Remedial Yoga module improves symptoms of irritable bowel syndrome: Replication in the Wait-list group and sustained improvements at 6 months

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\textbf{ABSTRACT}

\textbf{Introduction:} The data from our randomized controlled trial suggested that 12-week Remedial Yoga Module (RYM) was efficacious in improving the symptoms of Irritable Bowel Syndrome (IBS). Following on from the initial study, RYM was provided to the Wait-list group, (WL-Yoga), at the end of trial period. All intervention groups were further provided with an additional 12 weeks support to determine the impact of maintaining the intervention.

\textbf{Methods:} Wait-list Control group (WL-Yoga) from our previous 12-week Yoga intervention study was offered the same 12-week (one hour sessions, three times a week) RYM practices as was given to Yoga and Combination groups. Participants completing 12-week RYM intervention from all groups were combined into one Follow-up group (n = 28) and were offered an additional 12 weeks of once a week, one hour supervised maintenance RYM intervention.

\textbf{Results:} 12-week intervention of RYM in the WL-Yoga group showed similar improvements of IBS symptoms as observed in Yoga and Combination groups in the previous study. All the significant improvements observed at week 12 were sustained at week 24 in the follow-up group with significant further improvements in IBS-SS scores (p < 0.01), IBS-GAI (p < 0.05), right and left shoulder flexibility (p < 0.05), handgrip strength (p < 0.001), accuracy in mental arithmetic task (p < 0.05), decreased LF (p < 0.05), and increased HF (p < 0.05).

\textbf{Conclusion:} Efficacy of RYM for IBS is replicable, and the improvements were sustained/enhanced with a maintenance intervention. RYM alone or RYM within conventional care, as implemented in the present study, could be a safe and effective long-term solution for IBS symptoms.

\textbf{Trial registration:} ISRCTN, 42102754.

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1. Introduction

To date, Irritable Bowel Syndrome (IBS) remains a complex disorder to diagnose and treat. In the recent past, pharmacotherapy in conjunction with complementary and alternative medicine therapies, such as probiotics, acupuncture, and Yoga, have been recommended to better manage the primary and secondary symptoms of IBS \cite{1,2}. The initial randomized controlled trial reported that 12-week Remedial Yoga Module remarkably improved the symptoms in irritable bowel syndrome patients (Phase 1). RYM emphasizes tools drawn from the traditional discipline of Yoga, such as breathing, loosening the body, simple postures, regulated controlled breathing, and meditation \cite{3}.

In Phase 2 of the study we investigated: (1) whether we could replicate the effects of RYM on the Wait-list Control group from the previous study (Phase 1) and (2) if once a week monitored Yoga session (one hour of RYM) for 12 more weeks can sustain or further enhance those improvements observed during the first 12 weeks.
2. Materials and methods

2.1. Participants

2.1.1. Wait-list-Yoga group

Twenty seven patients randomized to the Wait-list Control group completed the 12 week waiting period as reported in our previous study (Phase 1). All the patients in this group were invited to participate in the RYM intervention program of three times a week for 12 weeks. They were allowed to be on their medications/supplements for IBS symptoms during the Yoga intervention. Seven patients were able to complete the 12 week RYM intervention. After the completion, these seven patients (referred to as WL-Yoga group) were offered once a week maintenance session for 12 more weeks.

2.1.2. Follow-up group

A total of 28 IBS patients, 24 females and 4 males from Phase 1 volunteered for the maintenance intervention study. The sample consisted of 11 patients from the Yoga group, 10 from combination group, and 7 from WL-Yoga group. The subjects from all three groups, (those who have completed 12 weeks of RYM intervention) were combined into one group, referred to as the “Follow-up group,” and were administered once a week, one hour monitored RYM sessions. The inclusion criterion for the follow-up group was the completion of 12-week RYM intervention, and the only exclusion criterion was that there should not be any Yoga practice at home during the 12 week follow-up period.

2.2. Study design and procedure

Protocol of this study was approved by White Memorial Medical Center Institutional Review Board, Los Angeles, California, USA and the Institutional Ethics Committee of Swami Vivekananda Yoga University (SVYASA) Bangalore, India.

