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RESEARCH ARTICLE

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Efficacy of Hot Herbal Compression *(Chingdug)* compared to Diclofenac gel in the management nonspecific low back pain in Bhutan: a randomized non-inferiority trial

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ABSTRACT

Introduction: In Bhutanese Traditional Medicine, *Chingdug* therapy is available for the treatment of chronic low back pain. In this study, the effectiveness of *Chingdug* was compared with self-administered Diclofenac 1% gel in the management of nonspecific low back pain.

Method: A randomized non-inferiority trial was conducted among patients with nonspecific low back pain at National Traditional Medicine Hospital, Bhutan. Participants were randomly allocated to the *Chindgug* therapy (n = 30) delivered as per standard protocol and self-administered Diclofenac 1% gel (n = 30) groups. Primary outcomes were at baseline and weekly for two weeks.

Results: At the end of Week 2, 83.33% in the *Chingdug* group had a moderate score on Visual Analogue Scale compared to 63.33% in the Diclofenac group (p = 0.080). The mean Visual Analogue Scale score reduced from 5.47 at baseline to 3.49 at Week 2 ($p < 0.05$) in the *Chingdug* group while it reduced from 5.67 to 3.63 in the Diclofenac group ($p < 0.05$). There was a decrease in the Oswestry Disability Index score from 57.17 at baseline to 39.93 at Week 2 in the *Chingdug* group ($p < 0.05$) while it reduced from 60.20 to 49.93 in the Diclofenac group ($p < 0.05$). There was an increase in Modified Lumbar Schober Test score from 1.22 at baseline to 2.29 at Week 2 in the *Chingdug* group while it increased from 1.23 to 2.33 in the Diclofenac group.

Conclusions: Both *Chingdug* therapy and diclofenac gel showed a reduction in pain symptoms and disability and an improvement in lumbar range of motion.

Keywords: Alternative Medicine; Analgesia; Anti-inflammatory Agents; Chronic Pain; Herbal Therapy; Pain Perception; Thermotherapy

INTRODUCTION

Low Back Pain (LBP) is one of the leading causes of disability globally [1], and ranks as the third leading cause of hospital visits in Bhutan [2]. In Bhutan, the Ministry of Health reported a total of 91,409 patients with musculoskeletal disorders in the country, where LBP was a major part of it [3]. LBP is reported among the top ten diseases treated at the National Traditional Medicine Hospital, with 4615 patients treated for LBP in 2017 and 3518 patients in 2022 [4, 5].

LBP is defined as a discomfort localized to the

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anatomic area of the lumbosacral region, with or without radiation to the legs [6, 7]. In some patients with LBP, a patho-anatomical relationship can be demonstrated between the pain and one or more pathological processes, including compression of neural structures, joint inflammation, or instability of one or more spinal motion segments [6]. Back pain is classified as nonspecific when there is no clear causal relationship between the symptoms, physical findings, and imaging findings [7].

Guidelines for the treatment of LBP recommend using paracetamol as the first choice, followed by Non-Steroid Anti-Inflammatory Drugs (NSAIDs) or opioids [6]. The use of NSAIDs is based on the analgesic and anti-inflammatory mechanisms of the drug. NSAIDs are often available as over-the-counter medicines but are also associated with adverse events, such as gastrointestinal and cardiovascular events. Diclofenac gel 1% is one of the over-the-counter lotions available for musculoskeletal pain.

In Bhutanese Traditional Medicine (TM), there are various therapies available to treat LBP: *Jukpa* (སྦྱོག་པ། massage), *Luejong* (ལུས་སྦྱོང་། physical exercise), *Chulum* (ཆུལུམས། herbal bath), *Langlum* (རླངས་ལུམས། steam bath), *Langdug* (རླངས་དུག་ས། local steam), *Chingdug* (བཅིངས་དུག་ས། Hot Herbal Compression), and *Serkhap* (གསེར་ཁབ། Gold Needle) [8]. According to a survey among 226 patients with LBP visiting NTMH in 2015, Hot Herbal Compression was the most preferred choice of therapy [9]. However, there is no study to assess the efficacy of *Chingdug* in the treatment of LBP. This study was conducted to assess the efficacy of Hot Herbal Compression, compared against Diclofenac gel, in the management of non-specific LBP among patients visiting the National Traditional Medicine Hospital, Thimphu, Bhutan.

