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## ABSTRACT

**Background:** Ginger (*Zingiber officinale*) has been used for medicinal purposes since antiquity for its carminative, anti-spasmodic, analgesics, antioxidant and anti-inflammatory properties.

**Aim:** To evaluate the effects of ginger foot soak among patients with non specific low back pain.

**Methods:** A randomized pre and post interventional study was carried out among 60 patients who reported nonspecific low back pain of variable duration at the Primary Health Care setting, Bangalore, Karnataka to evaluate the effects of Ginger versus plain water foot soak. Visual Analogue Pain Scale-100mm and Client Satisfaction opinionnaire were used to assess the effectiveness of non-pharmacological substance (Ginger) on reduction of low back pain severity and experiences with treatment.

**Findings:** There was clinically a significant reduction in the subjective reports of back pain severity at the end of the three weeks of treatment among the ginger foot soak group mean score 81.842 (SD=9.5) to 29.950 (SD=8.4) as compared to plain water foot soak group (mean score 81.947 (SD=8.8) to 64.250 (SD=17.5) with the diminished pain scores of 34.30 mm, " $t$ "=7.912 at  $p<0.001$ , than those in the plain water foot soak group. The ginger water foot soak was associated with a favorable participants experiences in terms of more perceived feelings of inner peace, calmness/improvements in physical/mental relaxation, mood improvement, self image, increased perception of regaining their physical energy/greater confidence/social functioning a fewer perception of boredom/dissatisfaction in life, work, reduced perception of negative thoughts. Majority (85.5%) of the participants in the experimental group expressed that they would recommend this ginger foot soak to friends and relatives as compared to (60.5%) in the plain water group.

**Conclusion:** Ginger water foot soak effectively reduces subjective reports of low back pain and results in positive subjective experiences.

**Keywords :** *Ginger - Zingiber officinale, foot soak, low back pain*

## INTRODUCTION

Low back pain is a leading cause of disability and it is not a disease but a constellation of symptoms that usually is acute and self-limited. Coping with back pain is the biggest obstacle to improvement, and heroic treatments that ultimately fail to help and may even be harmful, therefore must be avoided. It occurs in similar proportions in all cultures, interferes with quality of life and work performance, and is the most common reason for medical consultations (Ehrlich,

2003). Few cases of back pain are due to specific causes; most cases are non-specific and is usually self-limiting, lasting less than three months regardless of treatment. People with low back pain often turn to medical consultations and drug therapies (Chung, 2013), but they also use a variety of alternative approaches-Chiropractic adjustment, osteopathic manipulation, yoga, acupuncture, spa therapy and other forms of moist heat and physical therapy and herbals as medication alternative (Furlan, 2008).

Ginger (*Zingiber officinale*) has been used since ancient times as a food and a medicine for its carminative, anti-spasmodic, analgesics and anti-inflammatory properties (Terry, 2011). In particular, it has been an important plant for the traditional Chinese and Indian medicines. Ginger is popular world-wide due to its anti-inflammatory properties. It contains anti-inflammatory compound called as gingerols, which are also responsible for its flavor. It helps in reducing the pain caused by osteoarthritis or rheumatoid arthritis. It reduces their pain and increases mobility (Bliddal, 2000). Ginger is among the ten most common natural products used as a CAM-- complementary and alternative medical treatment. Studies have also shown that ginger has anti-oxidant and anti-inflammatory properties and it is a good pain killer. It is also found as a reliever for flu, cold, migraine, nausea, arthritis, headaches, menstrual cramps and muscle soreness (Lantz, 2007).

A ginger foot soak is a fresh approach to applying ginger externally for musculoskeletal tension. This is a simple, convenient and very effective therapy. Anecdotal experiences of groups of nurses with ginger therapy describe warmth penetrating through the body, activating a deep relaxation that enables reduction in mental and physical tension (Tessa, 2010). People with nonspecific back pain require a simple treatment that are: easy to administer, using minimal materials, comfortable to receive, with no known side effects, supports the management of chronic pain, relieves their anxiety and improves mobility. Considering non-pharmacological treatments for their effectiveness, more attention needs to be given to alternatives. Ginger therapy is one such non-pharmacological treatment that is worthy of further attention (Bode, 2004; Afzal, 2001)

Ginger therapy needs to be considered as a viable, non-invasive treatment option in caring for people with low back pain (Afzal, 2001; Eliopoulos, 2007). The potential socio-economic benefits are considerable and include a decrease in medication, decrease in surgical procedures and loss of working potential accompanied by improved quality of life and increased independence (Shukla, 2007; Chrubasik, 2005).

