



Short-term effects of high-intensity laser therapy *versus* ultrasound therapy in the treatment of low back pain: a randomized controlled trial

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Background. Low back pain (LBP) is a common musculoskeletal disorder that is highly prevalent in the general population. Management of this pathology includes numerous interventions depending on pain severity: analgesic, nonsteroidal anti-inflammatory drugs, steroid injections. However, the effect size and duration of symptom relief are limited. Physical therapy (ultrasound [US], laser therapy, manual therapy, interferential current therapy, Back School, aerobic work, therapeutic aquatic exercise acupuncture) have been reported often with mixed results. **Aim.** To evaluate the short-term effectiveness of high-intensity laser therapy (HILT) versus ultrasound (US) therapy in the treatment of LBP. **Design.** Randomized clinical trial. **Setting.** University hospital. **Populations.** Thirty patients with LBP were randomly assigned to a HILT group or a US therapy group. **Methods.** Study participants received fifteen treatment sessions of HILT or US therapy over a period of three consecutive weeks (five days/week). **Results.** For the 30 study participants there were no between-group differences at baseline in Visual Analogic Scale (VAS) and Oswestry Low Back Pain Disability Questionnaire (OLBPDQ) scores. At the end of the 3-week intervention, participants in the HILT group showed a significantly greater decrease in pain

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(measured by the VAS) and an improvement of related disability (measured by the OLBPDQ) compared with the group treated with US therapy.

Conclusion. Our findings obtained after 15 treatment sessions with the experimental protocol suggested greater effectiveness of HILT than of US therapy in the treatment of LBP, proposing HILT as a promising new therapeutic option into the rehabilitation of LBP.

KEY WORDS: Low back pain - Laser therapy - Ultrasonic therapy.

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Low back pain (LBP) is a common musculoskeletal disorder that is highly prevalent in the general population. It is the most common cause of long term disability in middle age and patients who are affected usually present persistent and frequent symptoms that justifies the use of self-management therapies. Musculoskeletal symptoms are most commonly felt in the back, and are frequently associated with functional limitations.¹ Of all adults complaining of LBP, only about five per cent can be classified

as having nerve root pain, with the remainder having LBP with or without referred leg pain. Spine disorders (e.g., degenerative disk disease, lumbar spinal stenosis or bulging disks) are only weakly correlated with presence of symptoms² so most primary care patients with LBP (approximately 85%) have pain termed nonspecific. Management of this pathology includes numerous interventions depending on pain severity: analgesic, nonsteroidal anti-inflammatory drugs (NSAIDs), and steroid injections. However, the effect size and duration of symptom relief are limited.³ Physical therapy [ultrasound (US), laser therapy, manual therapy, interferential current therapy, Back School, aerobic work, therapeutic aquatic exercise acupuncture] have been reported often with mixed results.⁴⁻⁷ Currently, there are no clear indications for surgery in nonspecific LBP. Several systematic reviews suggested that physical therapy has not provided unequivocal results due to the notable variability of the cause of LBP and the modalities of application, however several studies reported the effectiveness of laser therapy in the treatment of LBP especially combined with exercises.^{8,9} Low intensity laser therapy (LILT), when contrasted to a sham treatment, may be beneficial for pain relief and improved disability in patients with sub-acute or chronic non-specific LBP, although treatment effects are small. It seems that LILT effects are clinically modest respect to other beneficial interventions, such as exercise and intensive multidisciplinary pain treatment programmes for chronic LBP.¹⁰ Interestingly, a large meta-analysis on LILT suggested positive effect of various wavelengths on tissue repair and positive overall treatment effect for pain control although the included trials were not specific to LBP.¹¹ Laser therapy is based on the belief that laser radiation, and possibly monochromatic light in general, is able to alter cellular and tissue function in a manner dependent on the characteristics of light itself (e.g., wavelength, coherence).¹² By definition, LILT (often also known as “low energy” or “low power” lasers) takes place at low irradiation intensities. Therefore, it is assumed that any biologic effects are secondary to direct effects of photonic radiation, and are not the result of thermal processes.¹³ More recently, high intensity laser therapy (HILT) that uses higher intensity laser irradiation and causes minor and slow light’s absorption by chromophores has been utilized. Among physical therapeutic modalities, meta-analysis and systematic reviews suggested that there seemed to be little evidence to support the use of ultrasound (US) therapy

