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Foot Reflexology Therapy for Non-Specific Low Back Pain Condition : A Protocol For a Randomized Controlled Trial

Nor Dalila Marican[1,2], Rozita Hod[3], Nadiah Wan-Arfah[2] and Azmi Hassan[2]

[1]Faculty of Hospitality, Tourism and Wellness, Universiti Malaysia Kelantan.
[2]Institute for Community (Health) Development, Universiti Sultan Zainal Abidin.
[3]Department of Community Health, Faculty of Medicine, National University of Malaysia.

**For reprint and all correspondence: Nor Dalila Marican, Faculty of Hospitality, Tourism and Wellness, Universiti Malaysia Kelantan, City Campus, Pengkalan Chepa, Locked Bag 36, 16100 Kota Bharu, Kelantan Darul Naim.*
Email: dalila.m@umk.edu.my

ABSTRACT

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Introduction Non-specific low back pain is one of the most common physical ailments affecting millions of people worldwide. This condition constitutes a significant public health problem and was listed as a prevalent health complaint in most societies. Even though there are many anecdotal claims for reflexology in the treatment of various conditions such as a migraine, arthritis and multiple sclerosis, but very little clinical evidence exists for reflexology on the management of low back pain per se. This study aims to evaluate the effects of foot reflexology therapy as an adjunctive treatment to the Malaysian low back pain standard care in relieving pain and promoting health-related quality of life among people with non-specific low back pain.

Methods This is a parallel randomized controlled trial with pre and post-treatment study design. The study setting for the intervention located at Penawar Reflexology Center, Kuala Terengganu, Malaysia. A total of 100 participants with non-specific low back pain will be allocated to one of two groups, using a randomization computer program of Research Randomizer. The control group will receive low back pain standard care, while the intervention group will receive standard care plus eight sessions of foot reflexology therapy. The pain intensity and health-related quality of life scores will be measured using Visual Analogue Scale and Euro-quality of life scale respectively in both groups. The study was approved by the Human Research Ethics Committee of University Sultan Zainal Abidin (UHREC/2016/2/011). The study protocol was registered at ClinicalTrials.gov, with the ID number of NCT02887430.

Measurements Outcome measures will be undertaken at pre-intervention (week 1), post-intervention (week 6) and follow-up (week 10).

Conclusions This will be the first trial to compare the foot reflexology therapy with control group among people who medically diagnosed with non-specific low back pain in Malaysia. The result of this study will contribute to better management of this population, especially for Malaysia healthcare setting.

Keywords low back pain - foot reflexology - protocol.

INTRODUCTION

Low back pain (LBP) is a common health complaint in most societies. Even though there are many treatments for LBP which aim to reduce suffering, quicken recovery and minimize recurrence or development of chronic disability, LBP continues as a societal enigma. The prevalence of back pain in the general population has been reported to be as high as 50% or more in both developed and developing countries.[1] A study has indicated that LBP is an important health problem in all developed countries and it was associated with high levels of disability.[2] The lifetime prevalence of low back pain is estimated at 60-70% in industrialized countries which is one-year prevalence 15-45%, adult incidence 5% per year.[3]

Low back pain is frequently classified as specific or non-specific. Specific LBP is defined as symptom caused by a specific mechanism or known specific pathologies such as infection, tumors, osteoporosis, ankylosing spondylitis, fracture, or inflammatory.[3] Non-specific low back pain is known as symptom without a clear specific cause and often results of simple soft tissue disorder such as strain.[5] Epidemiology studies have indicated that approximately 85% of the population, experience non-specific low back pain during their lifetime,[6] and about 18% of the population experiences non-specific low back pain at any given moment.[7] In Malaysia, LBP was reported as being among the most common types of musculoskeletal disorder.[8] According to Alshagga and friends,[9] the prevalence of Malaysian with LBP was the highest in the past week and in the previous year, which is 27.2% and 46%, respectively, followed by neck pain and shoulder pain. The highest percentages of Malaysian low back pain sufferers were presented by the age range of 40 to 50 years old and the lowest from the age of 70 to 80 and below 18 years old.[10]

LBP is the second most common condition for which patients seek primary care consultation, making it one of the most costly medical conditions.[11] It is a costly and disabling disorder that plagues the modern world, creating substantial personal, society and financial burden.[12] As part of the Global Burden of Disease Study in the year 2010, it showed that LBP is among the top ten high burden disease and injuries, with an average number disability-adjusted life years (DALYs) higher than HIV, tuberculosis, and lung cancer. In the United Kingdom, LBP was identified as the most common cause of disability in young adults, with more than 100 million workdays lost per year.[3] Whether the LBP is minor or disabling, recurrent or chronic, localized or more global, a resolution is frequently sought for this common problem. There is a large volume of published studies describing some of the common conventional treatment approaches such as conservative, surgery, and pharmacology is costly and sometimes ineffective, with significant adverse effects.[13]

