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Nerva digital therapeutic: A catalyst for alleviating physical and psychological symptoms through primary care provider referral.

Simone L Peters, Peter R Gibson, Emma P Halmos

Department of Gastroenterology, Monash University, Alfred Health, Melbourne, Victoria, Australia

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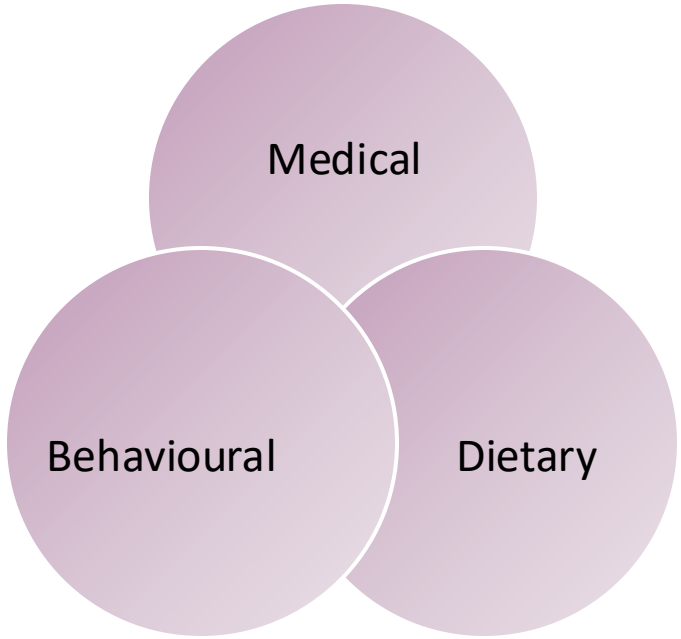
Disclosures

- Speaker Honorarium Janssen
- Founder & Managing Director, Mind + Gut Clinic
- Consultant to Mindset Health
- Shareholder in Mindset Health
- Sales from Nerva, Mindset Health
- Study supported by Mindset Health

Introduction

Irritable Bowel Syndrome (IBS)

- **Definition:** Recurrent abdominal pain associated with defecation or a change in bowel habit
- **Global prevalence:** Common, worldwide prevalence of 11%
- **Pathogenesis:** Multifactorial – Gut-brain dysregulation, altered gastrointestinal motility, visceral hypersensitivity, gut microbiota alterations, psychological factors etc
- **No cure:** Treatment typically begins with medical management and dietary changes, with behavioral therapies generally applied as third-line options



Integrated care = Optimal patient outcomes

Oka et al Lancet Gastroenterol Hepatol 2020; 5: 908-917
Tornkvist et al United European Gastroenterol J. 2021; 9: 1178-1188
Chey et al Gastroenterology 2021; 160: 47-62

Introduction

Gut-Directed Hypnotherapy (GDH)

- **GHD:** Targets the subconscious mind for the control and normalization of gastrointestinal function (motility, visceral hypersensitivity)
- **Efficacy:** Clinical trials show 24-73% symptom reduction, on par with a low FODMAP diet
- **Accessibility:** Hindered by high costs and limited therapist ability
- **Digital innovations:** Introduction of digital therapeutics, such as Nerva, allow for improved affordability and accessibility

Peters et al. Aliment Pharmacol Ther 2015; 41: 1104–1115

Introduction

Efficacy of Nerva

Comparison of Digitally Delivered Gut-Directed Hypnotherapy Program With an Active Control for Irritable Bowel Syndrome

Ellen J. Anderson, BNutSci, MDiet[1,2], Simone L. Peters, BSc (Psychophysiology) (Hons), PhD[1], Peter R. Gibson, MBBS(Hons), MD[1,2] and Emma P. Halmos, BNutDiet, PGradDipBSc, PhD[1,2]

INTRODUCTION: **Gut-directed hypnotherapy (GDH) treats irritable bowel syndrome (IBS), but its accessibility is limited. This problem may be overcome by digital delivery. The aim of this study was to perform a randomized control trial comparing the efficacy of a digitally delivered program with and without GDH in IBS.**

