0.54
Improvement of SF-MPQ†, mean (SD)						
Total score of descriptors	4.4 (4.2)	3.0 (4.6)	0.27	3.9 (4.2)	2.3 (4.2)	0.16
Visual analog scale, cm	1.1 (1.9)	0.9 (2.3)	0.90	1.0 (1.8)	0.7 (2.1)	0.87
Present pain intensity	0.4 (0.8)	0.4 (0.8)	0.83	0.4 (0.8)	0.3 (0.8)	0.61
Improvement of ODI§, mean, % (SD)	2.7 (4.7)	1.5 (5.2)	0.38	2.4 (4.5)	1.2 (4.6)	0.28
Improvement of QOL‡ in EQ-5D, mean, % (SD)	0.091 (0.129)	0.023 (0.096)	0.07	0.076 (0.123)	0.018 (0.086)	0.08

*RMDS: Roland-Morris Disability Questionnaire, †SF-MPQ: Short-Form McGill Pain Questionnaire, §ODI: Oswestry Disability Index, ‡QOL: quality of life Numbers in bold represent that the p value is less than 0.05.

Table 3
Improvement of outcomes at week 8 between Shiatsu group and standard care group.

	Per-protocol analysis			Intension-to-treat analysis		
	Shiatsu therapy (n = 26)	Standard care (n = 24)	p value	Shiatsu therapy (n = 30)	Standard care (n = 29)	p value
Improvement of RMDQ*, mean (SD)	3.4 (3.0)	1.7 (3.7)	0.11	3.0 (3.0)	1.4 (3.4)	0.06
Improvement of SF-MPQ†, mean (SD)						
Total score of descriptors	4.3 (4.8)	1.6 (5.4)	0.06	**3.9 (4.7)**	**1.3 (4.9)**	**< 0.05**
Visual analog scale, cm	1.5 (2.3)	0.8 (2.2)	0.15	1.4 (2.2)	0.6 (2.1)	0.07
Present pain intensity	0.8 (0.9)	0.3 (1.0)	0.05	**0.7 (0.9)**	**0.2 (0.9)**	**0.04**
Improvement of ODI§, mean, % (SD)	**4.6 (5.2)**	**0.6 (5.0)**	**< 0.01**	**4.1 (5.1)**	**0.5 (4.5)**	**< 0.01**
Improvement of QOL‡ in EQ-5D, mean, % (SD)	**0.110 (0.145)**	**0.011 (0.110)**	**0.01**	**0.096 (0.140)**	**0.009 (0.100)**	**0.01**

*RMDS: Roland-Morris Disability Questionnaire, †SF-MPQ: Short-Form McGill Pain Questionnaire, §ODI: Oswestry Disability Index, ‡QOL: quality of life Numbers in bold represent that the p value is less than 0.05.

0.009, difference 0.0.087, p = 0.01 in intention-to-treat analysis) in the Shiatsu therapy group compared to the standard care group. Only visual analog scale scores were statistically similar between Shiatsu therapy and standard care groups.

For adverse events, 3 patients reported muscle pain and 1 patient reported headache in the Shiatsu group, while 1 patient reported dizziness, 1 reported herpes zoster and 1 reported abdominal pain in the standard care group.

4. Discussion

In our randomized controlled trial, patients with chronic backpain who received Shiatsu therapy in addition to standard care tended to have significant improvement of EQ-5D at week 4 and improvement of RMDQ and SF-MPQ at week 8, but not statistically significant and significant improvement of ODI and EQ-5D at week 8 compared to those who received standard care alone. These improvements of symptoms and QOL were considered to be clinically meaningful. In terms of RMDQ, Stratford et al. suggested that a minimum clinically important change is 1–2 points for patients with little disability.[28] Our patients with Shiatsu therapy had 2.2 points improvement from baseline to week 8 and 2.6 lower points than those with standard care at week 8. In terms of QOL, Tsiplova et al. estimated the minimum important difference (MID) for chronic back pain as 0.096.[29] In our sample, patients with Shiatsu therapy had 0.096 improvement in QOL from baseline to week 8 and 0.077 higher QOL score compared to those with standard care at week 8.

