

CHANGES IN PROMIS GLOBAL PHYSICAL AND MENTAL HEALTH FOLLOWING A 21-DAY INTEGRATED AYURVEDA–YOGA PROGRAM FOR LOW BACK PAIN: A SECONDARY ANALYSIS OF A RANDOMISED CONTROLLED TRIAL

Sudha S¹, Mrudul Y Chitrakar², Madan Kumar M K³

¹PhD scholar, DY Patil College of Ayurveda, Nerul, Navi Mumbai.

²Associate Professor, Department of Swasthavritta, D Y Patil College of Ayurveda, Nerul, Navi Mumbai, Maharashtra, India

³Assistant Professor, Department of Rachana Sharir, Government Ayurveda College, Thiruvananthapuram, Kerala, India

ABSTRACT

Background: Low back pain affects pain, physical function, participation, emotional well-being and perceived overall health. Disease-specific outcomes such as pain and disability may not fully capture changes in global health. PROMIS Global Health provides standardised summary measures of Global Physical Health (GPH) and Global Mental Health (GMH).

Objective: To examine changes in PROMIS GPH and GMH following a 21-day integrated program of alignment-oriented Yoga, Kukundara Marma self-mobilisation and selected Swasthavritta practices compared with a structured lifestyle-modification program in adults with low back pain.

Methods: This secondary analysis used data from a two-arm parallel-group randomised controlled trial. Two hundred and ninety adults aged 18–50 years were randomised equally to the integrated program (n=145) or lifestyle-modification control (n=145). PROMIS Global-10 was assessed at baseline (Day 1), immediately after intervention (Day 21), and follow-up (Day 61). The principal outcomes were GPH and GMH. We used between-group comparisons, baseline-adjusted ANCOVA, and linear mixed-effects models. The original analysis was performed on the raw 4–20 summary-score metric, with T-scores additionally reported.

Results: Baseline GPH and GMH were similar between groups. Mean GPH T-score increased from 34.30 at baseline to 46.70 at Day 21 and 49.42 at Day 61 in the integrated group, compared with 34.33, 36.35 and 38.13 in controls. The between-group difference in change was 10.59 T-score points at Day 21 and 11.31 at Day 61 (both $p<0.001$). GMH T-score increased from 41.71 to 49.41 and 52.86 in the integrated group, versus 42.08, 42.58 and 44.63 in controls. The between-group difference in change was 7.12 points at Day 21 and 8.36 at Day 61 (both $p<0.001$). In raw-score mixed models, group-by-time interactions were 3.92 and 4.07 points for GPH and 2.90 and 3.18 points for GMH at Days 21 and 61, respectively (all $p<0.001$).

Conclusion: The integrated program was associated with greater improvements in patient-reported global physical and mental health than lifestyle modification, with differences persisting at two-month follow-up. This was a secondary analysis of a multicomponent intervention, and the available inferential models used raw PROMIS summary scores.

KEYWORDS: low back pain; PROMIS Global Health; Global Physical Health; Global Mental Health; Ayurveda; Yoga; Swasthavritta; Kukundara Marma; randomised controlled trial; patient-reported outcomes

1. INTRODUCTION

Low back pain is a major contributor to disability and affects multiple dimensions of health, including physical functioning, activity participation, fatigue, emotional well-being and perceived overall health.¹ Non-specific low back pain is influenced by interacting physical, behavioral, and psychosocial factors, supporting interventions that address more than pain intensity alone.²

Clinical trials in low back pain commonly assess pain intensity and back-specific functional disability; however, these outcomes may not fully capture broader changes in patients' health-related quality of life and overall physical and mental health. The NIH Pain Consortium Research Task Force on chronic low back pain recommended a standardised minimum dataset incorporating patient-reported measures across important domains, including pain, physical function, mood, and sleep. Subsequent international consensus recommendations identified health-related quality of life as a core outcome domain for nonspecific low back pain trials and recommended the 10-item PROMIS Global Health measure as an appropriate instrument for its assessment.^{3–5}

The Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health 10-item scale provides a concise assessment of overall physical and mental health. It generates Global Physical Health and Global Mental Health summary scores, expressed as standardised T-scores referenced to a population mean of 50 and a standard deviation of 10. PROMIS Global Health has also been evaluated in populations with chronic low back pain, supporting its relevance as a patient-reported global outcome.^{4,6,7}

Researchers have studied yoga for low back pain, with systematic reviews reporting improvements in pain and disability, although effects on broader quality-of-life outcomes are less consistent and evidence certainty varies. Trials comparing yoga with physical therapy or education further show that yoga can influence patient-centred outcomes, while emphasising the importance of comparator choice and longer-term follow-up.^{8,9}

The present randomised trial evaluated a multicomponent program integrating alignment-oriented Yoga, Kukundara Marma self-mobilisation, and selected Swasthavritta practices. Alignment-oriented Yoga emphasized postural awareness, controlled movement, flexibility, mobility, muscular function, and functional alignment. Kukundara Marma self-mobilisation was included as a targeted lumbopelvic self-care exercise involving gentle, controlled self-mobilisation of the region corresponding to the bilateral Kukundara Marma sites. The technique was developed from the Ayurvedic concept of Kukundara Marma and was informed by the biomechanical rationale underlying lumbopelvic and sacroiliac-region mobilisation; it was not intended to represent or be equivalent to conventional sacroiliac joint mobilisation performed in physiotherapy.¹⁰ The Swasthavritta component included recommendations for daily health-promoting practices, including Ushajala Pana as instructed, self-Abhyanga, lukewarm bathing, and sleep regulation. The intervention components were delivered as an integrated package, and their individual effects were not intended to be estimated separately in the present trial.