in the treatment of musculoskeletal disorders.^{14, 15} In particular, the evidence-based clinical guidelines of the Philadelphia Panel in 2001 suggested that for US therapy there was a lack of evidence regarding efficacy for acute or chronic LBP.¹⁶ However, a recent randomized clinical study (RCT) on nonspecific LBP suggested that the US group had significantly better functional status and range of motion (ROM) but not significantly different electromyographic findings in comparison with the control group.¹⁷ Furthermore, some studies have shown US to be effective in improving the symptoms, proposing this treatment as an acceptable physical modality for musculoskeletal diseases characterized by trigger point or muscle spasms as LBP.^{18, 19} Few studies have been conducted to compare the effectiveness of different physical therapies,⁴ due to the difficulty in selecting homogeneous groups of patients to reduce the variability of the results. To the best of our knowledge, no studies to date have been conducted on the possible effects of HILT on LBP. The aim of the present study was to evaluate the short-term effectiveness of two different physical modalities in the treatment of LBP: HILT and US therapy.

Materials and methods

Consecutive outpatients attending the Department of Physical Medicine and Rehabilitation, University of Foggia from June 2009 to January 2011 were invited to participate in the study. Patients experienced LBP for at least 3 weeks prior to the study. Diagnostic criteria for LBP were: the presence of lumbar pain at rest, pain during movements of the spine, absence of sciatica. All patients were also evaluated by computed tomography scan or magnetic resonance imaging of the lumbar spine. Patients were excluded from the study if they met any of the following criteria: anaesthetic or corticosteroid injections within 4 weeks of study enrollment, radicular pain, osteoporosis, surgery or previous fractures of the spine, spinal stenosis, a history of acute trauma, known osteoarthritis, myofascial pain syndrome, inflammatory rheumatic disease, systemic lupus erythematosus, diabetes mellitus type I or II, thyroid dysfunctions, obesity, pace-maker, neurological pathologies, and anxious-depressive syndromes. We diagnosed these conditions according to the Italian translation of the International Classification of Diseases, 9th

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revision, Clinical Modification (ICD-9-CM) (available at URL <http://icd9cm.chrisendres.com/icd9cm/>). A total of 55 consecutive patients (35 women and 20 men) were screened for study eligibility. At the end of the evaluation, 30 patients affected by subacute or chronic LBP who fulfilled the selection criteria, agreed to participate, and were enrolled in the study (19 females and 11 males; age range: 35 to 65 years; mean age [SD]: 51.2 [6.0] years). After complete description of the study, written informed consent was obtained from all subjects and/or their relatives. Reasons for exclusion are shown in Figure 1, which is a flow diagram of subject recruitment and retention. These participants were randomly assigned to two groups: a group of 15 participants (10 women and 5 men) received HILT; a group of 15 participants (8 women and 7 men) received US therapy. Patients received no other physical therapy intervention for LBP during the study and in the 4 weeks prior to the study. The patients were instructed to avoid analgesic/anti-inflammatory drugs for all the time of the physical therapy and to abstain from the execution of painful activities of daily living involving the lumbar spine. All the patients included in the present study were evaluated using the Visual Analogue Scale (VAS) ²⁰ and the Italian version of the Oswestry Low Back Pain Disability Questionnaire (OLBPDQ).²¹⁻²³ The protocol applied two different forms of physical modalities for a total of fifteen treatment sessions over a period of three consecutive weeks (five days/week). A group (HILT group) received HILT treatment with a neodymium YAG laser (Nd:YAG) to pulsed waveform, produced by HIRO 1.0 device (ASA srl, Arcugnano, Vicenza, Italy). The treatment consisted of a high power of peak (1 KW), wavelength of 1 064 nm, maximum energy for single impulse of 150 mJ, average power of 6 W, fluency of 760 mJ/cm², and duration of the single impulse less than 150 milliseconds. Pulsated waveform (5000W/cm²) can transfer light intensity to the soft tissue one-thousand times higher than continuous waveform (5W/cm²) with the same average power (1W) and bright spot (0.2 cm²). These ultra-short impulses establish a deep action in biological tissue (3-4 cm) with homogenous distribution of light sources on the radiated soft tissue without excessive thermal enhancements. For the treatment a standard handpiece endowed with fixed spacers was used to ensure the same distance to the skin and also the verticality to 90° to the zone to be treated with a bright spot diameter of 5 mm. Three phases of treat-