METHOD

Study design

This was a randomized non-inferiority trial to evaluate efficacy of *Chingdug*, hot herbal compression in the treatment of nonspecific LBP in comparison with Diclofenac 1% gel.

Study setting

The research was conducted at National Traditional Medicine Hospital, Thimphu, Bhutan between May and August 2020. The primary mandate of the hospital is to deliver high-quality TM services to patients from all twenty districts of the country. At present, hospital offers a variety of therapeutic services including acupuncture treatment. The facility receives a daily patient load of 150 to 200 in its outpatient department [10].

Study population

Patients visiting the National Traditional Medicine Hospital with nonspecific LBP during the study period were recruited. A total of 60 participants were enrolled 30 in each group. The inclusion criteria were as follows: both sexes, 20 – 70 years, diagnosed with LBP by TM physicians, pain lasting ≥6 weeks, pain score on Visual Analogue Scale measuring >3 and ≤7 [8]. The exclusion criteria were as follows: injection of local anaesthesia for pain relief within 2 weeks, post-surgical procedures around the spine or in the abdominal area within 3 months, patients with neurological signs, compression of the spinal nerve root, pregnancy or lactation, allergy to herbs used in *Chingdug* formula and Diclofenac, temperature 100 °F [6, 7], and those receiving any medications or injections.

Sample Size Calculation

The sample size calculated was 60 patients using G*power program with the following assumptions: α = 0.05, effect size = 0.8, power of test (β) = 0.9, and dropout rate = 10%. There were 30 participants were enrolled in each group.

Recruitment and randomization

Participants who fulfilled the inclusion criteria were randomized using a computer-generated simple randomization technique into two groups. Allocation cards were placed in an opaque, sealed and stapled envelopes by a research assistant who wasn't involved in assessment procedures.

Intervention group: *Chingdug*

Chingdug is a form of water-based therapy prescribed by Bhutanese TM practitioners. It is a local application of a moist-heated pouch of five prime (or five elixirs) herbs: *Ephedra gerardiana* Stapf, *Juniperus squamata* Buch, *Myricaria rosea* W. W. Smith, *Rho-*

dodendron anthopogon D. Don and *Tanacetum nubigenum* DC (Figure 1). In addition to these five major ingredients, 14 minor ingredients are added to pacify different natures of ailments. This product is called *dudtsi ngalum* (bath of 5-elixirs). *Chingdug* pack weighs 250 grams of prepared *dudtsi ngalum*.

Ephedra gerardiana Stapf is found in Lingshi, Dagala and Bumthang in Bhutan on stony slopes, gravel terraces and in drier areas at altitudes 2400 – 5000 metres above sea level (masl). Its aerial parts possess antibacterial activity against *M. leuteus, B. bronchiseptica, S. Setubal* at concentrations 5 – 25 mg/mL, anti-inflammatory, anti-influenza and analgesic effects, and anti-metastatic properties [11-13].

Juniperus squamata Buch is found in Lingshi, Dagala and Bumthang in Bhutan in inner valleys and alpine slopes at altitudes 3000 – 4500 masl. Its leaves contain various phytochemicals possessing anti-microbial activities. It is an alternative source of podophyllotoxin and deoxypodophyllotoxin [14].

Myricaria rosea W. W. Smith is found in Lingshi, Haa, Thimphu, Trongsa, Bumthang, Upper Mo Chu, Upper Mangde Chu and Upper Kulong Chu in Bhutan along stream sides at altitudes 3350 – 4250 masl. Its aerial parts are used in the treatment of *dugtshad, khrag-tshad* and *sha-dug* and as a febrifuge agent [11].

Rhododendron anthopogon D. Don is found in Haa, Lingshi, Dagala and Phajoding, Punakha, Trongsa, Bumthang, Sakteng and Upper Mo Chu in Bhutan in open hillsides, rocky slopes, cliff ledges at altitudes 3650 – 4700 masl. Dwarf rhododendron scrubs are also found above the tree line. Its flowers are found to possess anti-inflammatory and anti-bacterial properties [11].