The primary trial outcomes were pain, disability and quality of life. This manuscript reports a secondary analysis of PROMIS Global-10 outcomes, with particular interest in whether the integrated program was associated with changes in global physical and mental health beyond disease-specific measures.

2. Objective

To assess changes in PROMIS Global Physical Health and Global Mental Health in adults with low back pain after a 21-day integrated program of alignment-oriented Yoga, Kukundara Marma self-mobilisation, and selected Swasthavritta practices, compared with structured lifestyle modification.

3. MATERIALS AND METHODS

3.1 Study design and reporting

This was a secondary analysis of a two-arm, parallel-group randomised controlled trial. The parent trial randomised 290 adults aged 18–50 years in a 1:1 ratio. Reporting should be aligned with CONSORT 2010, including transparent description of randomisation, participant flow, outcomes, attrition and analysis.

3.2 Participants and setting

Adults aged 18–50 years with low back pain were recruited through the study centre and community recruitment procedures described in the parent trial. We randomised 290 participants, with 145 assigned to each group. PROMIS assessments were available for 134 integrated-program participants and 140 controls at Day 21, and 132 and 129 participants, respectively, at Day 61.

3.3 Randomisation and intervention

Participants were randomly allocated to the integrated program or structured lifestyle modification. The intervention group received a 60-minute daily program for 21 consecutive days comprising: (1) alignment-oriented Yoga; (2) Kukundara Marma self-mobilisation; and (3) selected Swasthavritta practices. The control group received a structured lifestyle-modification program delivered through a manual. The intervention components were delivered as an integrated package; therefore, the analysis estimates the package effect rather than the independent contribution of any individual component.

3.4 Outcome assessment

PROMIS Global-10 was administered at Day 1 (baseline), Day 21 (immediately after the 21-day intervention) and Day 61 (follow-up). Outcome assessment was performed by an assessor reported to be blinded to group allocation. The principal secondary outcomes were GPH and GMH.

3.5 PROMIS Global-10 scoring

The dataset contained ten recorded columns labelled G1–G10. The source manuscript mapped these columns to PROMIS Global Health items as follows: G1=Global01, G2=Global02, G3=Global03, G4=Global04, G5=Global05, G6=Global06, G7=Global07 (pain), G8=Global09, G9=Global10 (emotional problems), and G10=Global08 (fatigue). GPH was calculated from Global03, Global06, recoded Global07 and Global08; GMH was calculated from Global02, Global04, Global05 and Global10.

The pain item was recorded on a 0–10 scale and recoded to the standard five-level direction for higher-is-better scoring. The PROMIS scoring manual specifies additional recoding requirements for Global 07, Global 08 and Global10 for earlier Global Health versions and recommends use of official Health Measures scoring resources. The current analysis used the raw 4–20 summary-score metric for inferential models and reported corresponding T-scores for interpretation.

3.6 Ethics and trial registration

Ethics approval was obtained from the Institutional Ethics Committee of Government Ayurveda College, Kannur (Approval No. GACK/2025/1/PhD-3; dated 03 March 2025). The trial was registered prospectively with the Clinical Trials Registry–India (CTRI/2025/04/083874) on 02 April 2025. The first participant was enrolled on 14 April 2025, and the study was completed on 31 October 2025. All participants provided written informed consent.

3.7 Statistical analysis

Participants were retained in their randomised groups. Descriptive statistics were reported as mean±standard deviation and, where relevant, median with interquartile range. Distributional assessment used the Shapiro–Wilk test. Between-group comparisons at individual time points used the Mann–Whitney U test where non-normality was present. Within-participant changes were examined using Wilcoxon signed-rank tests when appropriate.

Baseline-adjusted ANCOVA models were fitted separately for Day 21 and Day 61, adjusting for baseline outcome, age, sex, body mass index, comorbidity, occupation, socio-economic status and education. Linear mixed-effects models included a participant-level random intercept, group, time and group-by-time interaction and used all available observations under a missing-at-random assumption. The primary inferential interpretation should emphasise the group-by-time interaction rather than within-group significance testing. The current source analysis was conducted on raw 4–20 summary scores, with T-scores presented for interpretation.

Two-sided $p < 0.05$ was considered statistically significant. No multiplicity adjustment was applied to item-level comparisons; accordingly, those analyses should be treated as exploratory and are better placed in supplementary material. Analyses were conducted using Python with pandas, SciPy and stats models.

4. RESULTS

4.1 Adverse events

There were no adverse events noted during the intervention

4.2 Participant flow and attrition

All 290 randomised participants completed the baseline assessment. At Day 21, 134 participants in the integrated group and 140 in the control group had outcome data. At Day 61, 132 and 129 participants had outcome data, respectively. Cumulative attrition at Day 61 was 9.0% in the integrated group, 11.0% in the control group and 10.0% overall. All randomised participants were retained in their allocated groups for the analysis framework, while the mixed-effects models used available repeated observations.

