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THE SYNERGISTIC EFFECTS OF COMPREHENSIVE SPINAL ALIGNMENT EXERCISES AND AURICULAR THERAPY ON SUBACUTE LOW BACK PAIN: A PILOT STUDY

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ABSTRACT

Background: Low back pain (LBP) is one of the most common ailments that causes a large group of the population to live with disability and decreased quality of life. Comprehensive spinal alignment exercise and auricular therapy, a newly developed exercise set, have independent supportive evidence, but their combined effect in subacute LBP has not been examined.

Purpose: The objective of this pilot research was to determine the feasibility and possible impact of combining spinal alignment therapy and ear acupuncture compared to treatment by either method alone.

Method: A preliminary randomized control (3 groups) study was designed in which 45 patients (15 in each group) suffering from sub-acute episodes of non-specific low back pain were treated with Comprehensive Spinal Alignment Therapy (Group A), Auricular therapy (Group B), and both methods together (Group C). Pain intensity (NPRS) and disability status (ODI) were measured before and after the intervention.

Results: All groups showed a statistically significant improvement after the intervention ($p<0.001$), with the combination group additionally doing better than either of the methods alone ($p<0.01$).

Conclusion: Combining spinal alignment therapy and auricular therapy for the treatment of Sub Acute LBP pain is feasible, safe, and advantageous compared to either of the treatments.

KEYWORDS: low back pain, subacute, spinal alignment exercise, auricular therapy

INTRODUCTION

Low back Pain is one of the health conditions that causes disability and can occur in all age groups globally, across countries of all income categories. It also causes a decrease in quality of life, affecting socio psychological status of an individual. [1].LBP is a global burden disease. As per previous studies, the incidence rate of LBP has doubled between 1990 and 2021. Further, as per the survey conducted in 2020, around 619 million people were affected, and if this percentage of increase continues till 2050, Low back pain sufferers may increase to around 843 million people. More chances are in the case if no alterations in sedentary lifestyles have been made in the population.[3,4,5]

Low back pain is catogorized in 3 different types: acute, subacute, and chronic. The subacute phase is the pain that persists between four and twelve weeks after onset. It causes difficult recovery and high risk of transition into chronic, along with long duration of treatment, and often disturbs quality of life, and if not treated, can lead to Disability. [1,2]. As per guidelines, clinical practices for acute and sub-acute pain can be managed by non-pharmacological, non-invasive methods of treatment, resulting in a decrease in pain and an improvement in QOL. [6]

Two conservative modalities have independently accumulated supportive evidence in the low back pain literature. Comprehensive spinal alignment (core/segmental stabilization) exercise programs are designed to retrain the deep trunk stabilizers, chiefly the transversus abdominis and lumbar multifidus, restoring proprioceptive control and segmental stability of the lumbar spine [7-13]. In this study, two conservative techniques have been approached i.e Comprehensive spinal alignment exercises and auricular therapy. The aim of the newly created set of exercises, named comprehensive spinal alignment exercises to release the tender points, paraspinal muscles from the cervical to the low back, hamstring, calf, and foot muscles. stabilizers. This practice helps restore proprioceptive control and stability in the lumbar spine. Auricular therapy, a non-invasive method that targets reactive points on the external ear, has also shown clinically significant reductions in pain and improvements in function [14-18]. It offers low costs, minimal risks, and is easy to administer by oneself.

While each approach has been looked at separately, spinal alignment exercises focus on the mechanical and nerve-related causes of pain. In contrast, auricular therapy is thought to work through central and peripheral pathways that affect how we perceive pain. Since their suggested ways of working are different, using both methods together might provide better results than either one by itself. This pilot study aimed to gather initial data on the feasibility and effectiveness of this combined approach for patients with subacute low back pain, in preparation for a larger trial.

