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Research paper

# 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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ABSTRACT

*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.

*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.

*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 ($p < 0.05$).

*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.

*Trial registration:* ISRCTN, 42102754.



## 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 [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 [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.

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## 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-SS 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.