Assessment	Integrated program	Lifestyle modification	Total
Randomised	145	145	290
Day 1	145	145	290
Day 21	134	140	274
Day 61	132	129	261
Cumulative attrition at Day 61	9.0%	11.0%	10.0%

4.3 Baseline characteristics

Baseline characteristics were generally similar between groups. Mean age was 43.35 ± 6.23 years in the integrated group and 42.94 ± 6.52 years in controls ($p = 0.699$). Sex, education, occupation, socio-economic status, marital status, dietary pattern and recorded comorbidities did not differ significantly. BMI was higher in the integrated group (25.88 ± 1.48 vs 25.24 ± 2.52 kg/m²; $p = 0.028$) and was therefore included as a covariate in adjusted analyses.

Variable	Integrated (n=145)	Control (n=145)	p value
Age, years	43.35 ± 6.23	42.94 ± 6.52	0.699
BMI, kg/m ²	25.88 ± 1.48	25.24 ± 2.52	0.028
Male, n (%)	62 (42.8)	68 (46.9)	0.555
Female, n (%)	83 (57.2)	77 (53.1)	0.555
Any comorbidity, n (%)	103 (71.0)	108 (74.5)	0.598

4.4 PROMIS Global Physical Health

Baseline GPH raw scores were similar (9.83 ± 2.01 vs 9.85 ± 1.95 ; $p = 0.719$). In the integrated group, the mean raw score increased to 14.46 ± 2.99 at Day 21 and 15.30 ± 2.90 at Day 61. Corresponding control-group means were 10.61 ± 2.73 and 11.28 ± 2.56 . The between-group difference in change was 3.95 raw points at Day 21 (95% CI 3.38–4.52; $p < 0.001$) and 4.04 at Day 61 (95% CI 3.50–4.58; $p < 0.001$).

On the standardised T-score metric, mean GPH increased from 34.30 at baseline to 46.70 at Day 21 and 49.42 at Day 61 in the integrated group. The corresponding control values were 34.33, 36.35 and 38.13. The between-group difference in change was 10.59 T-score points at Day 21 and 11.31 at Day 61 (both $p < 0.001$).

Between-group comparison of PROMIS Global Physical Health T-scores.

Comparison	Study (Mean $\pm$ SD)	Control (Mean $\pm$ SD)	Difference (95% CI)	Test	Statistic	p value	Effect size
Day 1	34.30 ± 5.36	34.33 ± 5.26	-0.03 (-1.25 to 1.19)	Mann–Whitney	U = 10274	0.719	-0.02
Day 21	46.70 ± 8.44	36.35 ± 7.27	10.35 (8.48 to 12.22)	Mann–Whitney	U = 15548	<0.001	0.66
Day 61	49.42 ± 8.66	38.13 ± 6.71	11.29 (9.42 to 13.17)	Mann–Whitney	U = 14452	<0.001	0.70
Change Day 1→21	12.59 ± 6.97	2.00 ± 6.01	10.59 (9.05 to 12.14)	Mann–Whitney	U = 16260	<0.001	0.73
Change Day 1→61	15.29 ± 7.09	3.98 ± 5.33	11.31 (9.79 to 12.83)	Mann–Whitney	U = 15261	<0.001	0.79