METHODS: **Adults with IBS were randomized to a 42-session daily digital program with the GDH Program (Nerva) or without (Active Control). Questionnaires were completed to assess gastrointestinal symptoms through IBS Symptom Severity Scale (IBS-SSS), quality of life, and psychological symptoms (Depression Anxiety and Stress Scale-21) at regular intervals during the program and 6 months following the conclusion on the intervention. The primary end point was the proportion of participants with ≥50-point decrease in IBS-SSS between the interventions at the end of the program.**

RESULTS: **Of 240/244 randomized participants, 121 received GDH Program—the median age 38 (range 20–65) years, 90% female, IBS-SSS 321 (interquartile range 273–367)—and 119 Active Control—36 (21–65), 91% female, IBS-SSS 303 (255–360). At program completion, 81% met the primary end point with GDH Program vs 63% Active Control ($P = 0.002$). IBS-SSS was median 208 (interquartile range 154–265) with GDH and 244 (190–308) with control ($P = 0.004$), 30% reduction in pain was reported by 71% compared with 35% ($P < 0.001$), and IBS quality of life improved by 14 (6–25) compared with 7 (1–15), respectively ($P < 0.001$). Psychological status improved similarly in both groups.**

DISCUSSION: **A digitally delivered GDH Program provided to patients with IBS was superior to the active control, with greater improvement in both gastrointestinal symptoms and quality of life and provides an equitable alternative to face-to-face behavioral strategies.**

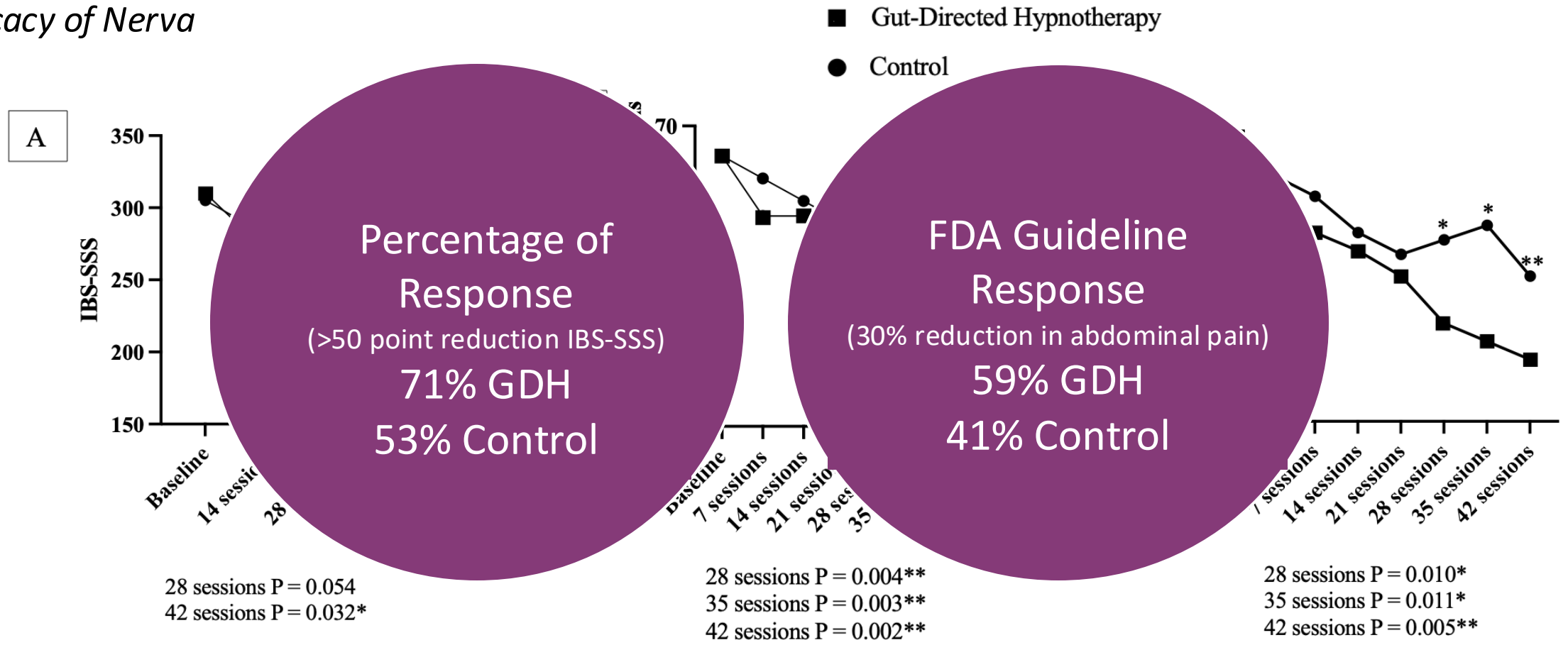
KEYWORDS: psychological therapy; disorders of gut-brain interaction; gastrointestinal symptoms; abdominal pain; digital medicine