Unlike other complementary alternative medicines, Shiatsu therapy had better effects on symptoms of chronic back pain in the short-term compared with immediate-term. Previous systematic review and meta-analysis of spinal manipulation on chronic back pain concluded that there was no clinically relevant difference between spinal manipulation and other interventions.[30] Some studies reported that patients received benefits immediately after spinal manipulation and the benefits became less over time.[30,31] Although massage or acupuncture suggested short-term improvement in symptoms for chronic low back pain,[32,33] immediate-term improvement was larger than short-term improvement.[34–36] Although our study evaluated only immediate and short-term effectiveness of Shiatsu for chronic lower back pain, long-term effectiveness for chronic back pain should be evaluated in the future.

In addition to mitigation of symptoms for chronic lower back pain, Shiatsu therapy improved patient's QOL score immediately after therapy and in short-term by approximately 0.1. The magnitude of QOL score improvement by Shiatsu therapy was considerable. A previous randomized controlled study with nonsteroidal anti-inflammatory drugs for lower back pain demonstrated improvement of QOL by 0.1-0.2 after intervention.[37] Another randomized controlled study with intradiscal biacuplasty for lower back pain showed 0.13 improvement after intervention.[38] In terms of complementary alternative medicine, massage improved QOL score by approximately 0.05[39] and acupuncture improved QOL score by 0.2.[40] Compared to these conventional therapies or other complementary alternative medicines, Shiatsu therapy is still valuable for improvement of QOL score among patients with chronic lower back pain.

The reasons for the fact that both symptoms and QOL score among patients with lower back pain had improved shortly after Shiatsu therapy rather than immediately after therapy, which was not observed in other complementary alternative medicines, are unknown. However, the following characteristics of Shiatsu therapy might play a role. First, Shiatsu therapy is aimed to prevent and cure illness by stimulating the body's natural powers of recuperation, eliminating fatigue-producing elements and promoting general good health. [1] In addition, Shiatsu therapy is not only a localized treatment, which would have temporal effects but is also whole-body treatment.[1] Moreover, patients may have favourable effects from communication with Shiatsu practitioners. Emotional social support resulting from communication may be one of the important effects of CAM.[41,42] These characteristics of Shiatsu therapy may induce later-onset benefits on chronic lower back pain.

There are some limitations in our study. First, patients were not blinded, although investigators were blinded. Because patients know

which groups they belonged to, those allocated to Shiatsu therapy may have positive placebo effects, while those allocated to standard care may have negative placebo effects. All participants may be somewhat interested in Shiatsu therapy, so they would expect positive effects of Shiatsu. Although placebo effects may play some role in the improvement of symptoms or QOL, the placebo effect itself is considered to be a part of the effectiveness of complementary alternative medicine. Similar to placebo effect, other effects, such as emotional social support as we discussed above, may play somewhat roles in our findings. Therefore, our findings may be effectiveness of Shiatsu therapy rather than rigorous efficacy on lower back pain. In addition, we could include only limited number of participants because recruitment was terminated due to expiration of funding and not all participants completed the study. Therefore, external validity of the findings from this study may be limited. Another limitation was that Japanese participants may be enthusiastic to Shiatsu therapy, because it was developed in Japan. People in other countries may have different effectiveness from Shiatsu therapy. Further fully powered studies were required to investigate efficacy and its validity.

5. Conclusion

In our limited sample trail, Shiatsu therapy combined with standard care for lower back pain improves some symptoms and QOL shortly after Shiatsu therapy.

Conflict of interest

None of the authors have any conflict of interest.

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Details of trial registration

The name of the registry: UMIN-CTR

The trial number: UMIN000017146

The trial URL: https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000019887.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ctim.2019.05.019.

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