This study investigates the significant effect of ginger water foot soak on non specific low back pain

and the knowledge sought from this study may influence the governing attitudes of health personnel on ginger's therapeutic qualities for clients with non-specific low back pain. This study is based on the hypothesis that subjective reports of reduction in low back pain ratings after ginger water foot soak would be higher in the group receiving ginger foot soak compared to a group receiving a plain water foot soak.

## **METHODS**

### **Study design**

The study was a randomized two groups pre and post interventional design performed at the Primary health care setting, Arekere, Bangalore, Karnataka from February 2015 to March 2016. A simple random sampling technique of coin toss method was used to assign the participants to experimental and control group. The head was assigned to experimental and tail was assigned to control group. The research consists of two sequential parts (Figure:1- Participants Flow Chart) a recruitment period, randomization and a treatment period of three weeks (twenty one consecutive days).

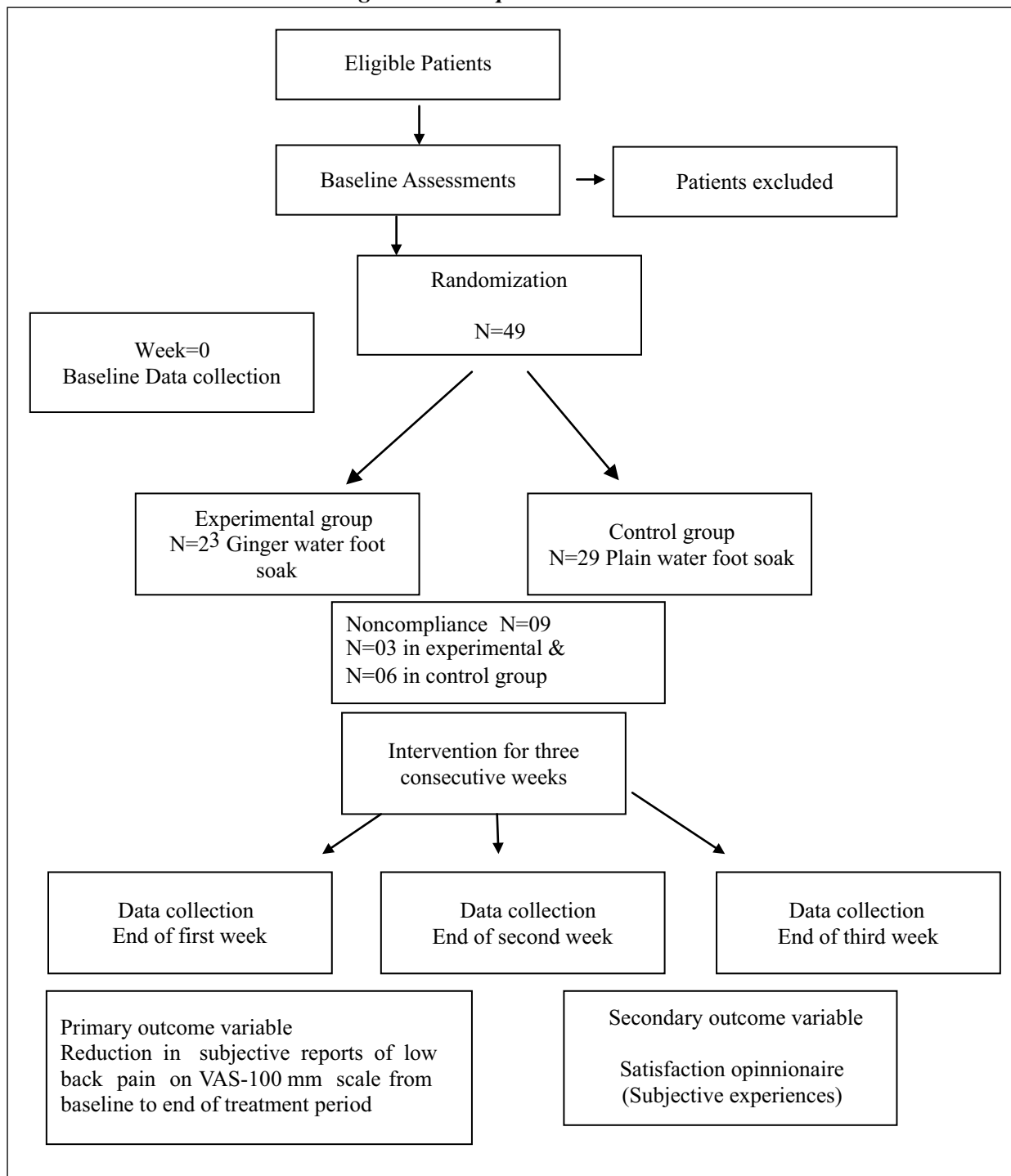
### **Sampling**

A priori power calculation determined that a sample size of at least 40 subjects 20 in interventional and 20 in control group would be able to detect a 25% difference in the primary outcome measure - the subjective reports of reduction of low back pain by 20 mm or more on a VAS-100mm with 80% power and an alpha level of 0.05 (two tailed). Considering 20% withdrawal or loss of subjects, the adjusted sample size was 49 clients. Hence a total of 49 eligible participants who met the inclusion and exclusion criteria were recruited. Subject eligibility was determined by a history, clinician performed physical examination, routine complete blood count investigation, X ray examination to rule out vertebral column and spinal pathology and who reported low back pain on a VAS 100 mm scale ranging from 40 to 90 mm, aching back as a cause of inability to work, an interference with the quality of life and as a reason for medical consultation were selected. During the first visit, potentially qualified patients were provided with detailed information about this study, including the research objective, study procedure, potential benefits and risks. When patients showed willingness to