Tanacetum nubigenum DC is found in Lingshi, Dagala and Bumthang in Bhutan along stony slopes and sandy grounds at altitudes 3600 – 4800 msal. Its aerial parts are found to possess antiplasmodial, cytoxicity and antimicrobial activities and are used as vulnerary, expectorant, styptic and anti-epistaxis agents [11].

The combination of *Chingdug* is heated to 46.1 – 52 °C and compressed over the lumbosacral region. Participants received *Chingdug* as per the Standard Operating Procedure approved by the Department of Traditional Medicine Services, Ministry of Health, Bhutan in 2015 [8]. *Chingdug* therapy was delivered by TM physicians as follows: Patients were laid on a bed in a prone position, the lumbosacral region was gently cleansed and massaged for 5 minutes, most and heated *Chingdug* therapy was applied over the lumbosacral region for 15 minutes, and the region was cleaned with a towel. The treatment group received *Chingdug* compressions of 20 min/session for five days a week i.e. Monday to Friday for two weeks.

Figure 1. There are five major herbal ingredients used in *Chingdug* therapy (hot herbal compression) in Bhutanese Traditional Medicine. All ingredients are sourced from the pristine environment of Bhutan

Control group: Diclofenac gel

The control group received Diclofenac 1% gel with an instruction to self-apply on the lumbosacral region, twice a day as recommended by a pharmacist or medical doctor for 2 weeks. The amount of Diclofenac gel was measured by applying it to the oblong area of the dosing card up to the 4-gram line (Figure 2). After having washed hands, the gel from the dosing card was applied to the lumbosacral region area measuring approximately 400 cm^2 of skin. To ensure that the participants followed the instructions, participants were briefed and made to sign an agreement consenting to do so.

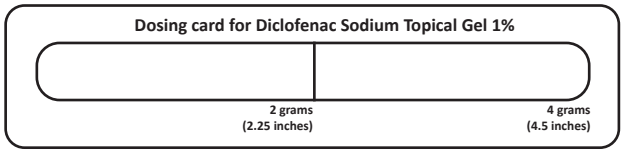

Figure 2. Card for measuring the dosing of 4 grams of Diclofenac 1% gel

Measurement of outcomes

Primary outcomes were assessed at baseline and weekly for two weeks by trained research assistants. Pain symptoms were assessed using the 10-cm Visual Analogue Scale. This scale is the most frequently used method to assess pain intensity [15]. The patients were instructed to mark a line in each of three different postures to indicate pain severity, and pain was independently evaluated in three different postural situations (in motion, standing, and sitting). It was quantified by measuring the distance in cm from 0 (no pain) to the patient's marked rating.

Functional disability was assessed using the Oswestry Low Back Pain Disability Index [16]. This is a self-reported questionnaire of a patient's perceived disability based on 10 areas of pain and daily activities (pain intensity, personal hygiene, lifting, walking, sitting, standing, sleeping, sexual activity, social activity and travelling). Each section is scored on a 6-point scale (0 – 5), with 0 representing no limitation and 5 representing maximal limitation. The subscales combined add up to a total maximal score of 50. The score is then doubled and interpreted as a percentage of the patient-perceived disability (the higher the score, the greater the disability). In cases where patients did not answer all 10 sections, the sum score of the answered sections was divided by the number of completed sections.

The range of motion of lumbar flexion was determined using the Modified Lumbar Schober Test [17]. Patients were asked to stand with their back towards the assessor. The assessor marked a horizontal line at dimples of Venus approximately at the level of L5 as the point of the lumbosacral junction. Point A, 5 cm below the line at dimples of Venus is marked and point B, 10 cm above the line at dimples of Venus is marked. The patient was then asked to touch his/her fingers to toes. By doing so, the distance between the two points (above and below the line of dimples of Venus) increases.

Additionally, quality of life was assessed using the Quality of Life SF-12 questionnaire at baseline and at the end of follow-up [18].

