



A randomized clinical trial of the Unified Protocol for Transdiagnostic treatment of emotional and gastrointestinal symptoms in patients with irritable bowel syndrome: evaluating efficacy and mechanism of change



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ABSTRACT

Objective: The aim of this randomized controlled trial was to evaluate the efficacy of Unified Protocol (UP) for transdiagnostic treatment of psychological problems, such as anxiety, depression, and stress, and treating the intensity of gastrointestinal symptoms in individuals with Irritable Bowel Syndrome (IBS). Another aim of the study was to test whether emotion regulation mediates the effect of UP.

Methods: Among 91 patients diagnosed with IBS (using ROME III criteria), 64 patients were eligible to participate in the study based on the inclusion/exclusion criteria. These patients were randomly assigned to either an intervention group (n = 32) that participated in 12 weekly UP treatment sessions or to a wait-list control group (n = 32). All patients completed the Depression, Anxiety, and Stress Scale (DASS-42), Emotion Regulation Questionnaire (ERQ), and Gastrointestinal Symptoms Rating Scale (GSRs) pre- and post-intervention. The data were analyzed with SPSS 20.0 software.

Results: The results of intention-to-treat (ITT) analysis indicated a significant decrease in depression, anxiety, stress, and gastrointestinal symptoms, as well as significant improvements in emotion regulation scores in the intervention group post intervention. All results were significant at $P < .001$. Mediation analyses indicated that changes in emotion regulation mediated the effect of UP on changes in emotional and gastrointestinal symptoms.

Conclusion: UP was effective and influential in emotion regulation among the intervention group and caused a decline in emotional and gastrointestinal symptoms. Hence, this intervention is promising, but larger RCTs are needed to more investigate its efficacy. Future studies could also examine the efficacy of the UP in other medical conditions with co-occurring psychological conditions.

The study is registered at the irct.ir database under registration number IRCT2017010431765N1.

1. Introduction

Irritable bowel syndrome (IBS) is the most prevalent functional gastrointestinal disorder, affecting 10%–22% of the adult population [1]. IBS is characterized by abdominal discomfort, changes in bowel habits, and pain without any structural abnormalities. Since there are no clear-cut diagnostic signs of IBS, its diagnosis is based on clinical manifestations [2]. This syndrome is widespread among all countries and socio-economic classes, and it is more prevalent among women than men [3]. Indirect effects of IBS include social isolation, employee absenteeism, and financial problems, and it may put undue financial pressure on the society's economy [4]. In Iran, the overall incidence of IBS has been reported to be between 1.1% and 25% [5].

Many studies have confirmed that various psychological disorders

are widely prevalent among patients with IBS [6, 7]. IBS is more closely associated with anxiety and depression than with other psychiatric disorders [8]. It has been reported that patients IBS suffer from generalized anxiety disorder, depression, or panic disorder [9, 10]. Psychological comorbidities, especially depression and anxiety in IBS, are correlated with personal suffering, decreased social functioning, reduced treatment adherence, poor quality of life [11].

Moreover, patients with depression and anxiety may apply inefficient or passive coping skills for emotion regulation [12]. Previous studies have indicated that many patients with IBS suffer from emotion dysregulation and are not able to identify and express their emotions may be at risk of somatoform disorders and may have more intense physical symptoms, as they are unable to distinguish emotions from physical states [13].