In recent years, and as a response to these concerns, a new approach of complementary medicine which is foot reflexology therapy could be considered as adjunctive treatments for low back pain. Reflexology is a complementary therapy which can be defined as the use of the sophisticated system of touch, applied to the specific reflex points which are located on all part of feet, hands, or ears.[14-15] According to the International Institute of Reflexology, by applying pressure on these reflex areas, is thought to correspond to a map of the whole body by stimulating the normal functions of glands, organs as well as parts of the body and finally will encourage the body healing process.[15-17] Recent evidence[18] suggests that reflexology is a simple, less expensive and non-invasive method that effective to regulate the autonomic nervous system activities, coordinates physiological responses, alleviates anxiety, and induces relaxation.

Based on the previous research conducted, reflexology seems to be effective in helping the body systems return to their natural state. A number of studies showed the significant differences between reflexology and particular health condition. The study carried out by Vardanjani[19] and Tsay[20] explored the effect of reflexology on anxiety among 100 patients who were undergoing coronary angiography and 61 postoperative patients respectively. The finding revealed that reflexology therapy is effective in order to reduce the level of anxiety. The research by Gozuyesil and Baser[21] also found a significant effect on quality of life scores among 120 women who received reflexology. A part of that, the intervention studies were done by Ghavami[22] and Dolation[23] indicated that the pain intensity among 75 patients and 120 pregnant women respectively were significantly reduced in foot reflexology group compared to support and control groups.

Even though complementary medicine has been for many decades, and rated as the most popular healthcare for pain management, yet, a lack of evidence for foot reflexology therapy intervention has led to controversy and uncertainty within the medical and health allied professions. Therefore, this study purposely designed to investigate the effect of foot reflexology therapy as additional to standard care on pain intensity and health-related quality of life in people with non-specific low back pain. This randomized control trial is the first to study the specific, commonly use a form of complementary medicine called foot reflexology therapy in Malaysia. The results of this study may contribute to a better understanding of the efficacy of therapy plus more research is

needed before foot reflexology becomes a widely accepted alternative remedy. These data will benefit the complementary medicine profession by defining whether foot reflexology therapy is beneficial for a patient with LBP problem.

METHODS

Study Design

This is a randomized controlled, parallel group, with pre and post-treatment trial study design. A total of 100 eligible participants will be randomly assigned into two groups which are intervention group or control group, using a simple random sampling method. Randomization will be conducted using a computer-generated random allocation sequence with a 1:1 ratio. The randomization process will be performed by a statistician with no clinical involvement in this trial. The design, conduct, analysis, and interpretation of the study will be reported in the format suggested by the CONSORT statement. Figure 1 shows the trial design and Table 1 summarizes the timing of the trial.