ment were performed for every session: 1) a starting/initial phase, with fast manual scanning (100 cm²/30 s) on the zones of muscular contracture, particularly on the lumbar and dorsal muscles, latissimus dorsi, obliquus externus and magnus gluteus. Scanning was performed both transversally and longitudinally with the patient in prone position. In this phase, a total dose of energy of 1200 J was administered; 2) an intermediate phase, applying the fixed handpiece vertically to 90° on the trigger points, until to a pain reduction of 70-80% was achieved. In this phase, the mean dose of energy was of 200 J; 3) a final phase, with slow manual scanning (100 cm²/60 s) on the same areas treated in the starting/initial phase, until a total dose of energy of 1 200 J was achieved. Three steps were predicted in the starting/initial and final phases of the treatment; the used fluency has been of 710 mJ/cm². Therefore, the total dose of energy administered was approximately 2 600 J. The time to apply all 3 stages of HILT was approximately 10 minutes. Another group (US therapy group) received continuous US for 10 minutes using a "SONOPLUS 492" (Enraf-Nonius BV, Rotterdam, the Netherlands), a device that operated at a frequency of 1MHz and at an intensity of 2 W/cm² with a duty cycle of 100%. The transducer head had an area of 5.8 cm² and an effective radiating area of 4.6 cm². The treating physical therapist, with the technique of using slow circular movements, applied the transducer head over the the lumbar and dorsal muscles, latissimus dorsi, obliquus externus and magnus gluteus, covering an area of approximately 150 cm². Subjects were assessed by a physical medicine physician at baseline (before the first treatment session, T₀), and at the end of physical therapy (after the last treatment session, T₁). Moreover, the pre-treatment (T₀) and post-treatment (T₁) clinical evaluation (VAS, OS) was determined by the same tester. After the baseline examination, subjects were randomly assigned to receive HILT or US therapy. Concealed allocation was performed with random numbers generated before the beginning of the study using the website <http://www.random.org/>. The procedure Random Integer Generator allowed us to generate random integers. A priori it generated 100 random integers and, before the beginning of the study, the number of randomization was already present. Individual, sequentially numbered index cards with the random assignments were prepared. The index cards were folded and placed in sealed opaque envelopes. A physician who was unaware of the baseline exami-