Statistical analysis

Data were entered into and analysed using SPSS (licensed). Continuous variables are summarized as mean and standard deviation, and categorical variables are summarized as frequency and percentages. In a within-group analysis, the mean values of the Visual Analogue Scale, Oswestry Disability Index and Modified Lumbar Schober Test between baseline and the consecutive weeks were compared by a one-way repeated measures analysis of variance. The comparison between groups was done using t-tests and comparisons within groups using paired t-tests and chi-square tests. P values less than 0.05 were considered statistically significant.

Ethics considerations

This study was conducted respecting the principles of the Declaration of Helsinki. Ethics approval was obtained from the Research Ethics Board for Health (Ref. No: PO/2019/109, dated 31 January 2020). Administrative approval was obtained from the Policy and Planning Division, Ministry of Health, Royal Government of Bhutan and Medical Superintendent of National Traditional Medicine Hospital, Thimphu, Bhutan. Informed written consent was obtained from the participants as per the consent process approved by the ethics board.

RESULTS

There were 30 patients who completed the follow up sessions in both arms as shown in the CONSORT diagram in Figure 3. The basic characteristics of the groups are shown in Table 1.

Outcome assessment

At baseline and Week 1, all patients in both groups scored moderate pain on VAS. At the end of Week 2,

there were 25 patients (83.33%) who scored better with moderate pain on VAS in the *Chingdug* group while there were 19 patients (63.33%) who scored moderate pain in the Diclofenac group, p = 0.080.

On the Visual Analogue Scale assessment, *Chingdug* reduced the pain score from 5.47 ± 0.69 at the baseline to 4.59 ± 0.68 at Week 1, and to 3.49 ± 0.52 at Week 2 ($p < 0.05$). In the Diclofenac group, the pain score decreased from 5.67 ± 0.59 to 4.62 ± 0.77 at Week 1 and to 3.63 ± 0.63 at Week 2 ($p < 0.05$) as shown in Table 2. Based on the Oswestry Low Back Pain Disability Index, *Chingdug* led to a reduction in functional disability score from 57.17 ± 14.87 at baseline to 50.13 ± 14.08 at Week 1 ($p < 0.05$) and 39.93 ± 11.89 at Week 2 ($p < 0.05$). In the Diclofenac group, the disability score reduced from 60.20 ± 10.38 at baseline to 50.07 ± 9.73 at Week 1 and 43.93 ± 7.97 at Week 2 ($p < 0.05$) as shown in Table 2.

Based on the Modified Lumbar Schober Test, in those receiving *Chingdug*, there was an increase in the range of motion score from 1.22 ± 0.54 at baseline to 1.67 ± 0.60 in Week 1, which was a 36.99% increment ($p < 0.05$). There was a further increase in the range of motion by 88.22% at Week 2 with a score of 2.29 ± 0.61 ($p < 0.05$). In the Diclofenac group, the range of motion at Week 1 had increased by 29.79% ($p < 0.05$) from 1.35 ± 0.97 at baseline to 1.75 ± 0.84, which was an increment by 29.79%. At Week 2, the range of motion increased by 72.44% to 2.33 ± 0.61. When the two treatment arms were compared, those who received *Chingdug* had a higher overall increment in the range of motion at follow-up (Table 2).

There was a 5.61% reduction in the SF-12 score in the *Chingdug* group compared to a 6.55% reduction in the Diclofenac group (Table 2).

DISCUSSION

In this study, participants in both groups experienced a statistically significant reduction in pain, functional disability, and an increase in lumbar range of motion at follow-up. Based on the findings, *Chingdug* compression is an effective option for alleviating pain associated with non-specific low back pain. However, there were no statistical differences in the primary outcome assessment of the two groups.

