

CLINICIAN INFORMATION

Brief Summary Instructions

Parallel™ Prescription Digital Therapeutic Software

Important Safety Information:

Warnings/precautions: Parallel is intended for patients whose primary language is English and who have access to a Microsoft Windows/MacOS laptop or desktop computer with a web browser and internet connectivity. Parallel is intended for patients who are familiar with the use of web-based software.

The ability to use Parallel may be limited for patients who are visually impaired.

Parallel is not intended to be used as a standalone therapy for Irritable Bowel Syndrome (IBS). Parallel does not replace care by the provider and is not a substitute for other IBS treatments the patient may be using. Patients should continue to take their medications as directed by their provider.

Patients should be clearly instructed that Parallel cannot be used to communicate with their healthcare provider about emergency medical issues. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

Users should seek medical care if they have feelings or thoughts of harming themselves or others while using Parallel.

What is Parallel?

Parallel is a Prescription Digital Therapeutic (PDT) web application designed to deliver Cognitive Behavioral Therapy (CBT) to patients with Irritable Bowel Syndrome (IBS). PDTs are a new class of treatment using software to treat medical diseases.

The Parallel CBT program has been tailored for patients with IBS. The rationale for applying CBT to treat IBS is grounded in the biopsychosocial model. This model states that one's biology, thoughts, emotions, and behaviors influence IBS symptom expression in a bidirectional way.¹ The biological substrate of these interactions that affect IBS outcomes is the 'brain-gut axis'. The brain-gut axis underlies the pathways (e.g., psychological, behavioral functioning, and physiological interactions) that contribute to IBS symptom manifestation.² CBT allows patients to influence brain-gut communication in order to reduce the severity of IBS.

Parallel is available by prescription only and is intended to provide 3 months (90 days) of cognitive behavioral therapy for adult patients, aged 22 years and older, with IBS. Parallel is intended to provide CBT, as an adjunct to other IBS treatments. Parallel is intended to be used together with the patient's other IBS treatments. The Parallel software uses the patient's desktop or laptop computer web browser to deliver therapy on demand as a complement to the provider's care.

¹ Moss-Morris, R., *et al.* (2010). A randomized controlled trial of a cognitive behavioural therapy-based self-management intervention for irritable bowel syndrome in primary care. *Psychological medicine*, 40(1), 85-94.

² van Tilburg, M. A., *et al.* (2013). Which psychological factors exacerbate irritable bowel syndrome? Development of a comprehensive model. *Journal of psychosomatic research*, 74(6), 486-492.

How to Start Using Parallel:

The following steps will help guide the patient's use of Parallel:

- You will prescribe Parallel by sending a prescription to a Mahana-specified pharmacy.
- Once the prescription is approved, the pharmacy will dispense the product and contact the patient via email with instructions for accessing the therapy on their device.
- The email will contain an access link which the patient will use to enter the Parallel web application.
- The patient will then create a username and password to gain access to Parallel.
- Once the patient gains access to Parallel, they can begin completing sessions, answering questions, and reporting on their symptom severity.
- Parallel incorporates review screens such that, as the patient progresses through the modules, they may review data that was entered earlier in the program.
- After 90 days from the start of therapy, the application will no longer allow progression or unlock new content. However, the patient may access existing content previously unlocked.

Parallel is optimized for computer (desktop/laptop) access and is supported on the following computer operating systems and web browsers:

- MacOS: Safari, Chrome, Firefox
- Windows: Chrome, Firefox

General Information About the Safe and Effective Use of Parallel:

Parallel is not intended to replace other IBS treatments. Clinicians should engage in their normal care practices to monitor patients for medical problems.

Patients complete the sessions in a specific order. A patient can only advance to the next session after successfully completing the prior session.

Indications for Use Statement:

Parallel is a prescription-only digital therapeutic intended to provide cognitive behavioral therapy for adults aged 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). Parallel is indicated as a 3 months treatment for patients with IBS. Parallel treats IBS by reducing the severity of symptoms and is intended to be used together with other IBS treatments.

Summary of Clinical Testing:

Parallel has been studied in a randomized, controlled trial in 558 patients with IBS. Patients with mild to severe IBS (IBS-Symptom Severity Scale [IBS-SSS] ≥ 75) were randomly assigned to one of three treatment groups: Treatment-as-Usual (TAU), Therapist-delivered Cognitive Behavioral Therapy (TCBT) via telephone, or Web-based CBT (Parallel). At Month 3, group mean changes in IBS-SSS scores were reduced in the Parallel group vs. TAU, and met the minimum clinically-important difference (MCID) of 50 points as defined for the IBS-SSS by Francis *et al.*³ The frequency of related,

bowel syndrome and its progress. *Alimentary pharmacology & therapeutics*, 11(2), 395-402.

³ Francis, C. Y., et al. (1997). The irritable bowel severity scoring system: a simple method of monitoring irritable

treatment-emergent adverse events (TRAEs) revealed no notable differences between treatment groups. The full clinical study summary is also available in publication.⁴

Additional Support Available:

For additional technical support with any aspect of the Parallel web application, you can contact Mahana via email at support@mahanatherapeutics.com or by phone at 1-844 MAHANA-0 (1-844-624-2620)

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⁴ Everitt, H., et al. (2019). Therapist telephone-delivered CBT

and web-based CBT compared with treatment as usual in refractory irritable bowel syndrome: the ACTIB three-arm