Figure 1 Flowchart of the study

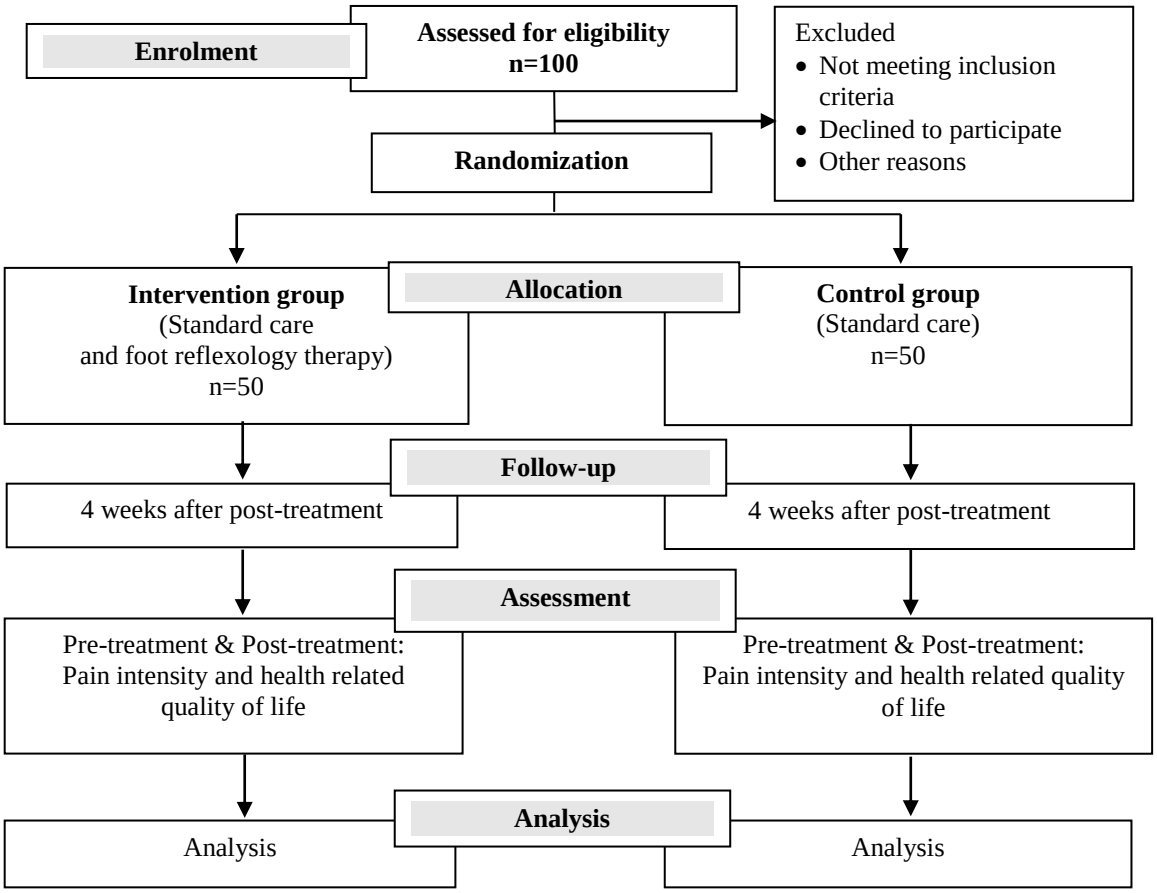

Table 1 Calendar summary

Period Week (W)	Screening	Baseline Week 0	Pre-treatment Week 1	Post-treatment Week 6	Follow-up Week 10
Inclusion and exclusion criteria	X				
Informed consent	X				
Demography information questionnaire	X	X			
Standard care		X			
Visual analogue scale		X	X	X	X
EQ-5D-5L		X	X	X	X

Study Setting
The study will be carried out in Kuala Terengganu area, which is the capital city of Terengganu. The chosen study setting for this intervention located at Penawar Reflexology Centre. This is a private centre and consists of five professional and experienced reflexologists. This centre was provided complementary healthcare services to the community for more than 20 years.

Participant Recruitment
The participant with non-specific low back pain will be recruited from communities who live in Kuala Terengganu district. The potential participant will be informed about the nature of the study as well as the events of LBP screening through the printed recruitment flyers as well as the social media platform such as Facebook and WhatsApp application. Potential participants will be screened by a medical officer and will be invited to participate in this study. Inclusion criteria will be as follows: has had been medically diagnosed with a non-specific low back pain; visual analogue scale score of at least 3; is aged at least 18 years old; has both feet and all toes intact and free from wounds; and not undergone any other complementary and alternative therapies during the study. The participants will be excluded if they suffer from severe coexistent disease and serious pathology or systemic illness such as diabetes mellitus, stroke, cardiovascular disease, hypertension, kidney failure, as well as liver disease; has a specific diagnosed cause of back pain such as infection, tumour, osteoporosis, fracture, an inflammatory condition or cauda equine syndrome; lack the ability to read and write Malay language; and had plans to move out of the area. An explanatory statement will be given to those deemed to be eligible to participate. Once consent is obtained, the consent form will be signed by the participants and another witness. Consenting participants will then be randomly assigned to the two groups.

Control Group
Standard care in general practice will be provided in accordance with the Malaysian low back pain management guidelines, which consist of activity modification, patient education, and address the psychosocial factors.

Intervention Group
The participants in this group will be received the same standard care as the control group. As an adjunct to the low back pain standard care, foot reflexology therapy will be provided by certified and experienced reflexologists with the treatment being applied for 30 minutes in one session, twice a week for four weeks. The reflexologist will follow the foot reflexology practice guideline that has been validated by the panel experts.

Outcome measures
The standardized validated instrument will be used to evaluate the effects of foot reflexology therapy on pain intensity and health-related quality of life towards people with non-specific low back pain. The outcome measures will be filled in at pre-treatment (week 1), post-treatment (week 6), and follow-up (week 10). The demographic information for baseline survey will be gathered using Demographic Information Questionnaire (DIQ). This questionnaire consists of two sections which are demographic (age, race, ethnicity, marital status, level of education, occupation, household income) and general health status (smoking status, alcohol consumption, use of alternative and complementary medicine, status of low back pain).