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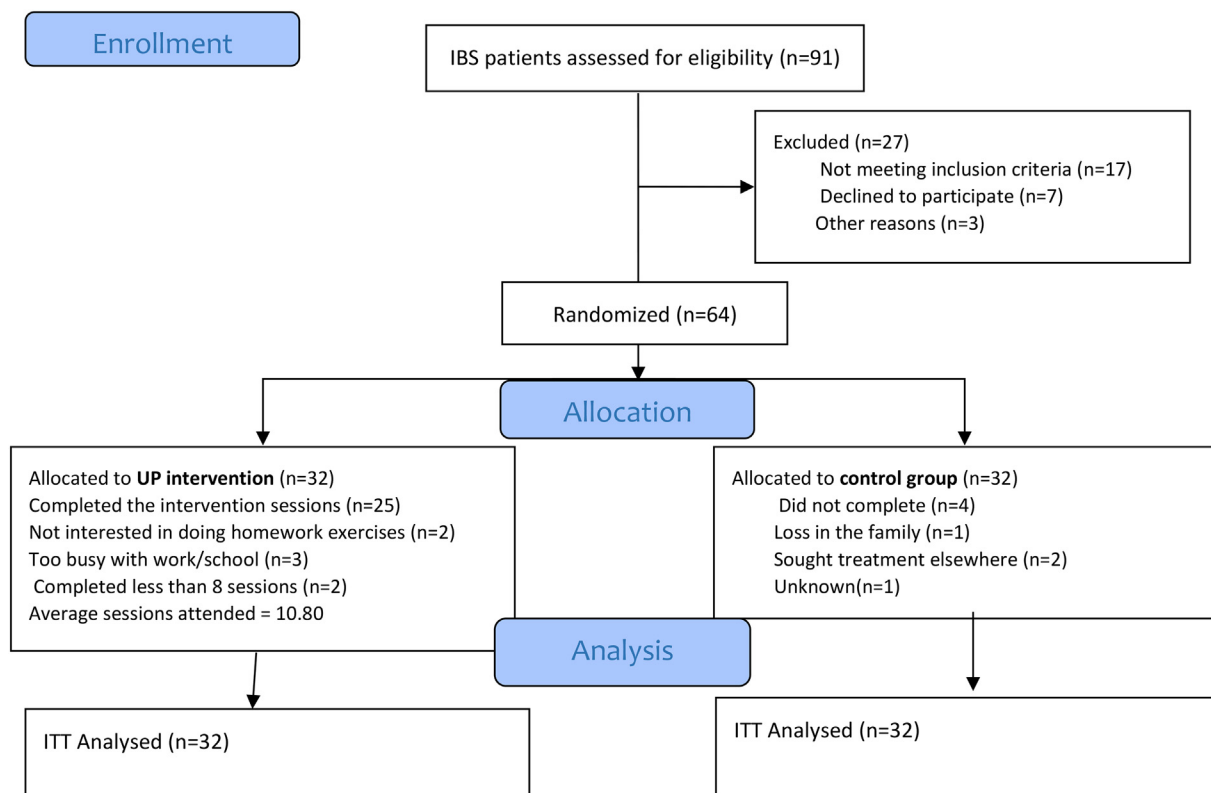


Fig. 1. Flow diagram of the study
Note: ITT = intention-to-treat.

Pharmacological and psychological treatments have both been shown to be effective in reducing the symptoms of IBS, but they have limitations. Pharmacological treatments can temporarily alleviate IBS symptoms [14], they are often expensive and may have negative side effects such as dry eyes, dry mouth, urinary retention, sedation, drowsiness, palpitations, and visual changes, as well as a risk of overdose (whether unintentional or deliberate) and cardiac arrhythmias [15, 16]. On the other hand, the psychological treatments used for IBS include cognitive behavioral therapy (CBT); hypnosis; and mindfulness-based, psychodynamic, and interpersonal therapies [17–19]. Psychological treatment improves physical symptoms severity, depression, and anxiety, overall with small to moderate effect sizes [20]. They involve numerous protocols for targeting specific disorders despite a high rate of comorbidity in patients.

To improve treatment, integrative treatments are recommended. The Unified Protocol for the transdiagnostic treatment of emotional disorders focuses on targeting emotional dysregulation as a common maladaptive coping strategy across different emotional disorders. UP is a cognitive behavioral intervention including 5 core components that target temperamental features, especially neuroticism and resulting emotion dysregulation, underlying all depressive, anxiety and associated disorders [21]. In a systematic review, improvements in emotional regulation was associated with improvements in depression and anxiety [22]. Various researches have examined the efficacy of transdiagnostic treatments in comorbid emotional disorders and improving the emotion regulation of patients with comorbid anxiety and depression [23–26].

The reasons for examining the usage of UP for the treatment of IBS include the high frequency of emotional disorders comorbidities in IBS and the efficacy of UP in targeting emotion regulation through emotional exposure and skills training. Consequently, the purpose of this paper is twofold: 1) examining the efficacy of UP in treating psychological problems such as anxiety, depression, and stress in patients

suffering from IBS and 2) examining the mediating role of emotion regulation in relationship between UP and reduce emotional disorder and IBS symptom severity.

2. Methods

This study was a parallel-group randomized clinical trial with intervention and waitlist control group to assess the efficacy of the UP in patients with IBS. The population consisted of all patients with IBS in Shahid Beheshti Hospital of Kashan who referred to the hospital in 2017 and gastroenterology experts confirmed that they had IBS based on ROME III criteria. All participants completed the informed consent form. The inclusion criteria consisted of: receiving the diagnosis of IBS based on Rome III criteria, 18–40 age range, Having emotional symptoms based on cut-off-score ≥ 15 in the depression and anxiety subscale of DASS-42, having at least a high school degree (because the UP required activity of individuals, and they had to do some assignment at home which needed their motivation, vigor, and their ability in identifying thoughts and emotions), to be willing and consent for participating in the study. Exclusion criteria consisted of: receiving other psychological treatments since last year and during the research process, having bowel surgery, psychotic characteristics or suicidal thoughts, organic mental disorder, history of drug abuse or drug dependence.

The present study was approved by the ethics committee of Kashan University of Medical Science with the number of IR.KAUMS.REC.1395.100. Written informed consents obtained from all participants. The study is registered at the irct.ir database under registration number IRCT2017010431765N1.

2.1. Participants

Among 91 patients with IBS who referred to the Shahid Beheshti

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