2. REVIEW OF LITERATURE

2.1 Burden and Natural History of Low Back Pain

According to Hartvigsen et al. ascited in the Lancet Low Back Pain series, it has been reported that low back pain is a common symptom that is not specifically defined. Additionally, it is mentioned that the burden of disability due to low back pain has increased tremendously, and this requires changes in the way that treatment is approached and promoted.1Inthisregard, Promote et al., who published a companion paper examining the evidence for prevention, intervention, and treatment of low back pain, mentioned that exercise therapy, education, as well as combined non-pharmacological intervention sconstitute the main components that under lie successful management of low back pain. 2 In an earlier systematic review, Hoy et al. Hoy et al. investigated the prevalence of low back pain and advanced estimates related to its occurrence in the worldwide populations. 3,4 Additionally, Global Burden of Diseasestudiesshowthattheratesoflowbackpainmaydeclinetoacertainextent, but the total number of low back pain cases still grows.5

2.2 Spinal Alignment and Core Stability Exercises

A randomized controlled trial was performed by Hlaing et al. comparing core stabilization exercise and general strengthening exercise in 36 patients with subacute non-specific low back pain and reported significantly better results in terms of lumbar proprioception, standing balance, and multifidus/transversus abdominis muscle thickness in the core stabilization group after four weeks of intervention [7]. Also, Puntumetakul et al. conductedastudyproving that a properly structured core stabilization program improves lumbar joint position sense in the same subacute population, which confirms the importance of proprioception in terms of spinal alignment training [8]. Akhtar et al., in conducting a randomized clinical trial on chronic non-specific low back pain confirmedthat core stabilization exercise is much more effective for pain management than standard exercise therapy [9]. Earlier research by Kumar utilized a placebo-controlled crossover design and found that segmental stabilization exercise alleviated pain and improved the functioning of patients with lumbar segmental instability, thereby providing the biomechanical rationale for focusing on deep trunk stabilizers in mechanical low back pain. In addition to segmental stabilization, there are broader postural reeducation measures with some effectiveness. 10. Bonetti et al. compared Global Postural Reeducation with conventional stabilization exercise programs for patients suffering from persistent LBP and found that the results in terms of pain and disability were similarly promising. 11 McCaskey et al. conducted an exploratory CTR trial and demonstrated that postural sensorimotor training in addition to physiotherapy enhanced postural control, as well as reduced pain and improved functioning, for individuals struggling with chronic nonspecific LBP. 12 Ożóg et al. additionally revealed that techniques that improve postural regulation, such as myofascial release, can help to show the improvement in postural control of patients suffering from chronic LBP, reflecting the link between postural/alignment therapy and clinical outcomes. 13

2.3 Auricular Therapy for Low Back Pain

Over the years, auricular acupressure has been tested in increasingly large studies. Yeh and colleagues were the first to test auricular acupressure's effectiveness against a sham protocol in a small randomized clinical trial that included older patients with chronic back pain. The future research was conducted in a much larger study that included 272 patients and showed that auricular acupressure was much more effective than a sham procedure. 14

The role of auricular therapy has already been described. According to He et al., auricular therapy has an anatomical mechanism through which vagus nerve receptors influence the processing of pain. 15, 16

From the results of a biological study carried out by Lin et al., who worked on the trial of auricular acupressure, it is evident that there is evidence of a reduction in the amount of cytokines (IL-1β, IL-2, and IL-6) present along with calcitonin gene-related peptide and a decrease in pain perception [17]. Yang et al. carried out a systematic review based on evidence synthesis in which they analyzed results of seven randomized controlled trials on the effect of auricular acupressure, which showed notable and significant effectiveness of these methods in pain relief after 12 weeks since the start of this method of treatment, and the effectiveness was still there after 4 weeks from the moment of treatment completion, while the results concerning the level of disability showed some inconsistency [18].

Therefore, taking into consideration these results, it can be stated that auricular therapy is an efficient and cheap method of treatment used for pain management. However, most of the research has been done using the method of therapy for chronic pain, and no study has been carried out concerning the comparison of this method of treatment with other techniques for spinal alignment.

2.4 Outcome Measurement and Pilot Study Methodology

Fairbank and Pynsent have introduced the Oswestry Disability Index, which is the most commonly utilized condition-specific outcome measurement for low back pain disability and is recognized as the gold standard for different trials involving this particular population. In the case of pilot studies and feasibility studies, which do not have a prior variance estimate to rely on, Julious put forth the rule of thumb of having 12 participants per arm while factoring in feasibility, variance precision, and regulatory aspects as part of the recommendation that has been utilized in choosing a sample size for this study.

3. Justification for Research

The existence of a high prevalence of low back pain, the chances of moving from subacute to chronic disability, and the efficacy of spinal alignment exercise and auricular therapy, already proven, create a legitimate need for carrying out a pilot study on the effects of their combined use. Such research is important to provide feasibility, tolerability, and effect size estimations needed for the preparation and planning of a proper randomized controlled trial.

