

Fu's subcutaneous needling versus massage for chronic non-specific low-back pain: long-term follow-up results from a randomized controlled clinical trial

Hypothesis

In comparison with respective baseline data, either Fu's subcutaneous needling(FSN) therapy or massage therapy will improve outcomes of chronic non-specific low back pain (NLBP) patients in short - and long-term follow-up. FSN therapy will be more effective than massage therapy for treating chronic NLBP in both short-term and long-term follow-up.

Aims

Compare the post-treatment, 3-month, and 12-month clinical outcomes in patients with chronic NLBP who receive FSN therapy versus massage therapy.

Goals

FSN therapy has been widely used in the treatment of pain-related musculoskeletal disorders, and achieved a satisfactory therapeutic effect. However, previous studies just focused on the immediate or short-term effects of FSN therapy in the treatment of LBP, and did not categorize LBP rigorously. A rigorous evaluation of the long-term curative effect of FSN therapy is still lacking. This study will prove that the FSN treatment is effective in chronic NLBP at short-medium- and long-term. This study will also discuss the underlying mechanisms regarding how FSN therapy effectively release the affected muscle to achieve the therapeutic effect.

1. Introduction

Non-specific low back pain (NLBP) is a global health issue that affects people of almost all ages and cause deterioration of physiological function and disability.[1] NLBP is defined as pain without any specific detectable pathoanatomical cause, mainly affecting the lumbosacral area, located from the bottom of ribs to inferior gluteal fold. [2-3] It was reported that about 70-85% of people would experience NLBP at least once in their lifetime.[4] Approximately 90% of patients with NLBP recover within a few months of onset. [5] However, about 10% of patients would develop chronic NLBP, which accounted for more than 90% of the economic burden of back disability. [6] Recurrence of low back pain is common, especially in the working population, with the percentage of episodes ranging from 20% to 44% within 1 year and a lifetime recurrence rate of up to 85%. [5,7] NLBP is listed as the fifth most common reason for medical consultation in the United States which imposes a tremendous burden on this nation. [8] The direct treatment costs of NLBP are estimated to range from \$12 billion to \$90 billion per year in the United States.[9] Similarly, in the United Kingdom, the total cost of medical care for NLBP patients has doubled, increased from about \$500 in 2005 to \$1,100 in 2010. [10]

Chronic NLBP is hard to cure clinically due to its unknown pathogenesis, but a number of interventions are available that can reduce pain, disability, and its consequences.[1]These interventions are generally divided into two categories, pharmacological therapies and Non-pharmacological therapies. Pharmacological therapies mainly include nonsteroidal anti-inflammatory drugs (NSAIDs),[11] opioid therapy,[12] skeletal muscle relaxants, and Benzodiazepines[13], et al. While Non-pharmacological therapies mainly include exercise therapy,[14] physical therapy[15], Radiofrequency denervation therapy[16], ultrasound therapy,[17] acupuncture,[18] and massage[19],et al. Clinically, non-pharmacological therapy is

recommended as a priority for chronic NLBP. [1]

Massage for LBP is popular in both eastern and western countries because of its powerful analgesic effects and few risks or adverse effects. A systematic review of 22 surveys across six Eastern and Western countries found that the percentage of adults who visited a massage therapist within a 12-month period ranged from 0.4% to 20%, while the estimated rate for older adults ranged from 1.5% to 16.2%.[20] Massage is considered to relieve pain symptoms and improve physiological and clinical outcomes by physical and mental relaxation through rhythmic pressing and stroking of the soft tissues of the body. [21] It works in a variety of ways, mainly including raising pain thresholds by releasing endorphins and closing pain gates at the spinal cord level. [22]

Despite its popularity, there is still debate about the effectiveness of massage in treating chronic NLBP. Data from two studies showed that massage could improve short-term pain relief and function in patients with chronic NLBP compared to other interventions. [23-24] Similarly, in the latest systematic reviews research of Furlan and colleagues, they identified 24 trials, comprising 3046 patients, which focused on the efficacy of massage for sub-acute and chronic LBP. [15] The evidence indicated that massage could improve pain and function only in the short-term follow-up. While Van Middelkoop et al. identified 3 RCTs with 163 chronic NLBP patients, which showed no significant improvement in pain relief in the massage group compared to the control group. [25]