The primary outcome measure of pain intensity will be assessed using the visual analogue scale (VAS). The participant will place a single "X" on the line to record the amount of pain perceived. The VAS is a '0' to '10' scale ranges standard line, labeled "no pain" at the left site and "worst pain ever" at the other. It is the most frequently used methods for the measurement of clinical pain, including low back pain with a reported correlation of 0.81 between the five point rating score[24]. The secondary outcome measure which is health-related quality of life status will be assessed using the Malay version of EuroQoL (EQ-5D-5L). It reflects society norm of individuals' preferences for a distinct set of health states which mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. This instrument was developed by an International Multidisciplinary Group since 1987 and was proved to be highly reliable[25].

Subject safety
Participants will be asked to examine by the medical doctor from Universiti Sultan Zainal Abidin Health Care Center. The medical doctor will diagnose the condition of low back pain and make sure it is not due to pathology causes. If the participant diagnosed with low back pain due to the pathology, they will be excluded from the study. Possible side effects or any adverse effect occurs during the trial will closely monitor. If the participants persistently experienced any symptoms of therapy side effects, they will be treated by medical doctor as soon as possible.

Quality control
Audits will be conducted regularly on compliance with intervention protocol every week. If participant withdraw from the trail either in the treatment period or in the follow-up phase, the reason will be clarified and the rate will be statistically analysed. The questionnaire will be weigh against the database to check the accuracy of the data entry. Each variable will systematically

examine to ensure that no incorrect entries will be made.

Sample size

We have calculated that a total of 100 participants will be needed for the study in order to get a more holistic view of participants in general. The sample size for this study was calculated by using group comparison of 2 means of pain intensity based on the following formula[26]:

$$n = \left[\frac{2\sigma^2 (Z_{1-\alpha/2}+Z_{1-\beta})^2}{(\mu_1-\mu_2)^2}\right] \text{ ; Effect size, ES}\mu = \frac{\mu_1-\mu_2}{\sigma}$$

In the formula, σ = 2.5, μ_1 = 5.33, μ_2 = 5.14, $Z_{1-\alpha/2}$ = 1.96, $Z_{1-\beta}$ = 0.842 [14], sample size calculated is 25. However, after we made an adjustment for estimated sample effect, expected response rate, expected proportion eligible, two arms design, and drop-outs consideration. A sample of 100 participants is therefore required for this study.

Data Analyses Plan

Data will be analysed using Microsoft Excel 2010 and IBM SPSS statistics for Windows, version 22. The data analysis will involve both descriptive and inferential statistics. Descriptive statistics including the mean, standard deviation, range, frequency distribution and percentage will be used in data cleansing as well as to summarize participants characteristics. Inferential statistics, including Chi-square and Independent t-test as well as repeated measure ANOVA will be adopted. The repeated measure ANCOVA model will be used to test the statistical hypothesis by adjusting the possible confounding variables, for comparison of changes of the two outcome variables which are pain intensity and HRQoL among the study groups. A p value of less than 0.05 which indicated a 5% risk of committing a Type I error will be considered to be statistically significant.

ETHICS AND DISSEMINATION

This research will be conduct on a voluntary basis. All participants will be brief regarding the manner and purpose of this research. Once consent is obtained, the consent form will be signed by the participants and another witness. No invasive procedure is involved in this study. The risk of side effects of the foot reflexology therapy has been found to be low. However, possible side effects of the foot reflexology therapy or any adverse effects occur–during the trial will closely monitor. The study protocol was approved by the ethics committee of the Universiti Sultan Zainal Abidin, Malaysia (UHREC/2016/2/011), and the study protocol was registered at ClinicalTrials.gov (NCT02887430).

DISCUSSION

Low back pain is a highly prevalent condition with no definitive treatment. In spite of the fact that huge amount of resources, money and personnel hours are devoted to the diagnosis and treatment of low back pain, it remains a major medical problem. Several attempts have been made to show the reflexology may be a suitable adjunct to the pain management by helping to reduce the number of medications and associated side effects from continued drug use. This research, therefore enters at a time when the call for scientific evidence is sought and more is needed to understand the therapy in order to build up evidence-based literature for its use. These data will benefit the complementary medicine profession by defining whether foot reflexology therapy is beneficial for a patient with a low back pain problem. Furthermore, this is the first study in Malaysia that represents the long-term assessment of health outcome pattern after a four-week trial. These types of analyses may be contributing to a better understanding of the therapeutic efficacy and may be used to guide health care professionals to facilitate the patients who have a low back pain problem.

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