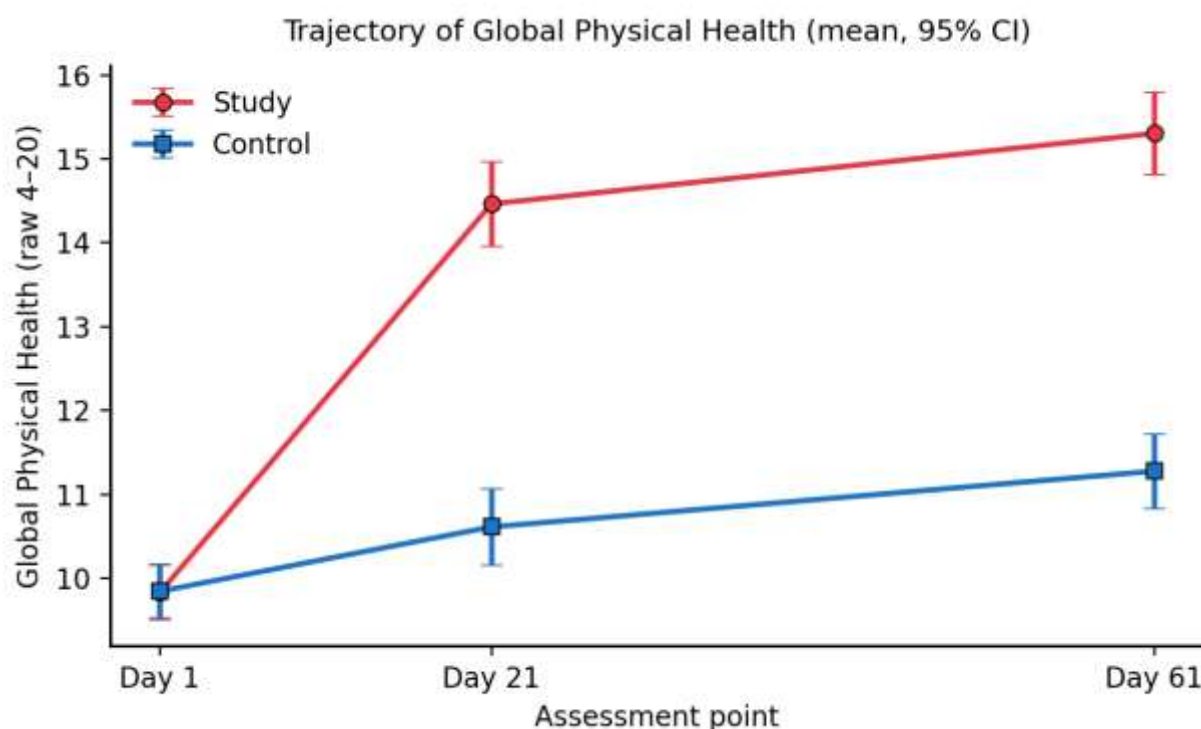


Figure 1. . Trajectory of PROMIS Global Physical Health with 95% confidence intervals.

4.5 Adjusted and longitudinal analysis of Global Physical Health

Baseline-adjusted ANCOVA estimated a group coefficient of 3.944 raw points (95% CI 3.360–4.528; $p < 0.001$) at Day 21 and 4.084 points (95% CI 3.535–4.633; $p < 0.001$) at Day 61. The linear mixed-effects model showed group-by-time interactions of 3.917 raw points at Day 21 and 4.071 points at Day 61 (both $p < 0.001$). These coefficients represent the additional improvement associated with the integrated program beyond change observed in the control group on the raw summary-score scale.

4.6 PROMIS Global Mental Health

Baseline GMH raw scores were similar between groups (11.27 ± 1.82 vs 11.43 ± 1.77 ; $p = 0.173$). In the integrated group, mean raw GMH increased to 14.38 ± 2.65 at Day 21 and 15.55 ± 3.22 at Day 61. In controls, the corresponding means were 11.62 ± 2.33 and 12.47 ± 1.63 . The between-group difference in change was 2.88 raw points at Day 21 (95% CI 2.38–3.39; $p < 0.001$) and 3.13 at Day 61 (95% CI 2.61–3.66; $p < 0.001$).

On the T-score metric, mean GMH increased from 41.71 at baseline to 49.41 at Day 21 and 52.86 at Day 61 in the integrated group, compared with 42.08, 42.58 and 44.63 in controls. The between-group difference in change was 7.12 T-score points at Day 21 and 8.36 at Day 61 (both $p < 0.001$).

Time point / change	Integrated	Control	Between-group difference	p
Day 1 T-score	41.71±4.46	42.08±4.33	-0.38 (-1.39 to 0.64)	0.173
Day 21 T-score	49.41±6.69	42.58±5.67	6.84 (5.36 to 8.31)	<0.001
Day 61 T-score	52.86±9.16	44.63±3.98	8.22 (6.52 to 9.93)	<0.001
Change Day 1→21	7.67±5.39	0.54±5.19	7.12 (5.87 to 8.38)	<0.001
Change Day 1→61	11.06±7.56	2.70±4.06	8.36 (6.89 to 9.83)	<0.001

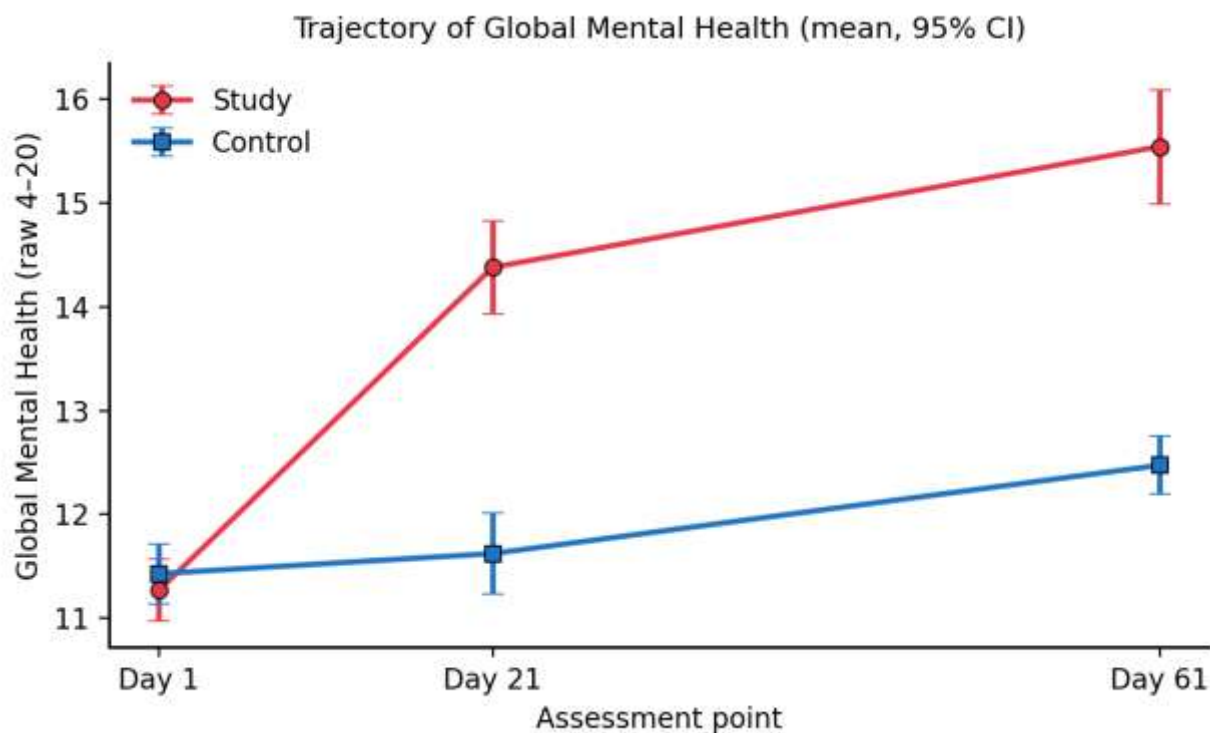


Figure 2. Mean PROMIS Global Mental Health T-scores at baseline, Day 21 and Day 61.