Recently, FSN therapy has gained popularity for the management of pain-related musculoskeletal diseases. [26] FSN was first described in 1996 by Dr. Fu Zhonghua, who developed the technique based on Ashi point therapy and wrist-ankle acupuncture therapy. [27] Since then, several clinical studies have reported the technique in knee osteoarthritis, lumbar sprain, chronic low-back pain, and

scapulohumeral periarthritis[28-31]. Dr. Fu Zhonghua reported that FSN therapy had a good immediate analgesic effect in the treatment of low back pain, but there was a lack of follow-up results on patients. [29] Lu et al [32] investigated the short-term efficacy of FSN therapy in the treatment of CLBP and found a reliable pain relief effect. However, this study lacked control group, functional outcomes, and long-term follow-up results. Therefore, this randomized controlled trial was conducted for two purposes:

Firstly, to investigate the long-term effects of massage therapy and FSN therapy in the treatment of chronic NLBP. Secondly, to evaluate whether FSN therapy are more effective than massage therapy in the treatment of chronic NLBP.

2. Methods

2.1 Design

This study randomized controlled trial is designed following the standard protocol items for randomized interventional trials (SPIRIT) and the results were reported consistent with the consolidated standards of reporting trials (CONSORT) guidelines.[33] Participants will be randomized to receive FSN therapy or massage therapy. The study is approved by the human ethics committee of Yongchuan hospital of Chongqing medical university.

2.2 Participants

Consecutive individuals with chronic NLBP from Orthopaedic Clinic of Yongchuan hospital of Chongqing medical university were screened by a physiotherapist and an orthopaedic specialist. The inclusion criteria were as follows: (1) Meets diagnostic criteria of chronic NLBP (pain affecting the lumbosacral area and adjacent tissues, located from the bottom of ribs to inferior gluteal fold); (2) Complaint of pain lasting longer than 3 months with the VAS scores of at least 3; (3) No accompanying systemic diseases, such as tumors and tuberculosis, no psychiatric

diseases, no neurological diseases that require surgery; (4) Age between 18-80 years old; (5) American Society of Anesthesiologists (ASA) grade I to III; and (6) Voluntarily signed the informed consent. The exclusion criteria for chronic NLBP cases are shown below: (1) Fear of needles; (2) Patients with a history of spinal surgery; (3) Known or suspected serious spinal pathology (fractures, tumors, inflammatory, rheumatologic disorders, infectious diseases of the spine, spinal degeneration with nerve root or cauda equina nerve damage); (4) Severe cardiovascular or cerebrovascular diseases; (5) Pregnancy; and (6) Coagulation abnormality.

The sample size calculation was based on a pilot study that compared the effects of FSN therapy (5 patients) with massage therapy (8 patients) on patients. The visual analog scale (VAS) in 3 months was 2.143 ± 1.569 for the FSN therapy group and 3.400 ± 1.430 for the massage FSN therapy group. These variances were used to calculate the sample size needed to detect a change of 1.257 in the VAS score with 80% power and 5% significance. Based on these criteria, 25 patients were needed in each group. No more than 20% of patients will be lost to follow up.

2.3 Randomized grouping

Randomization is performed using Microsoft Excel for Windows software by a trained evaluator who is not involved in the recruitment of participants. The allocation is concealed in continuously numbered and sealed opaque envelopes. After baseline assessment, qualified participants are referred to a physical therapist who randomly assign participants to different treatment group. The evaluators are not informed of the treatment allocation between the two groups. Given the nature of the intervention, the therapist or the patient cannot be deluded.

The evaluation will be performed at four time points: baseline, post-treatment, 3 months after treatment, and 12 months after treatment. All measurements will

made by a trained physiotherapist blinded to group allocation, and the primary analysis followed the intention-to-treat principle..

2.4 Treatment procedures

Treatment will start immediately after subjects are assigned to the treatment groups. All subjects participate in 10 visits over a period of 4 weeks. During the first two weeks, each treatment group will receive three treatments per week, one day apart in principle. For the next two weeks, each treatment group receives treatment twice a week, once every two days in principle. Interventions for each group are described below.

2.5 FSN therapy group

The procedures of FSN therapy were strictly in accordance with standardized manipulations proposed by Dr. Fu Zhong-hua[38]. It mainly involved six aspects including identifying tightened muscles(TMs), selecting the entry point, FSN Manipulation, reperfusion, assessing the tension degree of tightened muscles, and attentions after interventions.