Though the ingredients in *Chingdug* differ from hot herbal compressions used in other countries, there are similarities noted in the procedure. A ran-

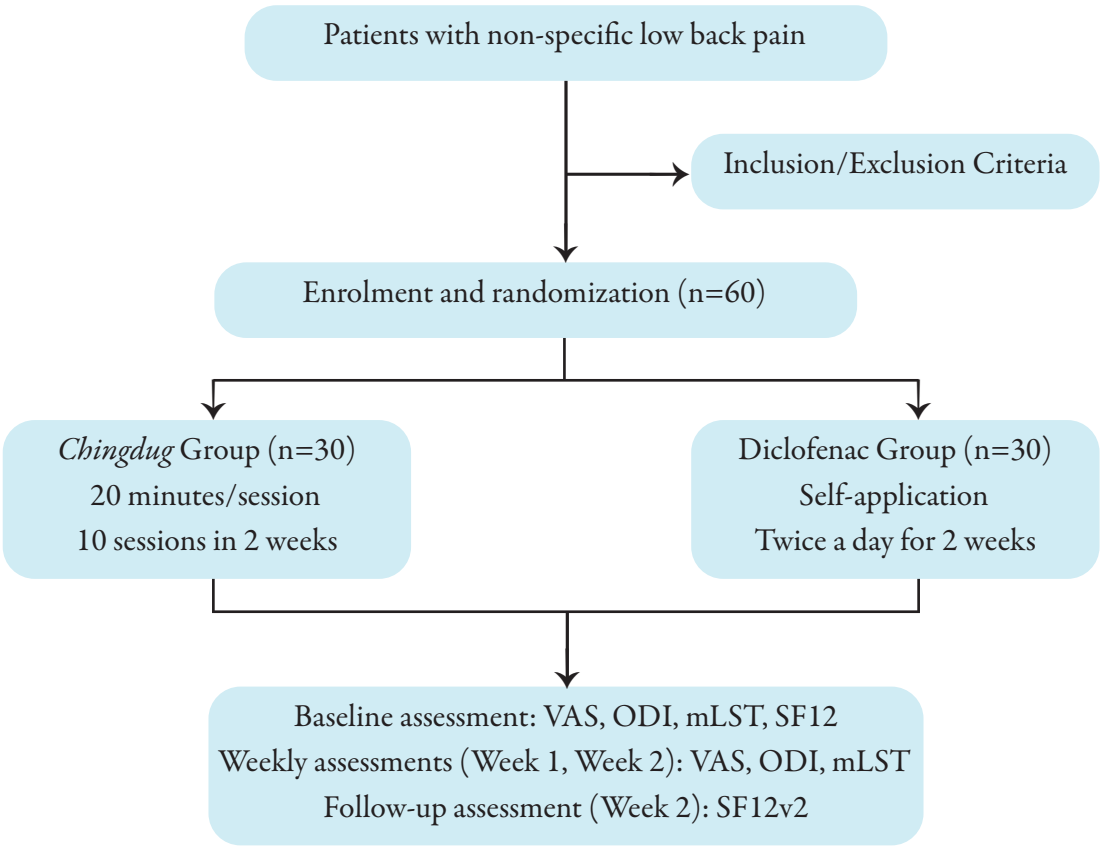

Figure 3. CONSORT diagram for the comparison of *Chingdug* therapy (hot herbal compression) vs Diclofenac 1% gelin the management of non-specific low back pain at National Traditional Medicine Hospital, Bhutan, 2020. mLST = Modified Lumbar Schober Test, ODI = Oswestry Low Back Pain Disability Index, SF-12 = Quality of Life Short Form-12, VAS = 10-cm visual analogue scale

domized control trial done in Thailand assigned 90 participants to 3 groups: a hot compression group, a hot herbal compression group, and a Diclofenac group for the treatment of pain among patients with myofascial pain syndrome [19]. This study reported that both the hot compression and hot herbal compressions were significantly effective in alleviating pain as Diclofenac gel. Similarly, a meta-analysis of clinical effects of Thai herbal compression covering 13 studies found that all the studies analyzed indicated that Thai herbal compression treatments were effective in alleviating pain among patients with osteoarthritis [20].

In our study, *Chingdug* treatment exhibited the capacity to alleviate non-specific low back pain but was not statistically different from that of the Diclofenac group. Although a definite reason for its effectiveness in the reduction of pain symptoms is yet to be studied, it can be hypothesized that the combination of heat and herbs including *Ephedra gerardiana, Juniperus squamata, Myricaria rosea, M. germanica, Rhododendron anthopogon* and, *Tanacetum nubigenum* contributes to resolution of symptoms. Among these five principal ingredients, *Ephedra gerardiana* is reported to possess anti-inflammatory properties [12, 13]. Therefore, the common indications for *Chingdug* in Bhutanese TM include post-traumatic pain, swelling of limbs, neurological disorders, muscular dystrophy, trembling, obstinate skin diseases, piles, gouts and arthritis.