participate, they were required to voluntarily sign a written informed consent. This was followed by baseline assessment of pain on a VAS-100mm scale

and randomization by coin toss method, head to experimental—(ginger water foot soak) and tail to control group (Plain water foot soak).

**Figure1: Participants Flow Chart**



### **Inclusion criteria**

Subject eligibility was determined by the history, clinician performed physical examination, routine complete blood count investigation, X ray examination to rule out vertebral column and spinal pathology along with the individual who reported low back pain on a VAS 100mm scale ranging from 40 to 90mm, aching back as a cause of inability to work, an interference with the quality of life and as a reason for medical consultation were selected.

### **Exclusion criteria**

Participants with low back pain that resulted from trauma, osteoporotic fractures, infections, neoplasm, history of rheumatoid arthritis, diabetes, hypertension, gastrointestinal, medical, orthopedic neurological/ psychiatric disorders, pregnancy lactation, age above 65 years, fever, open wounds in the foot, skin abrasions and on anti-inflammatory, steroids were excluded from the study.

### **Intervention: Ginger water foot soak -- Experimental group**

The method involved were filling a deep and broad basin with warm water and adding 100 milligram (measured by Braun weighing scale) of freshly ground raw ginger paste prepared with the help of mortar and pestle. The ground ginger was mixed with the hand, using a rhythmic lemniscates movement for about a minute to re-enliven the water. The participants sat in a relaxed position for the foot soak, encompassed in a warm soft blanket that were large enough to wrap around their shoulders and reached the floor.

The foot soak was given for 15-20 minutes, by immersing the feet till two inches above the ankles, as long as the foot soak was experienced as warm and comfortable. Then the feet were dried well and warm socks were put on. The participants were asked to rest a further 10 minutes. The procedures were repeated twice a day for twenty one consecutive days.

### **Plain water foot soak-- Control group**

The control group participants feet were soaked in a plain warm water for about 15-20 minutes.