Outcomes were measured twice for the subjects in WL-Yoga group—at the end of 12 week RYM intervention and at the end of week 24 as a part of the Follow-up group. The other subjects in the Follow-up group were appraised only once, at the end of week 24. The methodology and procedures used for assessments are described in detail in our previous study (Phase 1). A brief description is given below.

2.3. Primary outcome assessments

**IBS-SSS**: IBS-Symptom Severity Scale (IBS-SSS) is a self-reported visual analog scale questionnaire regarding the severity of the symptoms [4]. The score for each of the five questions ranges from 0 to 100 with a higher score indicating severity of the symptoms.

**IBS-QOL**: Irritable bowel syndrome quality of life (IBS-QOL) is a self-reported tool designed to assess various aspects of quality of life in IBS patients [5]. The questionnaire consists of a five point rating of 34 items. High score reflects improved quality of life.

2.4. Secondary outcome assessments

Secondary outcome assessments were HADS, IBS-GAI, autonomic symptom score, medicine and supplement use, BMI and physical flexibility, autonomic function tests of sympathetic reactivity (hand grip and mental arithmetic tasks), and parasympathetic reactivity (measured in deep breathing and supine to upright posture). Details of these assessments are in Phase 1.

2.5. Demographic and clinical variables

Information about standard demographic and clinical variables such as age, education, employment, marital status, and years since diagnosis was reported in our previous study (Phase 1).

2.6. Data analyses and statistics

The analyses were carried out to evaluate two aspects of the study. The first aim was to evaluate replication of improvements in the WL-Yoga group, as previously reported in Yoga and Combination groups. Paired samples t-test was performed to analyze the pre- and post-effect of RYM intervention on WL-Yoga subjects. In Phase 1, we reported that there were no differences between Yoga and Combination groups at the end of 12 week RYM intervention. One way ANOVA tests were performed to assess if any differences existed (after intervention) in the improvements between Yoga, Combination, and WL-Yoga groups.

The second aim was to evaluate whether the 12-week “maintenance” RYM intervention had sustained improvements (from the improvements seen in all three groups at end of 12 week RYM intervention) on a follow-up group. All 28 patients completed the initial 12-week intervention and 12 weeks of maintenance intervention (week 24 measurements). Repeated measures ANOVA was used to analyze changes from week 0 to week 12 and week 24. This allowed us to compare changes from week 0 to week 24 and compare maintenance or regression of improvements from week 12 to week 24. The nominal data of medicine and supplement use was analyzed using McNemar’s test. All the analysis was done using SPSS (Statistical Package for the Social Sciences, IBM Corporation, NY, version 20.0) software.

3. Results

3.1. Post-12 week RYM intervention in Wait-list (WL-Yoga) group

The 27 patients, who comprised the Wait-list group from Phase 1 study were offered the RYM intervention. Seven patients could not attend the Yoga intervention, due mostly to work schedule changes. A total of 20 patients were able to start the Yoga intervention. After a few weeks of Yoga intervention, 13 patients had dropped out either due to interference with their family-children’s activities (4), work-related problems (3), finding the Yoga sessions difficult (4), or pregnancy. Fig. 1 illustrates the flow chart of patients from the start of the study through the 3 month follow-up.

