

## **01** | Introduction

Irritable bowel syndrome (IBS) is a heterogeneous disorder of gut-brain interaction that impacts up to 10% of adults worldwide. Treatment of IBS requires an individualized, multidisciplinary approach, resulting in increased healthcare utilization. Self-help IBS education, diet advice, and psychological treatment delivered via mobile applications has the potential to augment medical care by providing a cost-effective and easily accessible treatment option.

**02** | **Aim** The aim of this real-world study was to provide preliminary evidence on whether digital health application delivered therapies can support the medical care of IBS patients by generating both medical benefits and patient-relevant structural and procedural improvements.

## **03** | Method

## The mobile digital treatment:

Individuals underwent a 12-week digital treatment program delivered via an app-based medical device (Hidoc Technologies GmbH, Berlin, Germany) that provided four personalized modules providing psychoeducation, nutritional therapy (low-FODMAP diet), and psychotherapeutic intervention (either cognitive-behavioral therapy skills training or gut-directed hypnosis).

## Population

Individuals who started the digital treatment program between 2021-04-01 and 2021-08-17 were included in the analysis Individuals were eligible for the analysis if they were: between 18 and 70 years of age, met Rome IV Criteria for IBS; reported having a diagnosis of IBS confirmed by a physician; absence of a serious organic, psychiatric or addictive disease.

## Questionnaires

IBS symptom severity (IBS-SSS; 0-500), IBS specific quality of life (IBS-QOL) were measured at baseline (T0) and every 4 weeks (T1, T2, & T3). Symptoms of anxiety (GAD-7) and depression (PHQ-9), as well as work productivity and activity impairment (WPAI:IBS) were measured at T0 and T3.

## Statistical analysis

Mixed effect models for repeated measures (MMRM) were performed on the compared outcomes at T1 - T3 to T0, with gender, age group, and IBS subtype of users as covariates and estimated least squares means for the up to four survey time points. A post hoc analysis was performed to evaluate the differential effects of treatment modules, which were included in the MMRM as a between subject factor, the module-by-time interaction was further explored using the least-squares means (LSMEANs) method.

# App-based digital treatment for irritable bowel syndrome to reduce symptoms and improve quality of life: A real-world evidence study

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## 04 | Results

## **Demographic characteristics of the population**

In total, 80 individuals with IBS (avg. age 34.7 years; 82.5% female) entered the study - 54 (67.5%) completed all 12-weeks of the study.

## **IBS-SSS**

IBS-SSS significantly decreased at T1, T2, and T3. A clinically relevant improvement ( $\geq$ 50 IBS-SSS score reduction) was reported by 72.5% of individuals.

## **IBS-QOL**

IBS-QOL significantly improved at all questionnaire time points study visits (p<0.001). A clinically relevant improvement (≥13 IBS-QOL) improvement) was reported by 50% of individuals at T3.

## Anxiety and depression

GAD-7 and PHQ-9 scores also improved significantly between T0 and T3. Further analysis indicated that improvement of both PHQ-9 (R-squared = 0. 26 [95% C.I. 0.05-0.52]) and GAD-7 (R-squared = 0.11) [95% C.I. 0.01-0.32]) were correlated with the improvement of IBS-SSS at T3.