4.7 Adjusted and longitudinal analysis of Global Mental Health

Baseline-adjusted ANCOVA estimated a group coefficient of 2.818 raw points (95% CI 2.313–3.324; $p < 0.001$) at Day 21 and 3.151 points (95% CI 2.631–3.672; $p < 0.001$) at Day 61. Linear mixed-effects models showed group-by-time interactions of 2.897 raw points at Day 21 and 3.176 points at Day 61 (both $p < 0.001$).

4.8 Item-level findings

All ten recorded PROMIS items showed statistically significant between-group differences at Days 21 and 61 in the source analysis. The largest separations were reported for physical health, everyday physical activity, fatigue and pain. Because ten item-level comparisons were performed without multiplicity adjustment and because the manuscript is focused on the two validated summary scores, item-level results should be regarded as exploratory and preferably moved to supplementary material.

Item-wise PROMIS Global-10 scores (1–5) by group and assessment point.

Item	Study Day 1	Study Day 21	Study Day 61	Control Day 1	Control Day 21	Control Day 61	p (Day 21)	p (Day 61)
G1. General health	2.46 ± 0.80	3.34 ± 0.94	3.55 ± 1.03	2.55 ± 0.73	2.81 ± 0.57	3.04 ± 0.44	<0.001	<0.001
G2. Quality of life	2.75 ± 0.56	3.63 ± 0.76	3.91 ± 0.91	2.78 ± 0.56	2.85 ± 0.60	3.07 ± 0.44	<0.001	<0.001
G3. Physical health	2.32 ± 0.61	3.57 ± 0.84	3.89 ± 0.95	2.36 ± 0.62	2.49 ± 0.82	2.67 ± 0.74	<0.001	<0.001
G4. Mental health	2.76 ± 0.54	3.63 ± 0.76	3.80 ± 0.93	2.79 ± 0.53	2.85 ± 0.60	3.07 ± 0.44	<0.001	<0.001
G5. Satisfaction with social activities	3.01 ± 0.51	3.50 ± 0.83	3.96 ± 0.98	3.08 ± 0.49	3.07 ± 0.76	3.26 ± 0.61	<0.001	<0.001
G6. Everyday physical activities	2.30 ± 0.60	3.57 ± 0.85	3.76 ± 0.87	2.31 ± 0.61	2.45 ± 0.82	2.66 ± 0.74	<0.001	<0.001
G7. Pain (recoded 1–5)	5.24 ± 1.26	2.81 ± 1.37	2.43 ± 1.57	5.37 ± 1.19	4.34 ± 1.33	3.84 ± 1.13	<0.001	<0.001
G8. Usual social activities and roles	2.74 ± 0.53	3.63 ± 0.76	3.83 ± 0.93	2.76 ± 0.53	2.84 ± 0.58	3.07 ± 0.44	<0.001	<0.001
G9. Emotional problems	2.74 ± 0.51	3.63 ± 0.76	3.87 ± 0.91	2.77 ± 0.50	2.85 ± 0.59	3.07 ± 0.44	<0.001	<0.001
G10. Fatigue	2.27 ± 0.56	3.57 ± 0.85	3.83 ± 0.97	2.25 ± 0.56	2.48 ± 0.82	2.66 ± 0.74	<0.001	<0.001

Values are mean $\pm$ standard deviation, all oriented so that higher scores indicate better health. Item G7 (pain) is shown after recoding from the 0–10 scale to the 1–5 PROMIS bands. p-values are for the between-group comparison (Mann–Whitney U test). The mapping of columns G1–G10 to PROMIS item numbers is set out in Appendix A.

5. DISCUSSION

5.1 Principal findings

In this secondary analysis of a two-arm randomised controlled trial, the integrated Ayurveda–Yoga program was associated with substantially greater improvements in PROMIS Global Physical Health (GPH) and Global Mental Health (GMH) than structured lifestyle modification. Baseline PROMIS scores were comparable between groups, supporting the interpretation that trajectories diverged after randomisation rather than reflecting a marked baseline difference in global-health outcomes. By Day 21, the between-group difference in change was 10.59 T-score points for GPH and 7.12 points for GMH; by Day 61, these differences were 11.31 and 8.36 points, respectively. The baseline-adjusted ANCOVA and longitudinal mixed-effects models showed the same direction of effect on the raw summary-score scale, with significant group-by-time interactions at both follow-up assessments. Thus, the finding was not dependent solely on a single cross-sectional comparison at Day 21.