Seven patients completed the 12 week RYM intervention. Even though, three RYM sessions per week for 12 weeks were offered, subjects of the WL-Yoga group attended an average 23 sessions (64%). Week 12 data (before starting Yoga intervention) of the seven patients was considered as baseline data for the WL-Yoga group. Data was confirmed to be normal by Shapiro Wilke’s test. Paired samples t-test revealed the efficacy of Yoga intervention on the WL-Yoga subjects. In the primary outcome assessments of IBS-SSS scores (Table 1), a 56% reduction in severity of symptoms (p < 0.001) and a 45% improvement in the QOL (p < 0.01) was observed. The secondary outcome assessments of HADS (p < 0.01), autonomic symptom score (p < 0.01), and IBS-GAI (p < 0.001) have all shown significant improvements with 12 weeks of RYM intervention (Table 1). Similarly, there was a significant improvement (p < 0.05) regarding medicine and supplement use-four patients reported reduced usage of medication/supplements, one patient was using the same dosage, and two patients were not using any medications/supplements for the relief of IBS symptoms at baseline.
The autonomic function tests of sympathetic reactivity (handgrip and mental arithmetic tasks) showed no changes in blood pressure or heart rate after 12 weeks of intervention. However, a significant improvement in the handgrip strength \( (p < 0.01) \) was observed (data not shown). In the parasympathetic tasks of deep breathing and supine to upright position (30:15), no significant changes were observed when compared to baseline values (data not shown).

We reported that after 12 weeks of RYM intervention, there were no differences between Yoga and Combination groups and that they had both improved similarly. To assess if there were any post-intervention differences between all three groups (Yoga, Combination and WL-Yoga), the data (Yoga, \( n = 25 \); Combination, \( n = 26 \); and WL-Yoga, \( n = 7 \)) was analyzed using one way ANOVA followed by post hoc analysis with Bonferroni correction. The results revealed no significant differences between groups in the primary outcome assessments of IBS-SSS and IBS-QOL (Fig. 2a) and secondary outcome assessments of HADS and autonomic symptom score. In the assessment of IBS-GAI, WL-Yoga group showed less improvement than the Yoga group \( (p < 0.05) \), and there were no

### Table 1

Comparison of primary and secondary outcomes in WL-Yoga group at week 12 with week 0.

<table>
<thead>
<tr>
<th>Assessments</th>
<th>Week 0</th>
<th>Week 12</th>
<th>Change (95% CI)</th>
<th>t-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBS-SSS</td>
<td>266 ± 54.22</td>
<td>117.86 ± 74.73* (55.69%)</td>
<td>148.14 (97.58, 198.58)</td>
<td>7.169</td>
</tr>
<tr>
<td>IBS-QOL</td>
<td>100.71 ± 27.23</td>
<td>146.14 ± 14.67** (45.11%)</td>
<td>−43.43 (−68.54, −23.11)</td>
<td>−4.81</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS-A</td>
<td>11.29 ± 4.46</td>
<td>6.14 ± 2.34** (42.96%)</td>
<td>5.14 (2.25, 8.04)</td>
<td>4.34</td>
</tr>
<tr>
<td>HADS-D</td>
<td>8.14 ± 3.02</td>
<td>4.71 ± 2.22** (42.14%)</td>
<td>3.43 (1.75, 5.11)</td>
<td>5</td>
</tr>
<tr>
<td>ANS-SS</td>
<td>4.57 ± 1.72</td>
<td>2.43 ± 1.72** (46.83%)</td>
<td>2.14 (1.15, 3.13)</td>
<td>5.3</td>
</tr>
<tr>
<td>IBS-GAI</td>
<td>2.71 ± .49</td>
<td>6.14 ± .69** (128.56%)</td>
<td>−3.43 (−4.33, −2.53)</td>
<td>−9.3</td>
</tr>
</tbody>
</table>

Data were analyzed using paired samples t test; values are means ± SD.

*: Percentage change when compared to week 0. **: Represents change from week 0 to week 12; *p < 0.01; **p < 0.001.
differences between WL-Yoga and Combination groups (Fig. 2b). The improvements observed with medicine and supplement use in WL-Yoga group were significantly less compared to both Yoga \((p < 0.01)\) and Combination \((p < 0.05)\) groups (data not shown).

3.2. Follow-up group

3.2.1. Subjects

Among the 58 patients (25 in Yoga, 26 in Combination, and 7 in WL-Yoga groups) that completed the RYM intervention [results of Yoga and Combination groups reported in Phase 1], 28 patients have completed all 24 weeks of intervention and were considered for per protocol analysis. Subjects comprised of IBS-C \((n=8,\) median age 46.5 years; 28.6\% of total completed), IBS-D \((n=10,\) median age 46 years; 35.7\% of total completed), and IBS-M \((n=10,\) median age 47.5 years; 35.7\% of total completed). The median duration of IBS from diagnosis to enrolling in this clinical trial was five years and medications used was one year. Table 2 depicts the characteristics of the 28 patients that volunteered for the 12 week follow up.