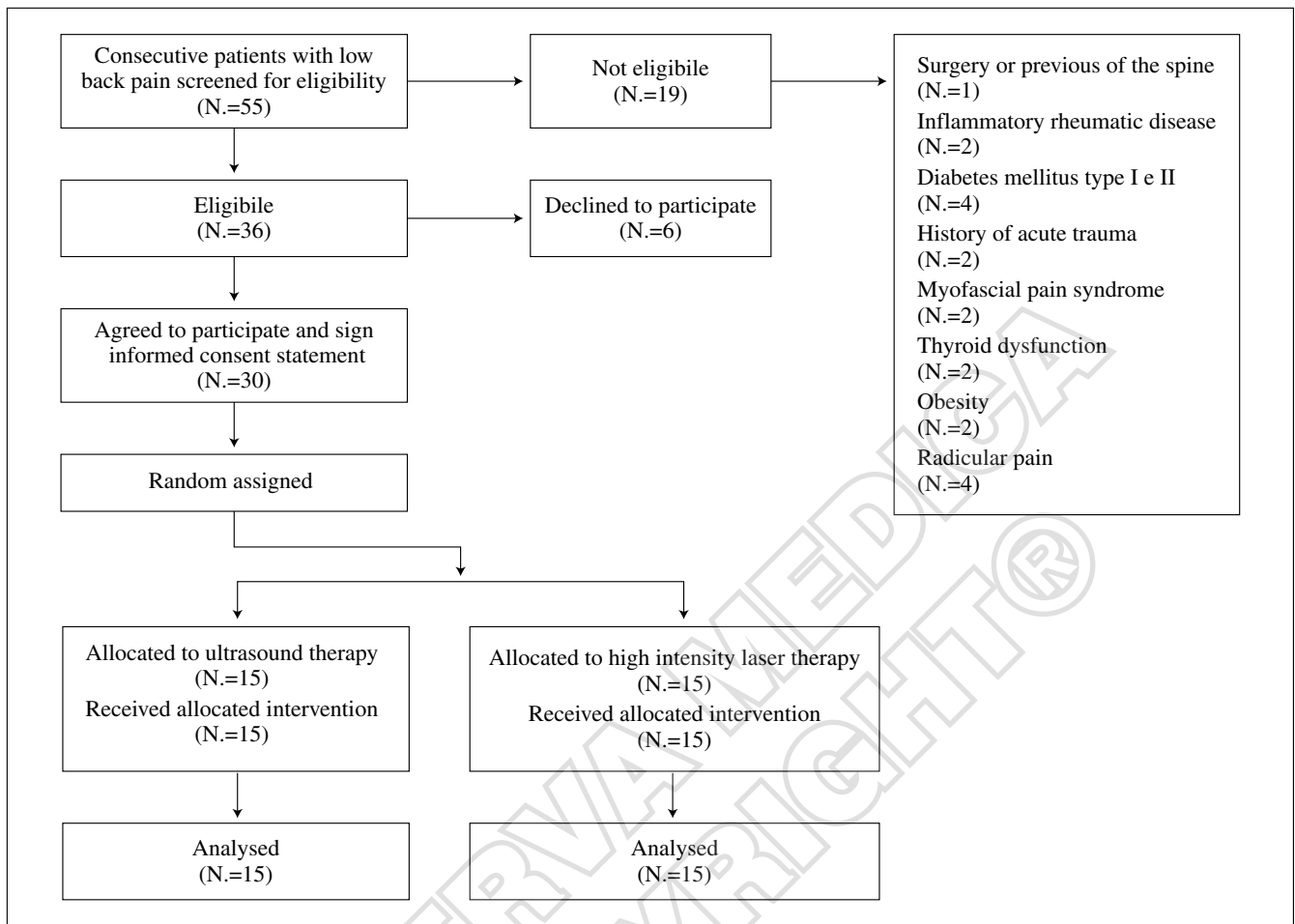


Figure 1.—Flow diagram of subject retention and recruitment for ultrasound therapy and high intensity laser therapy for low back pain.

nation findings opened the envelopes to attribute the interventions according to the group assignments. It is important to remember that the physicians who performed the clinical evaluation of the patients were blinded to the group assignment. All subjects in the two treatment groups received fifteen treatments in the three week period.

Statistical analysis

All analyses were performed using SPSS for Windows, version 6.1, except for the sample size and power calculations that were performed with nQuery Advisor statistical software (nQuery Advisor 6.0. Statistical Solutions, Cork, Ireland [www.statsol.ie], 2005). Difference between baseline (T_0)

and post-treatment scale scores (T_1) for each group was computed by Wilcoxon signed-rank test. Difference between each treatment-group was performed by Mann–Whitney U test. The level of statistical significance was set as $P < 0.05$.

Results

Sample size of 15 patients for the HILT group and 15 patients for the US therapy group achieved a power over 80% to detect a difference of 10% in the OLBPDQ (score: 13 points) in a design with 2 repeated measurements when the standard deviation was 3.5, the correlation between observations on the same subject was 0.7, and the alpha level was

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TABLE I.—Test scores at baseline and post-intervention of patients with low back pain submitted to ultrasound (US) therapy.

Patient	VAS t ₀	VAS t ₁	OLBPDQ t ₀	OLBPDQ t ₁
1	8	3	28	15
2	7	3	24	12
3	7	3	30	15
4	7	5	22	8
5	7	4	28	12
6	8	3	27	9
7	7	5	25	10
8	7	3	31	10
9	8	3	30	9
10	7	2	27	9
11	7	4	30	14
12	8	3	31	16
13	7	3	28	12
14	7	2	24	18
15	8	5	26	17

VAS: Visual Analogic Scale.
OLBPDQ: Oswestry Low Back Pain Disability Questionnaire.