The magnitude and persistence of these differences are notable because PROMIS Global Health captures a broader construct than pain intensity or back-specific disability. In the present trial, physical health increased markedly during the 21-day intervention and increased further, though less, by Day 61. Mental health also improved during the intervention, but its trajectory continued to rise during the follow-up period. This pattern is clinically plausible in a multimodal program in which changes in physical activity, movement confidence, daily routine, sleep-related behaviour and perceived ability to perform usual activities may occur at different rates. However, the present study did not directly measure these potential mediating pathways; therefore, the temporal pattern should be interpreted as an observed trajectory rather than evidence that physical recovery causes later mental-health improvement.

5.2 Relevance of PROMIS Global Health

Selecting PROMIS Global Health is an important strength of this secondary analysis. Low back pain is not restricted to a localised pain experience: physical limitations, activity restriction, emotional distress, sleep disturbance and social participation can interact and contribute to persistence or recurrence. Reviews identify higher pain and disability, emotional distress, negative recovery expectations and high physical work demand among factors associated with poorer long-term outcomes in non-specific low back pain. A PROMIS-based outcome therefore complements disease-specific measures by assessing participants' overall physical and mental health. PROMIS Global Health has demonstrated acceptable psychometric properties, including internal consistency, measurement invariance, and cross-cultural validity in a large Dutch population, and has also been evaluated in patients with chronic low back pain and in rehabilitation settings.

This study adds to the evidence by examining changes in self-reported physical and mental health after an integrated Ayurveda–Yoga intervention compared with a structured lifestyle modification programme. Using PROMIS Global Health as an outcome measure, this analysis provides further insight into the intervention's effects on overall health and well-being among individuals with low back pain. The results suggest that the intervention was accompanied by changes in participants' broader perception of physical and mental health in addition to the disease-specific outcomes reported in the parent trial. This broader outcome perspective is relevant because exercise and rehabilitation research has historically concentrated more heavily on pain and disability than on global well-being. Reviews of exercise interventions similarly noted that quality of life is reported less frequently than pain outcomes, despite its importance to patient-centred care.

5.3 Relationship to evidence on yoga and active rehabilitation

The observed improvement in GPH aligns with established evidence that active, movement-based interventions can improve pain and function in chronic low back pain. Systematic reviews of yoga have likewise reported short- to intermediate-term improvements in pain and disability. A meta-analysis of 18 randomised trials found yoga benefits over non-exercise for pain and disability, while differences versus physical-therapy exercise were less consistent and quality-of-life effects were not clearly different.¹¹ The certainty of evidence for yoga in low back pain is low to moderate and reported short-term improvements in pain, disability, mental health, and physical functioning versus passive controls, but no consistent advantage over active comparators.

These findings are relevant to interpretation of the present study because the comparator was not a no-treatment or wait-list group. Control participants received a structured lifestyle-modification program and therefore also received information, behavioural guidance, and an organised therapeutic framework. The larger improvement in the integrated group may therefore reflect the added contribution of structured movement practice, self-mobilisation, and the combined behavioural package rather than attention alone. Previous randomised trials have shown that yoga can improve back-related function compared with self-care education, and that yoga may perform similarly to stretching or physical therapy when both are active comparators. Yoga studies also reported improvements in pain and back-related function, with sustained benefits and improvement in sleep quality. Collectively, these studies support the plausibility of meaningful patient-reported changes following structured yoga-based care, but they do not establish that the present Ayurveda–Yoga package is superior to other active rehabilitation programs.

5.4 Possible interpretation of the physical-health findings

The large increase in GPH may plausibly reflect several overlapping domains of the intervention. Alignment-oriented Yoga emphasised postural awareness, controlled movement, flexibility, mobility and muscular function. These elements are compatible with the broader evidence supporting exercise for chronic low back pain and with evidence that trunk-focused exercise can improve pain, disability, quality of life and physical performance. We incorporated Kukundara

Marma self-mobilisation as a gentle lumbopelvic self-care movement, not as a physician-manipulated marma procedure.¹² Because the intervention was designed as an integrated package, however, the present data cannot determine whether the observed GPH change resulted from this component, from Yoga, from Swasthavritta practices, or from their interaction. The interpretation of Kukundara Marma self-mobilisation should remain conceptually distinct from conventional physiotherapy mobilisation. The manuscript describes the technique as being informed by biomechanical reasoning related to the lumbopelvic and sacroiliac region, but not as equivalent to a therapist-performed sacroiliac joint mobilisation. Evidence from studies of sacroiliac-region mobilisation and exercise indicates that targeted manual or movement-based approaches can influence short-term pain or disability in selected populations, but these findings cannot be directly transferred to the Ayurvedic self-mobilisation technique used here. Therefore, the appropriate conclusion is that the integrated program was associated with improved global physical health, not that it demonstrated a specific Marma mechanism.

5.5 Possible interpretation of the mental-health findings

The improvement in GMH is particularly relevant because chronic low back pain is associated with psychological and behavioural factors as well as physical limitations. Reviews of chronic low back pain have identified emotional distress and other psychosocial variables as relevant prognostic factors. In addition, systematic reviews of psychological interventions and mindfulness-based approaches indicate that interventions addressing psychological processes can influence pain, function and aspects of well-being, although the magnitude and durability of effects vary between interventions and comparators. Previous studies using the same broad yoga/PT/education framework as an earlier low back pain program found that yoga and physical therapy reduced perceived stress at the end of treatment, although the between-group effect attenuated during longer follow-up.