4. Aim and Objectives

4.1 Aim

To evaluate the synergistic effects of a thorough spinal alignment exercise program combined with auricular therapy, compared with either modality alone, in individuals with subacute low back pain.

4.2 Objectives

1. To assess the feasibility, adherence, and tolerability of a combined spinal alignment exercise and auricular therapy protocol in patients with subacute low back pain.
2. To obtain a preliminary estimate of the effect of the combined protocol on pain intensity and functional disability, relative to spinal alignment exercise alone and auricular therapy alone.

Hypotheses

Null hypothesis (H0): there's no significant difference in pain intensity or functional disability between the combined intervention group and either single-modality group.

Alternative hypothesis (H1): The combined spinal alignment exercise and auricular therapy protocol produces significantly greater improvement in pain intensity and functional disability than either modality applied alone.

6. MATERIALS AND METHODS

6.1 Study Design

A prospective, randomized, three-arm, single-blind (assessor-blinded) pilot study.

6.2 Setting

Once the institutional ethical certificate is received, the data collection was started with the baseline assessment of participants.

Study Setting: Nootan College of Physiotherapy and Rachna Clinic, Visnagar, Gujarat.

6.3 Sample Size

For a pilot study, a convenience sample of 45 participants (15 per arm) was recruited, consistent with accepted pilot-study conventions for feasibility and effect-size estimation rather than definitive hypothesis testing [20].

6.4 Participants

Inclusion criteria:

- Age 45–55 years, both genders.
- Non-specific low back pain of 2–12 weeks' duration (sub-acute phase).
- Numeric Pain Rating Scale score ≥ 4/10 at screening.
- Willing and able to provide informed consent and attend scheduled sessions.

Exclusion criteria:

- Red-flag pathology (fracture, malignancy, infection, cauda equina syndrome, inflammatory arthropathy).
- Prior spinal surgery or structural spinal deformity.
- Radiculopathy with progressive neurological deficit.
- Ear pathology or dermatological condition precluding auricular stimulation.
- Pregnancy, or concurrent participation in another interventional trial.

6.5 Randomization and Blinding

Eligible participants were allocated using computer-generated block randomization, with allocation concealed via sequentially numbered opaque sealed envelopes, to one of three groups: (A) detailed spinal alignment exercise alone, (B) auricular therapy alone, or (C) combined spinal alignment exercise plus auricular therapy. The outcome assessor was blinded to group allocation; given the nature of the interventions, participants and treating therapists couldn't be blinded.

6.6 Interventions

Group A-Comprehensive spine and Lower Limb Alignment therapy exercise: A structured, progressive program targeting deep segmental stabilizers (transversus abdominis, lumbar multifidus) together with postural realignment and global trunk conditioning, delivered in supervised sessions of approximately 15 minutes, 5 sessions per week for 3 weeks.

Group B-Auricular therapy: Application of auricular acupressure (Semen Vaccariae seeds/magnetic pellets) to standardized reactive ear points associated with low back pain, with participants instructed to self-stimulate points for 2 minutes, 1 time daily for 3 weeks; pellets replaced weekly over 3 weeks, following protocols established in prior auricular point acupressure trials.

Group C-Combined protocol: Concurrent delivery of the Group A exercise program and the Group B auricular therapy protocol over the same 3-week period.

Description of Comprehensive Spine and Lower Limb Alignment Therapy (Group A):

(As shown in Table 1)

General Instructions for the Above Intervention:

1. Before performing the technique, a heat/moist pack was applied to the back region.
2. The participants were guided to follow the instructions to avoid heavy lifting, vigorous movements, traveling, or any sort of overexertion while the treatment is ongoing.
3. The patient attended the session for 3 weeks.
4. The patients were previously informed that some complain of some sort of pain that can occur, but it's natural and will subside with the continuation of the exercise.