3.2.2. Per-protocol analysis

Repeated measures ANOVA were performed for each assessment with one factor, time point (week 0, week 12 and week 24). Significant main effects and interaction between time points and assessments are given in Supplement Table 1.

3.3. Primary outcome assessments—IBS-SSS and IBS-QOL

Post hoc analysis with Bonferroni correction of IBS-Symptom severity scale and Quality of Life score showed significant improvements at week 12 \((p < 0.001)\) and were maintained at week 24 \((p < 0.001)\), when compared to week 0. Furthermore, there was a significant reduction in IBS-SSS at week 24 (28\%; \(p < 0.01\)) when compared to week 12 (Fig. 3).

A detailed analysis of the five sub-scales of IBS-SSS and eight dimensions of IBS-QOL showed no regression of improvements from week 12 to week 24. In fact, there were significant further improvements observed in two sub-scales of IBS-SSS, severity of pain \((p < 0.05)\) and interference with life in general \((p < 0.05)\), and body image dimension of IBS-QOL \((p < 0.01)\) (Supplement Table 2a and b).

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Fig. 2. Comparison of between group differences in primary and secondary outcome measures, in IBS patients (Yoga, Combination and WL-Yoga groups) after 12-week RYM intervention. (a) IBS-SS scores and IBS-QOL in IBS patients (Yoga, Combination and WL-Yoga groups) after 12-week RYM intervention. (b) HADS-anxiety, HADS-depression, autonomic symptom score, and IBS-Global Assessment of Improvement. Data were analyzed using one way ANOVA followed by Post hoc analysis with Bonferroni correction; *: Represents significant difference between Yoga and WL-Yoga group; \(*p < 0.05.\)
3.4. Secondary outcome assessments—hospital anxiety and depression scale (HADS), IBS-global assessments of improvement (IBS-GAI), autonomic symptom score

There were significant improvements in all the secondary outcomes, HADS, Autonomic Symptom score, and IBS-GAI, at week 12 and week 24 when compared to week 0 (p < 0.001). The improvements were sustained in all the secondary outcome assessments from week 12 to week 24, and in IBS-GAI, there was significant further improvement (p < 0.05) (Fig. 4).

3.4.1. Medicine and supplement use.

At the baseline appraisal, 21 out of the 28 subjects in the Follow-up group reported medicine and supplement use and seven subjects did not use any medication/supplements. Most commonly used medication/supplements were dicyclomine, Bentyl, Amitiza, Linzess, Loperamide, Psyllium, fiber drinks, herbal teas, and probiotics. There were significant improvements in the medicine and supplement use at week 12 and week 24 (p < 0.001) when compared to week 0 (Supplement Table 3), and the improvements were sustained from week 12 to week 24.

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**Table 2**
Characteristics of follow-up group subjects completing the 12 week maintenance program.