Table 1. Sociodemographic characteristics of the patients with *Langshu* treated at the National Traditional Medicine Hospital, November 2021 to October 2022 (n = 70)

Characteristics	*Chingdug* hot herbal compression	Diclofenac gel 1%	p value
Age (years)			
21 – 30	6	1	
31 – 40	9	14	
41 – 50	7	8	0.090
51 – 60	6	6	
61 – 70	2	1	
Sex			
Male	12	15	0.436
Female	18	15	
Body mass index (kg/m²)			
<18.5	1	2	
18.5 – 23.9	7	8	0.417
24 – 26.9	14	8	
>27	8	12	
Occupation			
Office worker	10	8	
Shopkeeper	1	4	
Armed forces	1	1	0.651
Farmer	3	5	
Housewife	9	8	
Others	6	4	
Physical exercise	1	4	0.161

The strengths of this study includes the adoption of a standardized protocol for the delivery of *Chingdug* therapy. While the constituents of are manufactured as per standard national formulary, this is the first time it has been compared to over-the-counter Diclofenac gel in Bhutan. This is of particular importance because the data on the use of over-the-counter Diclofenac is not well documented. Given the improvements in pain score and functional status shown in this study, *Chingdug* therapy should be made accessible to patients with non-specific low back pain. In addition to improving symptoms, this therapy has the potential to improve the overall efficiency of the health system by reducing the patient load at allopathic medicine hospitals.

In addition to its use in nonspecific low back pain, the use of *Chingdug* therapy may be explored in chronic pain conditions such as myofascial pain, arthritis and in degenerative conditions. Given the properties contained in the various elements contained in *Chingdug* and the use of heat therapy, this might also be useful in inflammatory and degenerative conditions resulting from repetitive use injuries or sports injuries. It is, therefore, recommended to evaluate the effectiveness of *Chingdug* in other similar clinical conditions to reach its benefits to more patients.

As with other Bhutanese TM herbal formularies, there are multiple ingredients included in the *Chingdug* compressions. All these ingredients are collected from the natural environment based on standard procedures of collection and processing. The use of a combination of ingredients is to re-establish balances in elements and energies to relieve physical ailments. However, potential drug discovery of analgesic and anti-inflammatory agents contained in *Chingdug* may be possible with further detailed research. In addition, it is also important to study patient preferences given that Diclofenac is easily available over the