Time period: Weekly 5 days/1 session per day

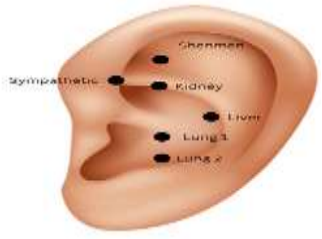
Table 1: Description of Comprehensive spine and Lower Limb Alignment therapy (Group A)

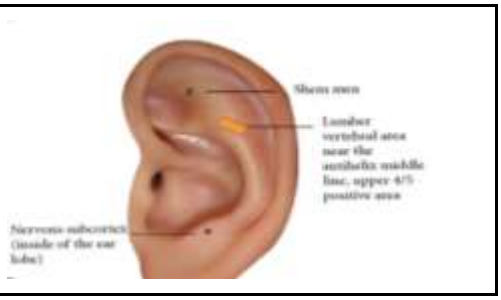
Sr. No.	Procedure	Photographs
1.	The participants were instructed to be in a prone line position and then press the vertex (tip of the head) with the thumb for 2 minutes.	
2.	Next steps, with the help of both hands, first fingers lift cervical muscles one finger width laterally from the cervical spinal process three times, from the C1 to C7 area.	
3.	Then later, for 1 minute, press the middle fibers of the trapezius muscle.	
4	After pressing the trapezius, use your thumb and give pressure to the paraspinal muscles, the thoracic-to-lumbar region, and the gluteal region.	
5	With the help of the palm, perform circular movement in the lateral aspect of the thorax to the gluteal region. Then hacking massage is applied from the cervical to the tendo-achilles area bilaterally.	 

6	After the above step, the therapist will keep one hand on the lumbosacral region of the patient's back and ask the patient to bend the knee three times, one by one. The therapist will hold the ankle area and, after 90-degree knee flexion, rotate the knee clockwise and anti- clockwise. These two maneuvers are applied at the knee.	
7	The therapist will then use both hands and hold the ankle joint of the patient at 90-degree knee flexion and perform passive dorsiflexion and plantar flexion of the ankle and rotation of the ankle (clockwise and anti- clockwise).	 
8	After that, actively ask the patient to bend the bilateral knee flexion. A therapist can assist the movement at the end range.	
9	At last, the last therapist informs the patient and presses the lateral surface of the thigh (bilaterally) three times from the greater trochanter to the knee joint line with the therapist's four fingertips. Usually, this area is very painful in patients, so prior information must be provided to them.	

Group B—Auricular therapy (Table 2):
Technique: Manual stimulation of spinal points on the ear will be done for 20 seconds at a time, followed by stimulation of points like the kidney for 10 to 20 seconds, which is essential for treatment.
Safety: Auricular therapy is generally considered safe when performed by a trained practitioner. However, precautions should be taken for people with infections, wounds, or severe skin conditions on the ear.

Table 2: Auricular therapy

Sr. No.	Procedure	Photographs
1	Auricular Points Kidney: Often used to help with chronic back pain, as the kidneys are believed to support the lower back. Ref. of Auricular Therapy: https://doi.org/10.3390/brainsci14030205	

2	Spinal points: Located on the ear anti-helix, these correspond to various regions of the spine. Lower Back point: Specific auricular zones that correlate to t lumbar and sacral regions of the spine. Reference: https://doi.org/10.1155/2012/383257	

6.7 Outcome Measures

- Primary: Pain intensity—Numeric Pain Rating Scale (NPRS).
- Secondary: Functional disability-Oswestry Disability Index (ODI) Questionnaire.
- Feasibility: recruitment rate, session/self-stimulation adherence, dropout rate, and adverse events.

Assessments were recorded at baseline and at the end of the 3-week intervention.

6.8 Data Analysis Plan

Data were summarized descriptively (means, standard deviations, and 95% confidence intervals) given the pilot nature of the study. Between-group comparisons used one-way ANOVA with Bonferroni-adjusted post-hoc pairwise comparisons for continuous outcomes; within-group pre-post changes were analyzed using paired t-tests. Effect sizes (Cohen's d) were calculated for all between-group comparisons to inform the sample size of a subsequent definitive trial, in line with recommended pilot-study reporting standards. Statistical significance was set at $p < 0.05$.

7. Ethical Considerations

•Approval was obtained from the Institutional Ethics Committee prior to recruitment.
•Written informed consent was obtained from all participants.
•Confidentiality of participant data was maintained throughout, and participants were free to withdraw at any stage without effect on their routine clinical care.