TABLE II.—Test scores at baseline and post-intervention of patients with low back pain submitted to ultrasound (US) therapy.

Patient	VAS t ₀	VAS t ₁	OLBPDQ t ₀	OLBPDQ t ₁
1	7	4	26	12
2	6	5	28	16
3	7	4	26	14
4	7	4	30	15
5	6	3	22	10
6	7	5	27	18
7	7	5	30	18
8	8	5	30	14
9	7	5	28	18
10	7	4	26	15
11	7	4	30	18
12	8	4	30	18
13	6	4	28	15
14	7	4	31	17
15	7	5	29	19

VAS: Visual Analogic Scale.
OLBPDQ: Oswestry Low Back Pain Disability Questionnaire.

0.05. Sample size of 15 patients for the HILT group and 15 patients for the US therapy group achieved a power over 80% to detect a difference of 20% in the VAS (score: 3.5 points) in a design with 2 repeated measurements when the standard deviation was 1.0, the correlation between observations on the same

TABLE III.—Test performance at baseline and post-intervention of patients with low back pain in High Intensity Laser Therapy (HILT) and ultrasound (US) therapy groups: evaluation within groups. Both groups showed an improvement of mean Visual Analogic Scale (VAS) and Oswestry Low Back Pain Disability Questionnaire (OLBPDQ) scores from T₀ to T₁ (<0.001).

	Scale	T ₀ median (IQR) 25°, 75° percentiles	T ₁ median (IQR) 25°, 75° percentiles	Wilcoxon test P value
HILT Group (N.=15)	OLBPDQ	28 (6) 24.30	12 (6) 9.15	<0.001*
	VAS	7 (1) 7.8	3 (1) 3.4	<0.001*
US Group (N.=15)	OLBPDQ	28 (4) 26.30	16 (4) 14.18	<0.001*
	VAS	7 (0) 7.7	4 (1) 4.5	<0.001*

*Statistically significant. IQR: interquartile range.

TABLE IV.—Test performance at baseline and post-intervention of patients with low back pain in High Intensity Laser Therapy (HILT) and ultrasound (US) therapy groups: evaluation between groups. HILT group showed a statistically significant reduction of mean Visual Analogic Scale (VAS) and Oswestry Low Back Pain Disability Questionnaire (OLBPDQ) scores respect to US group at the end of the treatment (P<0.005).

	Scale	HILT Group median (IQR) 25°, 75° percentiles	US Group median (IQR) 25°, 75° percentiles	Mann-Wilcoxon test - P value
HILT Group (N.=15)	OLBPDQ	28 (6) 24.30	28 (4) 26.30	0.512
	VAS	7 (1) 7.8	7 (0) 7.7	0.126
US Group (N.=15)	OLBPDQ	12 (6) 9.15	16 (4) 14.18	0.006*
	VAS	3 (1) 3.4	4 (1) 4.5	0.009*

*Statistically significant. IQR: interquartile range.

subject was 0.7, and the alpha level was 0.05.

There was no significant difference in the gender and age distribution between two groups. No subject reported taking analgesic/anti-inflammatory drug or adverse effects during the period of their participation in the study. All 30 participants completed the trial and were included in the analysis (Figure 1). In Table I, we showed the test scores at baseline and postintervention of patients with LBP submitted to HILT, while in Table II we showed the test scores at baseline and post-intervention of the same patients submitted to US therapy. In Table III, we showed evaluation within groups, with the mean

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VAS and OLBDPQ scores in both groups with an improvement of clinical symptoms (VAS) and functionality (OLBDPQ) comparing the mean score from T_0 to T_1 (<0.001). Table IV showed evaluation between groups, with the HILT Group with a statistically significant reduction in to the VAS and OS mean scores respect to US group at the end of the treatment ($P<0.005$).