2.5.1 Identification of TMs

TMs are the muscles that are still in pathologically tense status when patients are relaxed under the condition that the central nervous system functions normally. The essence of the TM is the muscle containing one or more MTrPs. Repeated clinical palpation reveals that TM usually has five characteristics: tightness, stiffness, hardness, slipperiness and pain. The joints associated with TMs are often weak and the range of motion is often reduced. In most cases, TMs are the most common cause of NLBP patients and meanwhile are the main targets of FSN. To locate the TMs, we should identify the suspected TMs firstly which have an anatomical relationship with pain area; and then we exclude irrelevant TMs whose function is irrelevant to the action of restricting movement; and finally we confirm the TMs by

clinical palpation. According to our clinical experience, the suspected TMs of NLBP are usually mainly including: The erector spinae, quadratus lumborum, latissimus dorsi, rectus abdominis, oblique abdominis, and hip muscles group, hamstring muscles. Therapists will use clinical reasoning to determine which muscles to treat at each session based on findings from the physical and historical examination.

2.5. 2 Selection of entry point

Unlike traditional acupuncture, FSN does not require the insertion of needles into acupoints or Ahshi points. Theoretically, the needles can be inserted anywhere surrounding TMs. However, two main principles should be known as follows: (1) For a single small nodule, the entry point should be close to the TM. For a large-sized taut band or nodules cluster, the entry point should be far from TM. (2)The the entry point should avoid the scars and hollow or prominent regions.

2.5. 3 FSN Manipulation

After disinfection of entry point, the FSN needle (figure 2) is inserted into subcutaneous layer with the help of a needle inserting device (figure 3), which is at 15-20 degree angle to the local skin (figure 4). After confirming the needle body is entirely inside the subcutaneous layer, the clinician can start the sweeping movement. Medial margin of thumb and middle finger is used to hold the needle handle, and the tip of the thumb is fixed on the skin as the fulcrum, and then index finger and the ring finger make a repeated sweeping movement in a way of seesaw-like sector. The range of sweeping movement should be as large as possible, generally with the radian between 20° and 25°.(figure 5) The process of sweeping movements should be as smooth, slow and gentle as possible in order to avoid the feeling of numbness, swelling, and pain. The frequency of the swaying movement is about 100 times a minute. The duration of the swaying movement for one insertion point is often less than 2 minutes.

2.5. 4 Reperfusion approach

Reperfusion approach, as a key procedure for FSN, is to make tightened muscles contract vigorously within a short time and then relax in order to supply more blood to the ischemic part. (figure 6) It is suggested to provide equal force back by practitioner when the muscles contract. Reperfusion approach is often used during swaying movements, and it can also be used separately for treatment of mild illnesses.

2.5. 5 Assessing the TMs

Clinician should check and assess TMs for every 30 seconds during treatment. If the TMs is eliminated or the pain symptom is significantly or completely relieved, the treatment can be stopped; otherwise, it should be continued.

2.5. 6 Attentions

There are two attentions that should be noted during the treatment of FSN.

2.5. 6.1 Subcutaneous bleeding

During the process of insertion or sweeping movement, the needle may injure the microcapillaries which may lead to subcutaneous bleeding. However, the bleeding usually disappear soon without any intervention. Practitioners should explain the reasons and eliminate the patient's worries and fears. If the local bleeding is serious and cause obvious local swelling and pain, practitioners should withdraw the needle immediately and apply cold compresses to stop bleeding.

2.5. 6.2 Fainting

A very small number of patients may develop the symptoms of needle fainting during the treatment. The needling manipulation should be stopped immediately when this condition occurs. The patient should be placed flat on the bed and kept warm. Generally, the patient will recover soon after taking some rest. If the patient's condition does not improve or even get worse, rescuing measures or first aid

treatment should be carried out immediately.

2.6 Massage therapy group

Swedish massage is one of the most classic massage techniques, and we used it in this study. It consists of five main stroking actions to stimulate the circulation of blood through the soft tissues of the body. [39] Swedish massage was performed by a professional rehabilitation therapist. Participants in the massage group received the following five basic manipulations: deep stroking, pulling, friction, rolling and wringing. Certainly, the affected muscle must be found before the manipulations can be performed.

Stroking is a one-way operation on the affected muscles, from the proximal to the distal, with the whole hand in contact with the skin and gentle but firm pressure. When performing the rolling and wringing, the therapist hands were placed on the skin with fingers adduction and thumbs abduction. Use both hands thumbs and fingers for managing small muscles and both whole of hands for managing large muscles. When rolling, the index finger and thumb of the opposite hand touch each other, forming a diamond. when twisting, the fingers and thumb are squeezed together so that a roll of tissue or muscle gathers between them. The massage was performed in the direction of the muscle fibers, starting at one end and ending at the other until the entire area of muscle attachment was covered. Each type of massage lasted for 3 minutes, and each session of the five massage types takes 15 minutes for each affected muscle..