### **Measurements:**

The primary outcome variable measured was the participants subjective reports of reduction in low

back pain on standing from the baseline and the end of first, second and the third week of treatment on a VAS-100mm scale with one end of the scale being “no pain and the other end, “extreme pain. The secondary outcome variable measured was participants' satisfaction opinionnaire (participants subjective experiences with treatment) on physical, mental and emotional relaxation, mood improvement, perceived feelings of inner peace, improvements in self image, perception of regaining their physical energy/ greater confidence/ social functioning, perception of boredom/dissatisfaction in life, work, perception of negative thoughts and increased vitality with response alternatives defined by four points ordinal scale (not at all =1, some extent=2, lot more=3 and very much=4) for both the groups. Validity of the research tool was determined by the experts and the content validity index (CVI) was computed CVI= 0.89. Pilot study was carried out on ten patients in another setting and the reliability of the tool was assessed by Cronbach's alpha, which yielded 0.86. No side effects were either observed or reported in either groups.

### **Data collection**

The data were collected from the participants by VAS-100 mm scale and the satisfaction opinionnaire. The participant's subjective reports of baseline low back pain, pre and post intervention scores on VAS for twenty one consecutive days of treatment period were measured. The mean pre and post treatment pain scores of each patient in the experimental and control groups were computed and the two groups scores were analyzed by unpaired “*t*” test. At the end of three weeks treatment each participant was interviewed by satisfaction opinionnaire to evaluate the subjective experience of the treatment and the mean percentage of their experiences was computed.

### **Ethical considerations**

The research protocol followed the Declaration of Helensinki ethical principles. The study was approved by the ethics committees of the primary health care settings. A written informed consent for participation in the study was taken from the participants of both the groups, with the provision that the consent may be withdrawn at any time. Safe guarding confidentiality of any obtained information were ensured to them.



**Statistical analysis**

Data were analyzed by descriptive and inferential statistics. Sample baseline characteristics and baseline low back pain were analyzed by descriptive statistics in terms of frequency and percentage. The significant differences in the subjective reports of low back pain by the participants in both the groups were statistically analyzed by student “t” test and the level of significance was at  $P < 0.05$ . The statistical differences between weight, BMI, sex and the reduction in back pain were analyzed by Chi square/ Fisher's exact probability test. The participant's satisfaction opinionnaire was assessed by mean percentage. The Analyses were performed with the SPSS version 15 (SPSS inc, Chicago, IL).

**RESULT**

**Sample characteristics**

The two groups were homogenous with regard to mean age, weight, low back pain, Hemoglobin and sex as analyzed by Chi-Square and Fisher's exact probability test. This indicates that random assignment was valid and the selection bias could not have influenced the outcome variables. The participants mean age were 54.1 (SD=0.31) versus 53.9 (SD= 0.34) ranging from 53-64 years. With regard to weight the participants in both the groups weighed between 61-74 Kg with the mean weight 62 (SD=4.97) versus 63 (SD=5.42) Kgs. The participants of both the groups had a hemoglobin level ranging from 10.2 to 11.0 gm with the mean hemoglobin level of 10.7 (SD=0.43) versus 10.6 (SD=0.41gm%). The pre intervention pain scores (VAS) were ranging from 40-90mm with the mean pain scores of 81.8 (SD=8.27) versus 81.9 (SD=8.173). The woman and man ratio were 14:6 versus 14:6 (Table 1).

**Table1: Baseline characteristics of the participants**

N=40		
Baseline data	Ginger water foot soak	Plain water foot soak
	Mean (SD)	Mean (SD)
Age (yrs)	54.1 (SD 0.31 )	53.9 (SD 0.34)
Weight in Kgs	62 (SD 4.97)	63 (SD 5.42)
Hemoglobin in gm%	10.7 (SD 0.43)	10.6 (SD 0.41)
Baseline pain score	81.8 (SD 8.27)	81.9(SD 8.173).

**Overall withdrawal rates**

Three participants in the experimental and six participants in the control group were noncompliant with the frequency of the treatment due to festivals, functions, ceremonies and dropped from the study after nine to seventeen days (Withdrawal rate was n=09

clients. That's the reason n=49 was mentioned), No replacements were made. The final analyses involved a total of 40 participants with 20 in both groups 14 women and 6 men in each group .

**Non compliance:** Noncompliance was defined as participants not taking foot soak for minimum of two days during the three weeks of treatment.