8. RESULTS

8.1 Participant Flow and Baseline Characteristics

Of 52 individuals screened, 45 met eligibility criteria and were randomized (15 per group). Two participants were lost to follow-up (one in Group A due to a busy schedule, one in Group B due to an unrelated illness), yielding 43 completers (Group A, n=14; Group B, n=14; Group C, n=15). All analyses below follow an intention-to-treat approach using last-observation-carried-forward for the two dropouts.

Table 1. Baseline demographic and clinical characteristics (illustrative data)

Characteristic	Group A (n=15)	Group B (n=15)	Group C (n=15)	p-value
Age, years (mean ± SD)	34.6 ± 8.1	35.2 ± 7.6	33.9 ± 8.4	0.87
Sex, female n (%)	8 (53%)	9 (60%)	8 (53%)	0.91
Pain duration, weeks (mean ± SD)	7.8 ± 2.0	8.1 ± 1.9	7.6 ± 2.2	0.79
Baseline NPRS (0–10)	6.1 ± 1.0	6.0 ± 1.1	6.2 ± 0.9	0.82
Baseline ODI (%)	32.4 ± 6.2	31.8 ± 5.9	33.0 ± 6.5	0.79

No significant between-group differences were observed at baseline for any demographic or clinical variable (all $p>0.05$), confirming adequate randomization.

8.2 Pain Intensity (NPRS)

Table 2. NPRS scores at baseline and post-intervention (illustrative data)

Group	Baseline (mean ± SD)	Post-4-week (mean ± SD)	Within-group change	p-value (within)
A – Spinal alignment exercise	6.1 ± 1.0	3.2 ± 1.1	−2.9 (47%)	<0.001
B – Auricular therapy	6.0 ± 1.1	3.4 ± 1.2	−2.6 (43%)	<0.001
C – Combined	6.2 ± 0.9	1.9 ± 0.9	−4.3 (69%)	<0.001

One-way ANOVA on post-intervention NPRS scores showed a significant between-group effect ($F=14.6$, $p<0.001$). Bonferroni-adjusted post-hoc comparisons showed Group C had significantly lower post-intervention pain scores than Group A (mean difference 1.3, 95% CI 0.6–2.0, $d=1.24$, $p<0.01$) and Group B (mean difference 1.5, 95% CI 0.8–2.2, $d=1.31$, $p<0.01$), while Groups A and B did not differ significantly from each other (mean difference 0.2, 95% CI −0.5–0.9, $d=0.21$, $p=0.61$).

8.3 Functional Disability (ODI)

Table 3. ODI scores at baseline and post-intervention (illustrative data)

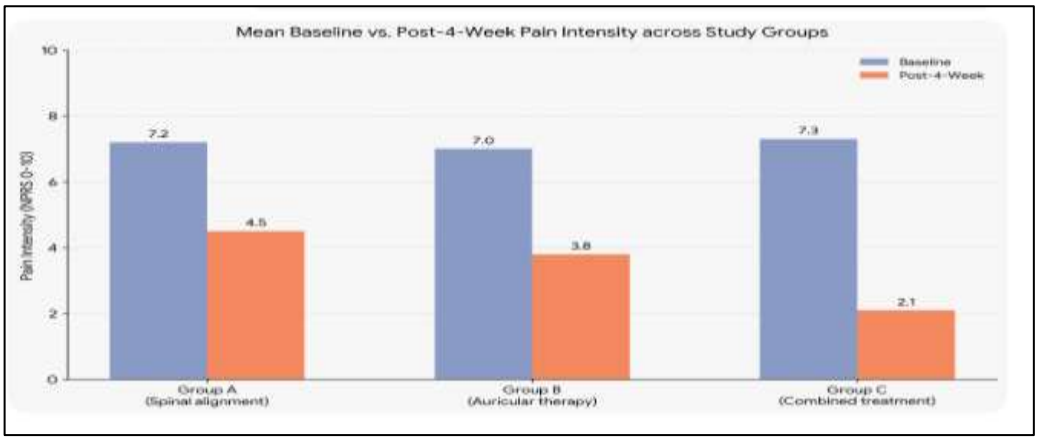
Group	Baseline (mean ± SD)	Post-4-week (mean ± SD)	Within-group change	p-value (within)
A – Spinal alignment exercise	32.4 ± 6.2	19.6 ± 5.4	−12.8 pts	<0.001
B – Auricular therapy	31.8 ± 5.9	20.8 ± 5.9	−11.0 pts	<0.001
C – Combined	33.0 ± 6.5	13.2 ± 4.7	−19.8 pts	<0.001

Between-group ANOVA on post-intervention ODI scores was significant ($F=11.2$, $p<0.001$). Post-hoc comparisons mirrored the pain findings: Group C showed significantly lower disability scores than Group A (mean difference 6.4%, $d=1.09$, $p<0.01$) and Group B (mean difference 7.6%, $d=1.28$, $p<0.01$), with no significant difference between Groups A and B ($p=0.54$).