<table>
<thead>
<tr>
<th></th>
<th>Total (28)</th>
<th>Yoga group (11)</th>
<th>Combination group (10)</th>
<th>Wait-list Yoga group (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitant</td>
<td>15 (53.7%)</td>
<td>8 (72.7%)</td>
<td>4 (40%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Single</td>
<td>11 (39.3%)</td>
<td>3 (27.3%)</td>
<td>5 (50%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Divorced</td>
<td>2 (7.1%)</td>
<td>0</td>
<td>1 (10%)</td>
<td>1 (14.2%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>20 (71.4%)</td>
<td>6 (54.5%)</td>
<td>8 (80%)</td>
<td>6 (85.7%)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>8 (28.6%)</td>
<td>5 (45.5%)</td>
<td>2 (20%)</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle school</td>
<td>3 (10.7%)</td>
<td>1 (9.1%)</td>
<td>1 (10%)</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>High school</td>
<td>12 (42.9%)</td>
<td>4 (36.4%)</td>
<td>4 (40%)</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>College</td>
<td>13 (46.4%)</td>
<td>6 (54.5%)</td>
<td>5 (50%)</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>18 (64.3%)</td>
<td>9 (81.8%)</td>
<td>5 (50%)</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>Part-time</td>
<td>7 (25%)</td>
<td>0</td>
<td>4 (40%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Retired</td>
<td>3 (10.7%)</td>
<td>2 (18.2%)</td>
<td>1 (10%)</td>
<td>0</td>
</tr>
<tr>
<td>Economic status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;$30k</td>
<td>14 (50%)</td>
<td>5 (36%)</td>
<td>6 (60%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>30–60k</td>
<td>9 (31.3%)</td>
<td>3 (40%)</td>
<td>3 (30%)</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>60–100k</td>
<td>3 (11.6%)</td>
<td>2 (20%)</td>
<td>0</td>
<td>1 (14.2%)</td>
</tr>
<tr>
<td>&gt;100k</td>
<td>2 (7.1%)</td>
<td>1 (4%)</td>
<td>1 (10%)</td>
<td>0</td>
</tr>
<tr>
<td>IBS subgroups</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBS-Constipation</td>
<td>8 (35.9%)</td>
<td>3 (27.3%)</td>
<td>3 (30%)</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td>IBS-Diarrhea</td>
<td>10 (39.3%)</td>
<td>5 (45.4%)</td>
<td>3 (30%)</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td>IBS-Mixed</td>
<td>10 (39.3%)</td>
<td>3 (27.3%)</td>
<td>4 (40%)</td>
<td>3 (42.9%)</td>
</tr>
</tbody>
</table>

Percent in parentheses represent value of the total in a given category.
patients either stopped or reduced medicine and supplement use at week 12, and at week 24, 20 patients reported to have stopped all medicine/supplement use. Only one patient was on reduced medication at the end of week 24.

3.5. Measurements

3.5.1. BMI and physical flexibility
There was a reduction in BMI at week 24 (from $27.14 \pm 5.28$ to $26.71 \pm 5.08$; $p < 0.05$) when compared to week 0, which was not observed at week 12. Hip-trunk flexibility improved from week 0 ($21.32 \pm 8.03$) to week 12 ($28.11 \pm 7.43$; $p < 0.001$) to week 24 ($29.54 \pm 7.57$; $p < 0.001$). Left and right shoulder flexibility improved significantly at week 12 when compared to week 0 with further improvements at week 24 (data not shown).

3.6. Autonomic changes

3.6.1. Sympathetic reactivity tasks
The handgrip strength (handgrip task) improved significantly from week 0 ($35.68 \pm 12.29$) to week 12 ($42.61 \pm 11.7$; $p < 0.001$) and week 24 ($46.07 \pm 11.9$; $p < 0.001$). In the mental arithmetic task, speed improved from $37.93 \pm 21.33$ at week 0 to $51.39 \pm 27.63$ at week 12 ($p < 0.01$) and continued to improve at week 24 ($57.86 \pm 32.96$; $p < 0.001$) when compared to week 0. In addition, there was a significant improvement in the accuracy from week 0

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**Fig. 4.** Changes in the secondary outcomes in IBS patients enrolled in the follow-up group. HADS-anxiety, HADS-depression, autonomic symptom score, and IBS-GAI at week 12 and week 24 when compared to week 0. Data were analyzed using repeated measures of ANOVA followed by Post hoc analysis with Bonferroni correction. *: Represents significant changes at week 12 and week 24 when compared to week 0; ***$p < 0.001$; §§ Represents significant changes at week 24 when compared to week 12; §§$p < 0.05$.

**Fig. 5.** Changes in heart rate variability in IBS patients enrolled in Follow-up group. Frequency domain during deep breathing at week 12 and week 24 compared to week 0. Data were analyzed using repeated measures of ANOVA followed by Post hoc analysis with Bonferroni correction. ms2: milliseconds per square; *: Represents significant changes at week 12 and week 24 when compared to week 0; **$p < 0.01$; ***$p < 0.001$; §§ Represents significant changes at week 24 when compared to week 12; §§$p < 0.05$. 