Discussion

The present study compared the results obtained after fifteen treatment sessions over a period of three consecutive weeks using two different physical modalities in patients diagnosed with LBP. The group of patients treated with HILT showed a greater reduction in pain and an improvement of functionality of the spine (measured by VAS and OLBDPQ) compared with the group treated with US therapy. There was a significant difference in change after fifteen treatment sessions over a period of three consecutive weeks from baseline by groups. Among physical modalities, US therapy and laser therapy showed contrasting findings in the treatment of musculoskeletal disorders.⁸⁻¹⁹ The pathogenesis varied, but the cause of pain is to some extent always inflammation. Theoretically, US therapy can have a different impact in various diseases and many explanations of the effect of this treatment have been postulated. However, in the literature there is neither evidence for such an assumption nor conclusive explanation for how pain is relieved by US. Well-designed studies are few; the description of drop-outs, randomisation method, apparatus, validation of apparatus, mode of delivery, size of head, treated area and follow-up time were found generally insufficient in published articles. Contrasting results are shown in literature also for laser therapy.^{8, 9, 11, 24} In fact, some authors suggested that LILT without association with exercise could be useful in the management of LBP.^{8, 9} Other authors, measuring pain in those receiving LILT and in those receiving exercise, did not show any significant differences between the groups in short-term and intermediate-term follow-ups, so concluding that there was no significant difference between LILT and exercises. LILT showed greater results comparing with sham laser, and pain was measured in LILT and sham groups using VAS, while pain-related disability was measured using the OL-

BDPQ.²⁴ Therefore, although the current evidence is conflicting, it appeared that LILT was more beneficial than placebo when applied as a single intervention for patients with LBP in the short time, and our findings with HILT may open new promising therapeutic options. The present study, after fifteen treatment sessions of the experimental protocol, suggested a greater effectiveness of HILT as compared to US therapy in the treatment of LBP. The group of patients treated with HILT showed a greater reduction in pain and related disability in LBP as measured by the VAS and the OLBDPQ compared with the group treated with US therapy. At present, no studies have been conducted to compare the effectiveness of these different physical therapies. HILT quickly reduces inflammation and painful symptomatology.²⁵ It utilizes a particular waveform with regular peaks of amplitude elevated value and distant among them to decrease thermal accumulation phenomenon, able to induce in the deep tissue photochemical and photothermal effects that increase blood flow, vascular permeability, cell metabolism, and photo-mechanical level of tissue,²⁶ reaching very fast times of application. The action of HILT developed on the nervous terminations with an analgesic effect, whereas there was not an evident diminution of the inflammation.^{27, 28} This type of radiation is characterized by a particular absorption that is obtained not with concentrated light but with diffuse light in all directions (scattering phenomenon), increasing the mitochondrial oxidative reaction and adenosine triphosphate, RNA, or DNA production (photochemistry effects) and resulting in the phenomenon of tissue stimulation (photobiology effects).²⁵ Limitations to the study include the lack of a control group that received no treatment whatsoever, which refrain our ability to claim cause and effect. Both groups may have improved just due to the passage of time, and avoiding strenuous activity for the treatment period. Furthermore, the median difference between the two groups looks modest as for both pain and function, and significance may be due to the very small variability within each group. However, notwithstanding the small number of patients in the two groups, this sample size achieved a power over 80% to detect a difference of 20% in the OLBDPQ score and 10% in the VAS score. At present, we compared a new treatment option (HILT) with an accepted physical modality, US therapy. Few report cited the effect of HILT on musculoskeletal disease.²⁹ As discussed above, some studies have shown US to be effective

in improving the symptoms and functional status in LBP.¹⁷⁻¹⁹ Another limitation is the lack of follow-up data, that reduced the clinical application of our findings study on short-term effects of HILT and US therapy in LBP. Furthermore, our protocol including 15 treatment sessions over a period of 3 weeks could be challenging to apply in clinical practice. Moreover, this treatment can be useful to reduce pain and disability related, but it is important add a rehabilitation programs with exercise of leg and spine and stretching to reduce the frequency of LBP.

Conclusions

Although further studies are needed to confirm the effectiveness of physical therapy interventions in this syndrome, the results of the present study suggested that HILT may have greater benefit in comparison with US therapy in reducing pain and related disability in LBP. The results of the present report are encouraging but other studies with greater samples, longer-term findings, and possible comparisons with other conservative interventions or placebo control groups are needed in the next future.

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