3.Statistical Analysis

The statistical analysis will be performed with SPSS statistical software (version 26.0; IBM, USA). Continuous variable is reported as mean± standard deviation and were assessed using Student's t-test analyses. Categorical variables are expressed as percentage and tested by chi-square test. The differences between groups are

performed using ANOVA with repeated measures and LSD post hoc. The estimates values is presented with 95% confidence interval (CIs) were shown in column bar graphs. The histogram is made using the graphpad PRISM. The significance level is established at $P < 0.05$.

4. Results

The results of this trial will be published on the website of the China Clinical Trial Registration Center and in peer-reviewed journals or academic conferences.

5. Discussion

Despite a large number of clinical trials, there is still considerable disagreement regarding the ideal treatment approach for individuals with chronic NLBP. Effective non-surgical and non-pharmacological treatment strategies for NLBP investigated in the literature to date with the most supportive evidence include FSN therapy with massage therapy.[19] Massage is considered to relieve pain symptoms and improve physiological and clinical outcomes by physical and mental relaxation through rhythmic pressing and stroking of the soft tissues of the body. [21] Despite its popularity, there is still debate about the effectiveness of massage in treating chronic NLBP. [26] FSN therapy has gained popularity for the management of pain-related musculoskeletal diseases. Dr. Fu Zhonghua reported that FSN therapy had a good immediate analgesic effect in the treatment of low back pain, but there was a lack of follow-up results on patients. [29] Lu et al [32] investigated the short-term efficacy of FSN therapy in the treatment of chronic LBP and found a reliable pain relief effect. However, this study lacked control group, functional outcomes, and long-term follow-up results.

It is currently not known if FSN provides long-term benefit for individuals with chronic NLBP. We anticipate the results of this study will help determine if FSN therapy. provides additive benefits over those observed with current commonly

applied interventions of massage therapy.

References

1. Balagué F, Mannion A F, Pellisé F, et al. Non-specific low back pain[J]. *The lancet* 2012; 379(9814): 482-491.
2. Dhondt E, Van Oosterwijck J, Cagnie B, et al. Predicting treatment adherence and outcome to outpatient multimodal rehabilitation in chronic low back pain[J]. *Journal of back and musculoskeletal rehabilitation* 2020; 33(2): 277-293.
3. Corwell B N, Davis N L. The Emergent Evaluation and Treatment of Neck and Back Pain[J]. *Emergency Medicine Clinics* 2020; 38(1): 167-191.
4. Furlan AD, Imamura M, Dryden T, et al. Massage for low back pain: an updated systematic review within the framework of the Cochrane Back Review Group[J]. *Spine* 2009; 34(16): 1669-1684.
5. Freburger JK, Jackman AM, Castel LD. The rising prevalence of chronic low back pain. *Arch Intern Med* 2009; 169(3):251e8.
6. Furlan AD, Imamura M, Dryden T, Irvin E. Massage for low-back pain (review). *The Cochrane Collaboration, The Cochrane Library* 2010;2:1e77.
7. Van Tulder M, Koes B, Bombardier C. Low back pain. *Best Pract Res Clin Rheumatol* 2002;16(5):761e75.
8. Chou R, Huffman L. Non pharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American college of Physicians clinical practice guideline. *Annals of Internal Medicine* 2007;147:492-504.
9. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J* 2008;8:8-20.
10. Hong J, Reed C, Novick D, et al. Costs associated with treatment of chronic low

back pain: an analysis of the UK General Practice Research Database[J]. *Spine* 2013; 38(1): 75-82.

11. Enthoven WT, Roelofs PD, Deyo RA, van Tulder MW, Koes BW. Non-steroidal anti-inflammatory drugs for chronic low back pain. *Cochrane Database Syst Rev* 2016; 2: CD012087.

12. Chaparro LE, Furlan AD, Deshpande A, Mailis-Gagnon A, Atlas S, Turk DC. Opioids compared to placebo or other treatments for chronic low-back pain. *Cochrane Database Syst Rev* 2013; 8: CD004959.

13. Abdel Shaheed C, Maher C G, Williams K A, et al. Efficacy and tolerability of muscle relaxants for low back pain: systematic review and meta-analysis[J]. *European Journal of Pain* 2017; 21(2): 228-237.

14. Hayden JA, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database Syst Rev* 2005; 3: CD000335

15. Cuenca-Martínez F, Cortés-Amador S, Espí-López GV. Effectiveness of classic physical therapy proposals for chronic non-specific low back pain: a literature review. *Phys Ther Res* 2018;21:16–22.