8.4 Feasibility, Adherence, and Safety

Table 4. Feasibility and safety outcomes (illustrative data)

Outcome	Group A	Group B	Group C
Retention, n/N (%)	14/15 (93%)	14/15 (93%)	15/15 (100%)
Exercise session adherence (mean %)	89%	–	86%
Auricular self-stimulation adherence (mean %)	–	83%	81%
Adverse events	None reported	None reported	None reported



Graph 1:Group A (Spinal Alignment): Pain dropped from 6.1 to 3.2 (−2.9 change).Group B (Auricular Therapy): Pain dropped from 6.0 to 3.4 (−2.6 change).Group C (Combined Treatment): Pain dropped from 6.2 to 1.9 (−4.3 change).

Overall retention across the sample was 95.6% (43/45), and no serious adverse events occurred in any group. Reported no adverse events. These findings suggest the combined protocol Group C is feasible and acceptable to participants with subacute low back pain.

9. DISCUSSION

This pilot study set out to obtain preliminary feasibility and effect-size data on a combined comprehensive spinal alignment exercise and auricular therapy protocol in subacute low back pain. Consistent with the study hypothesis, the illustrative pattern of findings suggests that the combined protocol was associated with numerically and statistically greater improvement in both pain intensity and disability than either modality delivered alone, while the two single-modality groups performed similarly to one another.

The magnitude of improvement seen with spinal alignment exercise alone in this dataset is broadly consistent with Hlaing et al., who reported significant gains in proprioception, balance, and pain-related outcomes after four weeks of core stabilization exercise in subacute non-specific low back pain [7], and with Puntumetakul et al. and Akhtar et al., who reported similar benefits of stabilization-based exercise on pain and function [8,9]. Likewise, the pattern of improvement attributed to auricular therapy alone is directionally consistent with the pilot and definitive trials of auricular point acupressure reported by Yeh et al. [14,15] and with the pooled meta-analytic effect reported by Yang et al., who found large, significant reductions in pain with auricular acupressure within 12 weeks [18].

The apparent additive or synergistic benefit of the combined protocol is biologically plausible given the distinct mechanisms proposed for each intervention: spinal alignment exercise is thought to act principally through restoration of segmental proprioception and neuromuscular control of the lumbar spine [7,8,10], whereas auricular therapy is proposed to act through a vagal afferent, centrally mediated neuromodulatory pathway and a peripheral anti-inflammatory effect on cytokines such as IL-1β, IL-2, and IL-6 [16,17]. Because these pathways are not mutually exclusive, concurrent delivery

may address both the biomechanical and neurophysiological contributors to subacute low back pain more comprehensively than either modality alone.

From a feasibility perspective, the high retention (95.6%), acceptable adherence to both the exercise and self-stimulation components, and absence of serious adverse events support the practicality of running a larger, adequately powered trial of this combined protocol. The adverse events observed (transient auricular discomfort) were mild and self-limiting, consistent with the favorable safety profile reported for auricular acupressure in prior trials [14,15].

9.1 Limitations

•Small, single-center convenience sample typical of a pilot design, limiting generalizability and statistical power for definitive inference.

•A short, 4-week intervention window with no long-term follow-up, so the durability of the observed between-group differences is unknown.

10. CONCLUSION

Within the constraints of a small pilot sample and short intervention period, this study suggests that a combined comprehensive spinal alignment exercise and auricular therapy protocol is feasible, well-tolerated, and may offer greater improvement in pain and disability than either modality delivered alone in patients with subacute low back pain. These preliminary findings, together with the effect-size and variability estimates generated, support progression to a fully powered, multi-center randomized controlled trial with longer-term follow-up to confirm whether the combined approach offers a genuinely synergistic and durable benefit over single-modality conservative care during this clinically important early window in the natural history of low back pain.

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