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(34.79 ± 21.82) to week 12 (47.75 ± 28.95; \( p < 0.01 \)) to week 24 (55.18 ± 34.15; \( p < 0.001 \)).

Although there were no significant improvements in the diastolic blood pressure during the handgrip task, a trend of lowered diastolic blood pressure was observed. A similar trend of lowered systolic and diastolic blood pressure was observed in the mental arithmetic task. There were no changes in heart rate during this task (data not shown).

3.6.2. Parasympathetic reactivity tasks

There were significant improvements in the frequency domain of heart rate variability during deep-breathing task from week 0 to week 24, but not from week 0 to week 12. There was a significant reduction in LF (\( p < 0.001 \)) from week 0 to week 24, but most of the improvement was seen from week 12 to week 24. Even though HF increased significantly (\( p < 0.01 \)) from week 0 to week 24, most of the improvement (a 27% increase (\( p < 0.05 \)) was observed from week 12 to week 24 (Fig. 5). In the LF/HF ratio, an indicator of parasympathetic activity, there was a trend of improvement at week 12, whereas significant improvements (\( p < 0.01 \)) were seen at week 24, when compared to week 0 (data not shown).

In the second parasympathetic task of supine to upright posture (30–15 ratio), a trend of improvement was observed at week 12, and this was significantly improved (\( p < 0.01 \)) at week 24 when compared to week 0. The parasympathetic dominance in this task had improved significantly from week 12 to week 24 (\( p < 0.05 \)) (Table 3).

4. Discussion

The results reported in the present study provide encouraging evidence that the main findings of our RYM (three times a week for 12 weeks) analyses (Phase 1) are replicable (WL-Yoga group) and can be sustained during the long-term (Follow-up group) with one hour supervised RYM practices, once a week for 12 more weeks.

The clinical significance of improvements observed in the two primary outcome assessments is substantial. At week 12, reduction in IBS-SSS was 195 points relative to week 0, which is substantially higher than the 50 point reduction that is considered to be clinically significant improvement [4]. The consequent improvement at week 24 (follow-up) was even superior with an improvement of 230 points. The improvements in IBS-QOL at week 12 was 26 points compared to week 0, which is significantly higher than the 14 point gain to be considered clinically improved [6].

The results of the WL-Yoga group after 12 weeks of RYM intervention were parallel with those of the Yoga and Combination groups in the primary outcomes of IBS-SSS and IBS-QOL and secondary outcomes of anxiety, depression, medicine and supplement use, and GAI (Phase 1). The non–significant changes observed in physical flexibility and autonomic tasks could be due to the reduced number of sessions attended by this group. These results could suggest that regular practice of RYM is essential to bring about significant changes.

The present follow-up study has shown improvements across all groups, which is in contrast to previous Yoga investigations on IBS [7]. The Global Assessment of Improvement is significantly higher than that reported in recent Yoga study (follow-up) carried out on adolescents and young adults [8]. Our results are analogous to several studies that have reported that Yoga reduces the medication usage [9–11]. Almost all the patients were able to stop using prescription/non prescription medicines and supplements for their IBS symptoms. However, one patient reported using prescription medication at a reduced level, once every other day. Improved hip-trunk and shoulder flexibility findings of this study concur with a previous investigation [12]. The reported results of BMI in this study are in agreement with a survey that reported long-term Yoga practitioners had reduced BMI [10].

Similar to what was observed in the present study, a previous study reported that a 6-month Yoga program had increased hand grip strength [13]. Our results of significant improvements in mental arithmetic task (accuracy and speed) are concurrent with the observation by Nagendra et al. [14]. The significant changes in heart-rate and blood pressure in healthy adults reported by India and Narhara [15] were not replicated in the present study, which could be due to unhealthy subjects (IBS), but a trend of lowered heart rate and blood pressure was observed. Our results of parasympathetic dominance in deep breathing (frequency domain) and supine to upright posture (30/15) extend support to observations of other Yoga investigations [11,14,16].