The continued increase in GMH from Day 21 to Day 61 in the present study may therefore be compatible with a delayed or cumulative change in perceived well-being. The Swasthavritta component included attention to Usha jala Pana, self-Abhyanga, lukewarm bathing, and sleep regulation. Sleep is also clinically relevant because evidence indicates a close and potentially bidirectional relationship between sleep disturbance and chronic spinal pain. Nevertheless, sleep, stress, self-efficacy, anxiety, depression and social participation were not measured as mediators in the present PROMIS analysis. It would therefore be inappropriate to attribute the GMH improvement to any single psychological mechanism.

5.6 Role of the Swasthavritta components

The Swasthavritta elements provide a preventive-lifestyle framework that may complement the intervention's movement component.¹³ The program included recommendations for Usha jala Pana, self-Abhyanga, lukewarm bathing, and sleep regulation.¹⁴ Interpret evidence on individual lifestyle components cautiously because this study did not separately randomise them. For example, a recent open-access randomised trial combining Yoga with Ayurvedic Kati Basti reported improvements in pain, disability, depression and quality-of-life domains, although its small sample and residential design limit direct comparison with the present trial. Likewise, evidence regarding sleep and chronic spinal pain supports addressing sleep problems as part of comprehensive management, but does not demonstrate that a particular bathing or morning-routine practice produces the PROMIS changes observed here. The most defensible interpretation, therefore, is that the Swasthavritta practices were part of a structured behavioural context that may have supported adherence to an active self-management program.

5.7 Persistence of effects and clinical interpretation

The persistence of between-group differences at Day 61 matters because the intervention lasted 21 days, while the follow-up extended for about two additional months. The continued separation between groups suggests that the observed patient-reported benefits were not confined to the immediate post-intervention assessment. The results should not be described as proof of long-term efficacy, because Day 61 represents only a relatively short follow-up period and no later assessment was conducted. The control group also improved over time, particularly in GPH and GMH, indicating that structured lifestyle advice itself may have beneficial effects. The appropriate inference is therefore a sustained between-group difference within the observed 61-day study window.

The PROMIS T-score values also require careful interpretation. A T-score of 50 represents the mean of the reference population used for the applicable PROMIS scoring system, with a standard deviation of 10; it is not a diagnostic threshold and should not be interpreted as a definition of recovery. Moreover, the current manuscript used raw 4–20 summary scores for the inferential longitudinal models and presented T-scores mainly for interpretation.

5.8 Strengths and limitations

Several methodological features strengthen interpretation of the findings. These include randomised allocation of 290 participants, equal baseline allocation, three assessment points, prospective trial registration, ethics approval, blinded outcome assessment, relatively low cumulative attrition by Day 61, and use of mixed-effects models that incorporated available repeated observations. The secondary analysis also addresses a meaningful gap by adding a global patient-reported outcome to the parent trial's pain, disability and quality-of-life measures.

The limitations require equal emphasis. First, participants could not be blinded to a behavioural intervention, so we cannot exclude expectation, preference, and attention effects. Second, the intervention was multicomponent, preventing estimation of component-specific effects. Third, the lifestyle-modification control was not attention-matched to the full intervention; therefore, differences in therapist contact, group interaction or treatment expectancy may have contributed to the observed effects. Fourth, the current PROMIS manuscript does not provide sufficient detail on adherence and intervention fidelity to establish how consistently the intervention was delivered or practised. Fifth, the current inferential models used raw PROMIS summary scores rather than the standardised T-score metric. Sixth, we conducted ten item-level comparisons without multiplicity adjustment; these findings should therefore remain exploratory and secondary.

Finally, the sample was restricted to adults aged 18–50 years and was recruited within the parent trial setting, limiting extrapolation to older adults, people with specific spinal pathology, or other healthcare populations.

5.9 Implications for research and practice

The findings support inclusion of a standardised global-health measure alongside pain and disability outcomes in future trials of multimodal low back pain interventions. The WHO guideline for chronic primary low back pain considers physical, psychological, educational, and multicomponent approaches within non-surgical care, consistent with the rationale for evaluating interventions that address more than a single symptom domain. Future studies should prespecify the exact PROMIS version and scoring algorithm, use official T-score conversion, report adherence and treatment fidelity, and include longer follow-up. Pragmatic trials comparing the integrated package with established active exercise or rehabilitation programs would clarify whether the observed PROMIS changes are specific to the Ayurveda–Yoga framework or are consistent with broader benefits of structured active care. Factorial or dismantling designs could further examine whether Yoga, Marma self-mobilisation and Swasthavritta practices contribute independently or synergistically. Overall, the present secondary analysis provides evidence of an association between the integrated Ayurveda–Yoga program and improved patient-reported global physical and mental health over the 61-day observation period. The findings are strengthened by the randomised parent-trial design and consistency across adjusted and longitudinal analyses, but they should be interpreted as effects of the integrated package rather than proof of a specific component or mechanism.

6. CONCLUSION

In adults aged 18–50 years with low back pain, a 21-day integrated program comprising alignment-oriented Yoga, Kukundara Marma self-mobilisation and selected Swasthavritta practices was associated with greater improvements in PROMIS Global Physical Health and Global Mental Health than structured lifestyle modification. Between-group differences were evident immediately after the intervention and persisted at Day 61, while mental health continued to improve during follow-up. These findings represent the effect of the integrated package as a whole.