**Effects of ginger foot soak on participants subjective reports of non-specific low back pain**

The findings of the present study showed that there was clinically a significant reduction in the non-specific low back pain severity at the end of the third week of treatment (29.95 mm versus 64.25 mm), among the participants in the experimental group with the diminished pain scores of 34.30 mm, “t”= 7.912 at  $p < 0.001$ , than those in the control group (Table-1). As the days increased there were remarkable improvement in the experimental group and all the participants were able to experience significant reduction in the subjective reports of pain intensity score from 81.84 (SD=9.5) to 29.95 (SD=8.4). Whereas in the control group the difference in pain scores were negligible with increasing in days from 81.95 (SD=8.8) to 64.25 (SD= 17.5). The experimental group was associated with a fewer reports of severe low back pain as compared to control group. Only fewer participants (5%) in the experimental group reported low back pain with the scores above 60 mm in VAS-100mm as compared to (60%) in the control group (Table:2).

**Table 2: Analysis of significant difference in the ginger vs. plain water foot soak group**

N=40				
Group	Mean (SD)	Mean difference	‘t’ value	p value
<b>Baseline</b>				
Ginger	81.842 (9.518)			
Plain water	81.947 (8.773)	0.015		
<b>First week</b>				
Ginger	62.947 (5.760)			
Plain water	71.733 (5.673)	8.786	4.862	p <0.001
<b>Second week</b>				
Ginger	47.101 (6.105)			
Plain water	66.105 (14.635)	19.004	5.359	p <0.001
<b>End of third week</b>				
Ginger	29.950 (8.413)			
Plain water	64.250 (17.471)	34.300	7.912	p <0.001

“t”(38)=3.307; p <0.001

**Participants' satisfaction opinionnaire:**

Participants satisfaction of their ginger water/ plain foot soak experiences were evaluated by Satisfaction Opinionnaire (participants subjective experiences with the treatment) with response alternatives defined by ordinal scale for both the groups. It displayed differences between the experimental versus control groups on their subjective experiences. There was a clinically significant reduction in the subjective reports of back pain severity at the end of the three weeks of treatment among the ginger foot soak group mean score 81.842 (SD=9.5) to 29.950 (SD=8.4) versus 81.947 (SD=8.8) to 64.250 (SD=17.5) with the diminished pain scores of 34.30 mm, “*t*”= 7.912 at  $p<0.001$ , than those in the plain water foot soak group.

Majority of the participants in the ginger foot soak group reported that they felt more physically mentally and emotionally relaxed/mood improvement/ increased vitality (79.5% versus 65.5%) as compared to plain water foot soak group.

The ginger water foot soak was associated with favorable participants experiences in terms of more perceived feelings of inner peace, calmness/ improvements in self image (80.75% versus 75%); increased perception regaining their physical energy/ greater confidence/ social functioning (91% versus 42.25%), a fewer perception of boredom/ dissatisfaction in life, work (53% Vs 77.5%); reduced perception of negative thoughts (55% versus 76%). Majority of the participants in the experimental group (85.5%) expressed that they would recommend this ginger foot soak to friends and relatives as compared to (60.5%) in the plain water group (Table:3).

**Table 3: Participants' satisfaction opinionnaire**

Patients experiences	N=40	
	Ginger water foot soak (n=20) Mean %	Plain water foot soak (n=20) Mean %
Physical/mental/emotional relaxation	79.5	65.5
Perceived feelings of inner peace, calmness	80.75	75
Improvements in self image	80.75	75
Perception of regaining physical energy/ confidence/social functioning	91	42.25
Fewer perception of boredom/ dissatisfaction in life, work	53	77.5
Perception of negative thoughts	55	76
Recommendation of ginger foot soak to friends and relatives	85.5	60.5

**DISCUSSION**

Low back pain is more disabling and dispiriting because of the physical impediment it causes and its psychological effects. The control, management and prevention of suffering are the major goals of quality care. Non pharmacological approaches towards these goals are consistent as all the analgesics and anti-inflammatory drugs are known to produce mild to serious side-effects, whereas the ginger foot soak offers relief to people suffering with back pain. It assists the body in healing by increasing blood circulation directly to the affected area, causes heat to penetrate deep into muscle where it then radiates back out benefiting those experiencing pain. The present study is a novel approach to low back pain management and it demonstrates the efficacy of ginger foot soak on participants subjective reports of reduction in low back pain from 81.84 (SD=9.5) to 29.95 (SD=8.4) in ginger foot soak group on three weeks of treatment which can be described as having clinical and practical importance in health related quality of life among people who continue to work despite their back problem.