The benefits of RYM intervention enjoyed by the IBS patients in our study are far reaching. Patients self-reported that Yoga had helped in relieving other health issues that they suffered from, such as headaches, arthritis, and inflexibility. In addition, Yoga helped them regain positivity, calmness, and energy, as well as made them feel more relaxed in stressful situations. Yoga therapy reportedly helped them regain control of their lives from IBS, and they now feel that IBS has little effect on their quality of life. The patients felt completely revitalized with the Yoga therapy and planned to continue practicing Yoga regularly (Supplement Table 4). There were no adverse events reported in the Follow-up group.

The limitations of this replication and follow-up study include a high dropout rate in the WL-Yoga and follow-up groups. This could be due to the fact that the working adult population in this study could not allocate extra time for the intervention (in addition to 12 weeks of waiting period) because of conflicts in work schedules, children’s after school activities, or other family matters. The number of Follow-up group patients (\( n = 28 \)) was small compared to initial numbers of 58 that completed the first 12-week RYM intervention. This could be due to our exclusion criterion of ‘no practice of Yoga at home.’ Time constraints and practicing at home were mentioned by patients for not being able to continue with the follow-up intervention. Another limitation was lack of a control group to compare the results of a weekly one-hour of RYM session.

In conclusion, our study provides potential evidence for the continuation and replication of RYM’s effects on IBS. More rigorous and longer-term trials with larger sample size are warranted to strengthen the efficacy of RYM for IBS that was seen in the present

<table>
<thead>
<tr>
<th>Week 0</th>
<th>95% CI</th>
<th>Week 12</th>
<th>95% CI</th>
<th>Week 24</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>30–15 ratio</td>
<td>1.077 ± 0.05</td>
<td>1.05, 1.09</td>
<td>1.02 ± 0.07</td>
<td>1.07, 1.12</td>
<td>1.148 ± 0.08** (6.59%)</td>
</tr>
</tbody>
</table>

Data were analyzed using repeated measures of ANOVA followed by Post hoc analysis with Bonferroni correction. Values are group means ± S.D. (%): percentage change when compared to week 0; [\( \% \)]: percentage change when compared to week 12; *: Represents changes at week 12 and week 24 compared to week 0; **: \( p < 0.01 \); \( \% \): Represents changes when compared to week 12; \( \% \): \( p < 0.05 \).
study. With the results presented, it can be concluded that RYM alone or RYM combined with conventional care as implemented in the present study could be a safe, efficient, and long-term solution for IBS symptoms. A group setting with personalized attention given by the instructor could be a motivating factor for patients to adhere to such physical activity programs.

4.1. Study approval

A signed informed consent was obtained from all eligible patients willing to enroll after a detailed explanation of the study. The study protocol was approved by the Institutional Review Board of White Memorial Medical Center, Los Angeles, USA, 20,120,012. The clinical trial was registered with ISRCTN, 42,102,754. As the study is being part of Ph.D. thesis, the protocol was also approved by the Institutional Ethics Committee of SVYASA (Swami Vivekananda Yoga University, Bangalore, India) IEC-SVYASA-010-2011.

4.2. Specific author contributions

Vijaya Kavuri participated in the planning of the follow up implementation of RYM, carried out the study, collected and analyzed the data, and drafted and contributed to the revision of the manuscript. Pooja Selvan contributed to the administration of assessments, acquisition and analysis of data, and editing of the manuscript. Alireza Tabesh, M.D. contributed to the planning of the study and recruiting patients for the clinical trial. Nagarathna Raghrum, M.D. advised on the design of the study and contributed in the planning of follow up study. Senthamil R. Selvan, Ph.D. directed the study including the planning, execution, design of the follow up clinical trial study, supervising data collection and analysis, evaluating and interpreting the data, and writing and critically revising the manuscript.

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Conflict of interest

The authors have declared that no conflict of interest exists.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijp.2014.08.011.

References