16. Maas ET, Ostelo RW, Niemisto L, et al. Radiofrequency denervation for chronic low back pain. *Cochrane Database Syst Rev* 2015; 10: CD008572.

17. Ebadi S, Henschke N, Nakhostin Ansari N, Fallah E, van Tulder MW. Therapeutic ultrasound for chronic low-back pain. *Cochrane Database Syst Rev* 2014; 3: CD009169.

18. Furlan AD, Yazdi F, Tsertsvadze A, et al. A systematic review and meta-analysis of efficacy, cost-effectiveness, and safety of selected complementary and alternative medicine for neck and low-back pain. *Evid Based Complement Alternat Med* 2012; 2012: 953139.

19. Furlan AD, Giraldo M, Baskwill A, Irvin E, Imamura M. Massage for low-back pain. *Cochrane Database Syst Rev* 2015; 9: CD001929.
20. Harris PE, Cooper KL, Relton C, Thomas KJ. Prevalence of visits to massage therapists by the general population: a systematic review. *Complement Ther Clin Pract* 2014;20(1):16-20.
21. Ernst E. Massage therapy for low back pain: a systematic review. *Journal of Pain and Symptom Management* 1999;17(1):65-69.
22. Ernst E. Massage therapy for low back pain: an update. *Altern Ther Women's Health* 2001;Sept:69-71.
23. Yoon YS, Yu KP, Lee KJ, Kwak SH, Kim JY. Development and application of a newly designed massage instrument for deep crossfriction massage in chronic non-specific low back pain. *Ann Rehabil Med* 2012; 36:55-65.
24. Preyde M. Effectiveness of massage therapy for subacute low-back pain: a randomized controlled trial. *Can Med Assoc J* 2000;162:1815-20.
25. van Middelkoop M, Rubinstein SM, Kuijpers T, et al. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *Eur Spine J.* 2011;20:19-39.
26. Wu F, Zhang W, Gan X, et al. Fu's Subcutaneous Needling: A Novel Acupuncture Treatment for Musculoskeletal Pain Diseases[J]. *International Journal of Clinical Acupuncture*, 2019, 28(4).
27. Fu Z. Floating Needling, a new approach to treat pain. *TCM.* 1996;21:4
28. Feng Y, Lin Y, Zhang Z, et al. Periarthritis of shoulder treated with Fu's subcutaneous needling and electroacupuncture: A control trail[J]. *World Journal of Acupuncture-Moxibustion*, 2021, 31(2): 89-94.
29. Fu Z, Chen X, Lu L, et al. Immediate effect of Fu's subcutaneous needling for low back pain[J]. *Chinese Medical Journal*, 2006, 119(11): 953-957.

30. Gu J, Xia Y, Liang Y, et al. Clinical observation on effect of FU's subcutaneous needling for acute lumbar sprain[J]. *Journal of Acupuncture and Tuina Science*, 2010, 8(4): 253-255.
31. Zheng LIU, Lin MA, BI H. Clinical effect on knee osteoarthritis treated with Fu's subcutaneous needling therapy[J]. *World Journal of Acupuncture-Moxibustion*, 2020, 30(1): 29-32.
32. Lijuan L, Jian L, Meihua Z. Clinical evaluation of Fu's subcutaneous needling for chronic low back pain[J]. *J Clin Anesthesiol* 2005; 21(12):827-828.
33. Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: defining standard protocol items for clinical trials. *Rev Panam Salud Publica* 2015;38(6):506-514.
34. Wilkie D, Lovejoy N, Dodd M. Cancer pain intensity measurement: concurrent validity of three tools: finger dynamometer, pain intensity number scale, visual analogue scale. *Hospice Journal* 1990;6:1-13.
35. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine* 2000;25:2940-52.
36. Azimi P, Mohammadi HR. An outcome measure of functionality and pain in patients with lumbar disc herniation: a validation study of the Japanese Orthopedic Association (JOA) score. *J Orthop Sci* 2012;17:341-345.
37. Grevitt M, Khazim R, Webb J, et al. The short form-36 health survey questionnaire in spine surgery[J]. *The Journal of bone and joint surgery. British volume* 1997; 79(1): 48-52.
38. Fu Z, Lu D. Fu's Subcutaneous Needling: A Novel Therapeutic Proposal. *Acupuncture-Resolving Old Controversies and Pointing New Pathways*. IntechOpen, 2019.
39. Cowen VS, Burkett L, Bredimus J. A comparative study of Thai massage and

Swedish massage relative to physiological and psychological measures. Journal of Bodywork and Movement Therapies 2006;10:266-275.

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