There was clinically a significant reduction in the back pain severity as reported by the participants at the end of the third week of treatment (30 mm versus 64 mm), in the experimental group pain diminished scores was 34 mm, than those in the control group. As the days passed by there were remarkable improvement in the experimental group and all the participants were able to experience significant improvement in reduction of their low back pain. This could be possible because ginger contains chemical substances with an analgesics, anti-inflammatory potential, and the effect might be attributed to the actions of gingerols, shogaols, which may inhibit the production of pain-triggering hormones (Al-nahain, Jahan & Rahmatullah, 2014).

Heat treatment of ginger has been shown to increase the concentration of shogaols, could potentially lead to greater pain-relieving effects. In the present study, 10 grams of raw ginger mixed with hot water produced a significant differences in reduction of pain intensity between the ginger versus plain water. Supportive findings were reported by Black (2010) who examined the effects of 11 days of raw in comparison to heat treated ginger supplementation on muscle pain among 34 and 40 volunteers, respectively.

The study revealed that raw (25%, -0.78 SD,  $P=0.041$ ) and heat-treated (23%, -0.57 SD,  $P=0.049$ ) ginger resulted in similar pain reductions 24 hours after eccentric exercise compared to placebo indicating that heat-treated ginger possesses hypoalgesic effects and result in moderate-to-large reductions of muscle pain.

### Participants' experiences

The ginger water foot soak was associated with favorable experiences of the participants in terms of subjective reports of mental, physical and emotional relaxation of the self, increased vitality, physical energy, more perceived feelings of inner peace, calmness, improvements in self image, a gradual release of tension, pain relief, increased perception regaining their energy, greater self confidence, social functioning, more focused on work, a fewer perception of boredom, less dissatisfaction in life, work and reduced perception of negative thoughts. Consistent findings were reported by Tessa (2010) who conducted a phenomenological study to explicate the phenomenon of ginger compresses for people with osteoarthritis that revealed the experience of the participants warmth penetrating throughout the body, a positive shift in thinking, rejuvenated interests in worldly activities, reduction in knee joint pain and more comfortable and flexible joint mobility.

Ginger's therapeutic qualities could be used as an alternative to the drugs among people with low back pain. Therefore nurses should consider the ginger foot soak as part of noninvasive, alternative method of pain relief measures for people with nonspecific low back pain.

### Limitations

The study has some limitations. The purpose was to explore the subjective reports of low back pain reduction after three weeks of ginger foot soak treatment without adjusting the confounding

variables. Hence the ginger foot soak should not be considered as the only or most important factor in the treatment of non-specific low back pain.

The study findings may have limitations for generalization as the sample size is small and pooled from single setting.

### RECOMMENDATIONS

Longer-term studies are required on larger number of people receiving ginger foot soak to advance the existing knowledge base and extend this treatment to increased number of low back pain sufferers. Limited literature is available and this is one of a novel study for experimental validation.

### Implications for practice

In the current study the ginger foot soak did not result in any adverse reactions and all the participants in the experimental group reported significant reduction in low back pain and more favorable subjective experiences. Hence ginger foot soak can be considered as a viable non-invasive option by nurses caring for people with low back pain.

### CONCLUSION

There is a need for a non-toxic, natural therapy that relieves low back pain, without any disadvantages of the conventional medication or surgical procedures involved. People with nonspecific back pain require a simple treatment that supports the management of chronic pain, relieves their anxiety and improves their work performance. The present study demonstrated that ginger foot soak is very effective, simple and convenient external applications that require minimal preparation and materials to manage low back pain as there were subjective reports of clinically a significant reduction of back pain severity and a positive subjective reports of experiences among the ginger foot soak group at the end of three weeks of treatment.

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