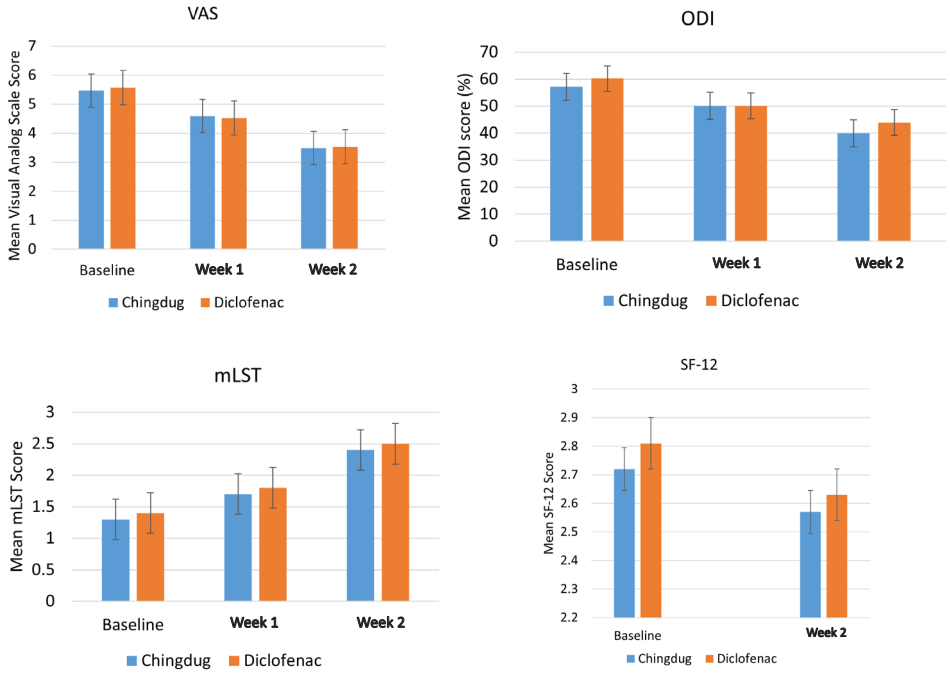

Figure 4. The assessment of primary outcomes in *Chingdug* therapy (hot herbal compression) vs Diclofenac gel in the management of nonspecific low back pain at the National Traditional Medicine Hospital, Thimphu, Bhutan, 2020. Primary outcomes were measured using (a) 10-cm visual analogue scale (VAS), (b) Oswestry Low Back Pain Disability Index (ODI), (c) Modified Lumbar Schober Test (mLST), and (d) Quality of Life Short Form-12 (SF-12)

Table 2. Comparison of outcomes treatment of non-specific low back pain with *Chingdug* therapy (hot herbal compression) vs Diclofenac gel at the National Traditional Medicine Hospital, Thimphu, Bhutan, 2020

Primary outcome assessment	Chingdug (mean ± SD)	Diclofenac gel (mean ± SD)	p value
Oswestry's Low Back Pain Disability Index			
Baseline	57.17 ± 14.87	60.20 ± 10.38	0.551
Week 1	50.13 ± 14.08	50.07 ± 9.73	0.983
Week 2	39.93 ± 11.89	43.93 ± 7.97	0.096
Visual Analog Scale			
Baseline	5.47 ± 0.69	5.67 ± 0.59	0.162
Week 1	4.59 ± 0.68	4.62 ± 0.77	0.853
Week 2	3.49 ± 0.52	3.63 ± 0.63	0.222
Modified Lumbar Schober Test			
Baseline	1.22 ± 0.54	1.35 ± 0.97	0.498
Week 1	1.67 ± 0.60	1.75 ± 0.84	0.673
Week 2	2.29 ± 0.61	2.33 ± 0.61	0.673
Quality of Life Short-Form 12			
Baseline	2.72 ± 0.19	2.81 ± 0.28	0.168
Week 2	2.57 ± 0.15	2.63 ± 0.16	0.156

counter and is self-administered.

Limitations

This was the first study on the comparison of *Chingdug* therapy with Diclofenac in Bhutan and only a relatively small sample size could be recruited. In this study, only one standard procedure was employed for the delivery of hot compressions while a combination of variations of the therapy may be recommended. In addition, the outcome assessor could not be blinded and might have contributed to differential subjectivity in some the measures.

CONCLUSION

Chingdug therapy when compared to Diclofenac gel showed reduction of pain and disability and improvements in lumbar range of motion among patients with nonspecific low back pain. This study adopted a standardized protocol for the delivery of *Chingdug* therapy. It is recommended that *Chingdug* should be accessible to more patients with nonspecific low back pain. The use of variations of *Chingdug* therapy and its effectiveness in other chronic pain conditions are recommended.

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Declarations

Ethics approval and consent to participate

Ethics approval was obtained from the Research Ethics Board for Health (Ref. No: PO/2019/109, dated 31 January 2020). Administrative approval was obtained from the Policy and Planning Division, Ministry of Health, Royal Government of Bhutan and Medical Superintendent of National Traditional Medicine Hospital, Thimphu, Bhutan. Informed written consent was obtained from the participants as per the consent process approved by the ethics board.

Consent for publication

Not applicable

Competing interests

SD and KT are editors of this journal. SD and KT were blinded from the peer review process of this article.

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Availability of data materials

The data set is available from the corresponding author upon request.

Author contributions

Conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing – original draft, writing – review and editing: SD

Conceptualization, investigation, methodology, resources, supervision, writing – original draft, writing – review and editing: KT, SK, PP, KS

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