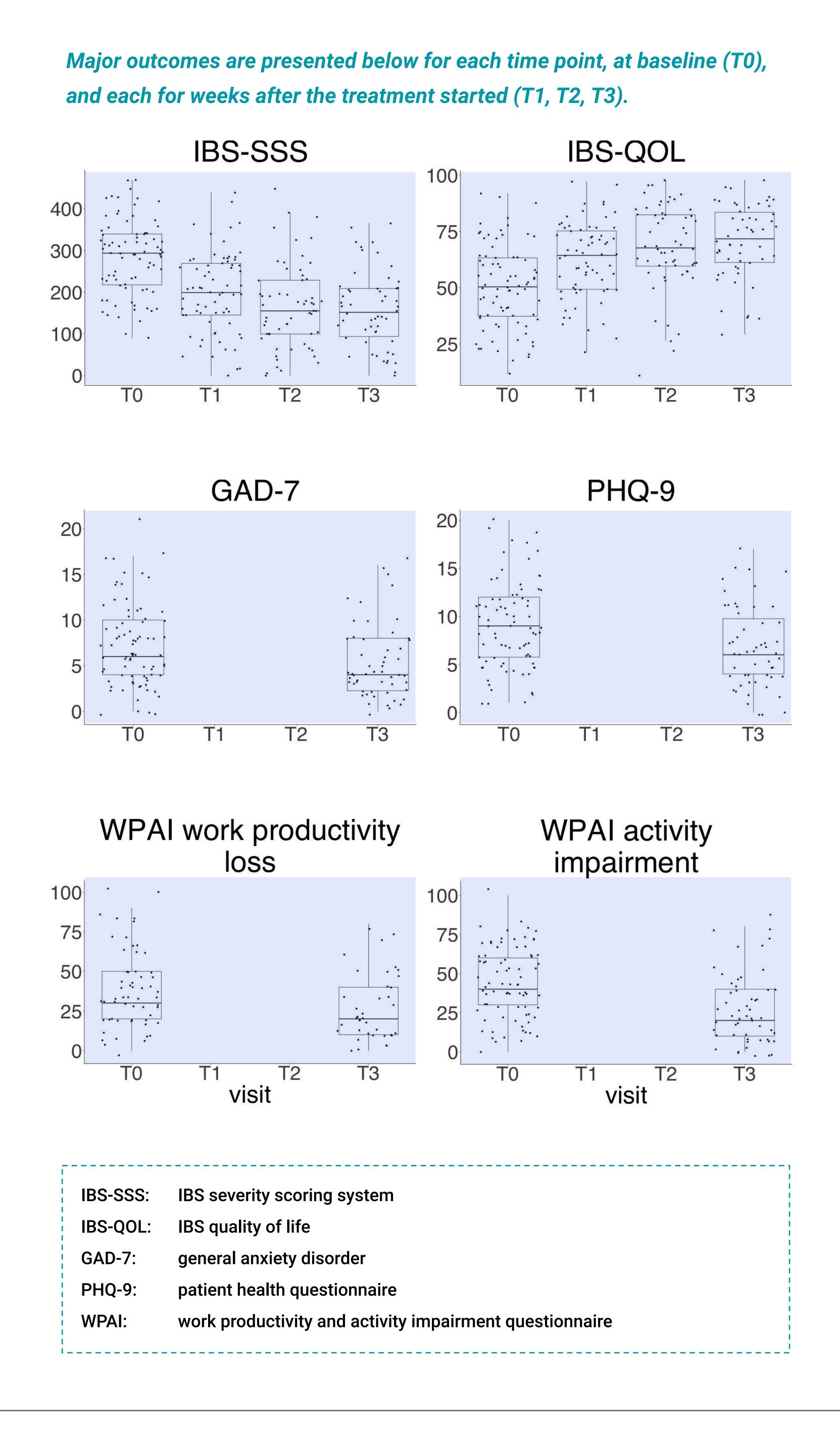
## WPAI:IBS

WPAI:IBS subscales also significantly improved at T3 compared to T0 (p<0.001). Interaction analysis indicated identical patterns of treatment effects for each personalized module.

Questionnaire	Questionnaire time point	
IBS symptom severity (IBS-SSS)	T0, T1, T2, T3	
IBS specific quality of life (IBS-QOL)	T0, T1, T2, T3	
Patient health questionnaire 9 (PHQ-9)	T0, T3	
General anxiety disorder 7 (GAD-7)	T0, T3	
Work productivity and activity impairment (WPAI:IBS) work productivity loss	T0, T3	
Work productivity and activity impairment (WPAI:IBS) activity impairment	T0, T3	

## 05 | Conclusions <

This real-world study provides preliminary evidence on the effectiveness of a 12-week app-based digital treatment program to treat IBS symptoms and improve quality of life in IBS patients.