7. Declarations

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee of Government Ayurveda College, Kannur (GACK/2025/1/PhD-3; 03/03/2025). We obtained written informed consent from all participants.

Trial registration: Clinical Trials Registry–India: CTRI/2025/04/083874; registered 02/04/2025.

Consent for publication: Not applicable.

Funding

Self-funded. No specific grant was received from public, commercial or non-profit funding agencies.

Competing interests

The authors declare no conflict of interest.

Data confidentiality

Participant data were coded using unique study identification numbers. Personally identifiable information was stored separately from outcome data.

Generative AI/language assistance

The authors used Grammarly for spelling, punctuation and grammar checking, as stated in the original manuscript.

Acknowledgement

The authors acknowledge D.Y. Patil University, Navi Mumbai, for academic support, and Government Ayurveda College, Pariyaram, Kannur, Kerala, India for facilitating the study.

REFERENCE

1. Ferreira ML, Luca K de, Haile LM, et al. Global, regional, and national burden of low back pain, 1990–2020, its attributable risk factors, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. *Lancet Rheumatol.* 2023;5(6):e316–e329. doi:10.1016/S2665-9913(23)00098-X
2. Otero-Ketterer E, Peñacoba-Puente C, Ferreira Pinheiro-Araujo C, Valera-Calero JA, Ortega-Santiago R. Biopsychosocial Factors for Chronicity in Individuals with Non-Specific Low Back Pain: An Umbrella Review. *Int J Environ Res Public Health.* 2022;19(16):10145. doi:10.3390/ijerph191610145
3. Pellicciari L, Chiarotto A, Giusti E, Crins MHP, Roorda LD, Terwee CB. Psychometric properties of the patient-reported outcomes measurement information system scale v1.2: global health (PROMIS-GH) in a Dutch general population. *Health Qual Life Outcomes.* 2021;19:226. doi:10.1186/s12955-021-01855-0
4. Hays RD, Slaughter M, Rodriguez A, Edelen MO, Herman PM. Analyses of Cross-Sectional Data to Link the PEG with the Patient Reported Outcomes Measurement and Information System (PROMIS®) Global Physical Health Scale. *J Pain.* 2022;23(11):1904–1911. doi:10.1016/j.jpain.2022.06.006
5. Ho E, Ferreira M, Chen L, et al. Psychological interventions for chronic non-specific low back pain: protocol of a systematic review with network meta-analysis. *BMJ Open.* 2020;10(9):e034996. doi:10.1136/bmjopen-2019-034996

6. Pellicciari L, Chiarotto A, Giusti E, Crins MHP, Roorda LD, Terwee CB. Psychometric properties of the patient-reported outcomes measurement information system scale v1.2: global health (PROMIS-GH) in a Dutch general population. *Health Qual Life Outcomes*. 2021;19:226. doi:10.1186/s12955-021-01855-0
7. Ho EKY, Chen L, Simic M, et al. Psychological interventions for chronic, non-specific low back pain: systematic review with network meta-analysis. *The BMJ*. 2022;376:e067718. doi:10.1136/bmj-2021-067718
8. Saper RB, Lemaster C, Delitto A, et al. Yoga, Physical Therapy, or Education for Chronic Low Back Pain. A Randomized Noninferiority Trial. *Ann Intern Med*. 2017;167(2):85-94. doi:10.7326/M16-2579
9. Zhu F, Zhang M, Wang D, Hong Q, Zeng C, Chen W. Yoga compared to non-exercise or physical therapy exercise on pain, disability, and quality of life for patients with chronic low back pain: A systematic review and meta-analysis of randomized controlled trials. *PLoS ONE*. 2020;15(9):e0238544. doi:10.1371/journal.pone.0238544
10. Yan H, Zhao P, Guo X, Zhou X. The effects of Core Stability Exercises and Mulligan's mobilization with movement techniques on sacroiliac joint dysfunction. *Front Physiol*. 2024;15:1337754. doi:10.3389/fphys.2024.1337754
11. Zhu F, Zhang M, Wang D, Hong Q, Zeng C, Chen W. Yoga compared to non-exercise or physical therapy exercise on pain, disability, and quality of life for patients with chronic low back pain: A systematic review and meta-analysis of randomized controlled trials. *PLOS ONE*. 2020;15(9):e0238544. doi:10.1371/journal.pone.0238544
12. Mundada P, Joshi SK, Khanduri S, et al. Evaluating the Efficacy of Marma Therapy for Pain in Lumbar Disc Herniation With Radiculopathy: Protocol for a Randomized Controlled Trial. *JMIR Res Protoc*. 2026;15:e85720. doi:10.2196/85720
13. Rahiman K J, Prakash J, Patel L, Wagh K, Munde CT, Jamdade YA. Ayurveda in Preventive and Supportive Healthcare: Current Evidence, Safety, and Clinical Integration. *Cureus*. 18(7):e112435. doi:10.7759/cureus.112435
14. Chang JR, Wang X, Lin G, Samartzis D, Pinto SM, Wong AYL. Are Changes in Sleep Quality/Quantity or Baseline Sleep Parameters Related to Changes in Clinical Outcomes in Patients With Nonspecific Chronic Low Back Pain?: A Systematic Review. *Clin J Pain*. 2021;38(4):292-307. doi:10.1097/AJP.0000000000001008