## 06 Disclosure & Acknowledgements

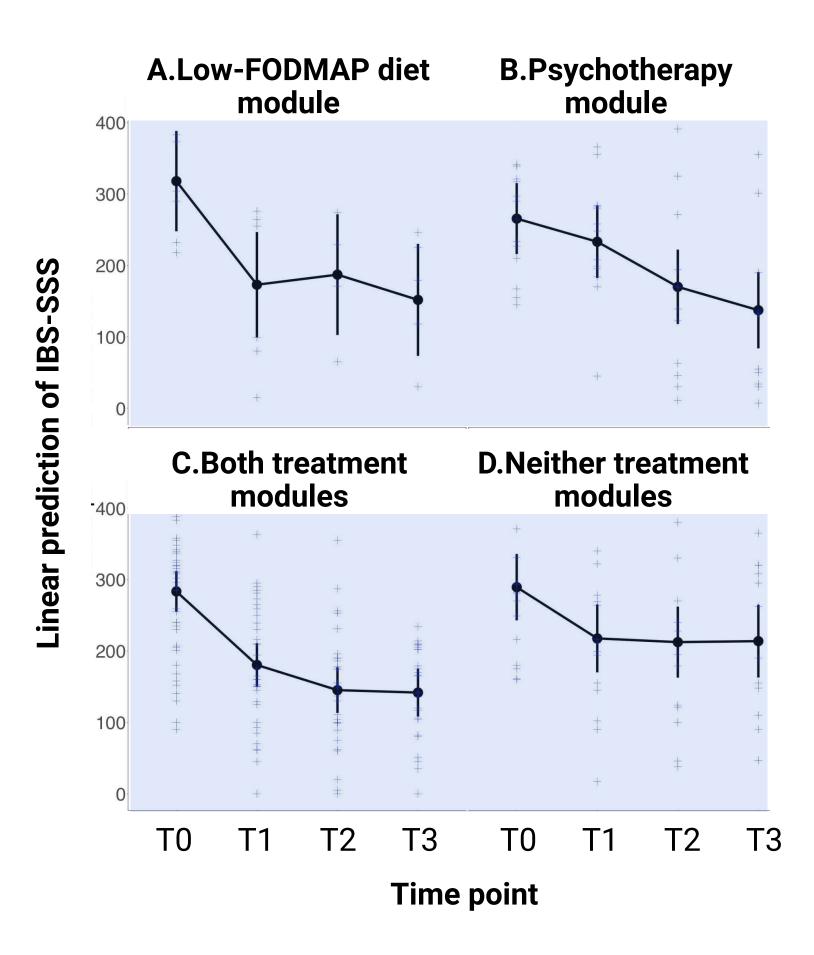
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#### Effect of modules

The impact on IBS-SSS among individuals with different combinations of modules is depicted below. Individuals assigned to the low-FODMAP diet module (N=50) showed rapid symptom improvement in IBS-SSS with a persistent effect, whereas individuals with the psychotherapeutic modules (either gut-directed hypnosis or cognitive behavioral therapy, N=57) showed gradient symptom improvement. Moreover, individuals receiving only psychoeducation (N=14) did not show significant symptom improvement throughout the treatment period.

Possible combinations	Psycho- education	low-FODMAP diet	Psycho- therapy*
Low-FODMAP diet module	Χ	X	
Psychotherapy module	Χ		X
Both treatment modules	Χ	X	X
Neither treatment modules	X		

Individuals who accessed (A) both low-FODMAP and psychotherapy (n=43), (B) neither modules (only basic psychoeducative content) (n=14), (C) only low-FODMAP (n=7), and (D) only psychotherapy (n=14) are presented. The x-axis represents time points, the y-axis represents the linear prediction of the mixed effect model, and the error bar represents the 95% confidence interval. Overlapping error bars indicate the effects of



the two data points are not significantly different. Individuals with the low-FODMAP module showed rapid symptom improvement with a persistent effect, whereas patients with psychotherapeutic module showed gradient symptom improvement. Moreover, patients with neither personalized modules did not show significant symptom improvement throughout the treatment period.

## **07** | Contact Information

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