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/AJG/D324

Am J Gastroenterol 2024;00:1–9. https://doi.org/10.14309/ajg.0000000000002921

Introduction

Efficacy of Nerva



Percentage of Response
(>50 point reduction IBS-SSS)
71% GDH
53% Control

FDA Guideline Response
(30% reduction in abdominal pain)
59% GDH
41% Control

Median scores in IBS patients receiving a 42-session program of GDH or Control. Baseline demographics and gastrointestinal symptoms of participants with IBS provided digitally delivered therapy with GDH or without (Control). A: IBS-SSS; B: Overall symptoms using IBS-VAS; c: Abdominal pain using IBS-VAS

Retrospective Analysis

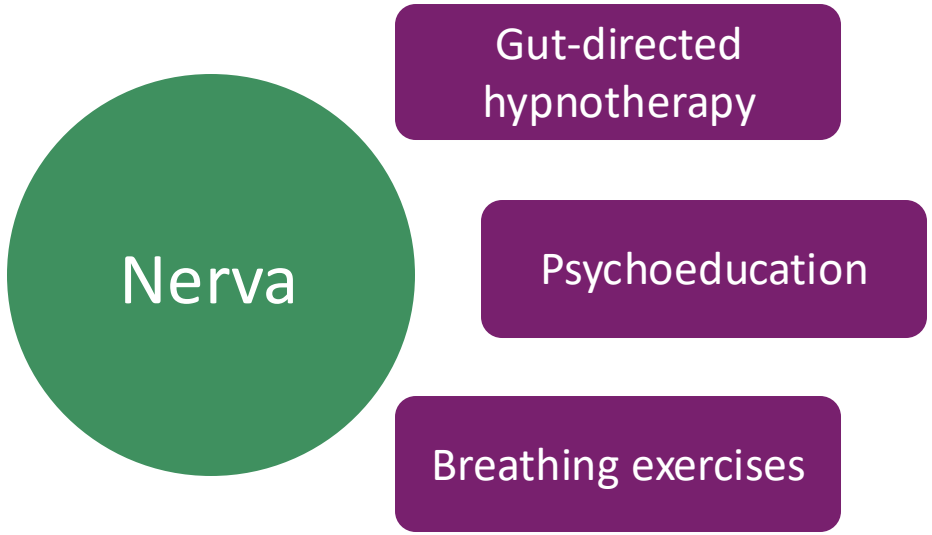
Aim

- To investigate the efficacy of Nerva, in reducing IBS symptoms, when referred by Primary Care Providers

Methods

Study Participants and Design

- **Participants:** Self-reported IBS
- **Inclusion criteria:** Self-reported IBS, referred to Nerva by their Primary Care Provider
- **Exclusion criteria:** Other GI disease, pregnant, diagnosed mental health condition, major GI surgery, previous GDH use, lacked a smartphone
- **Design:** Participants engaged in a 6-week GDH program



Methods

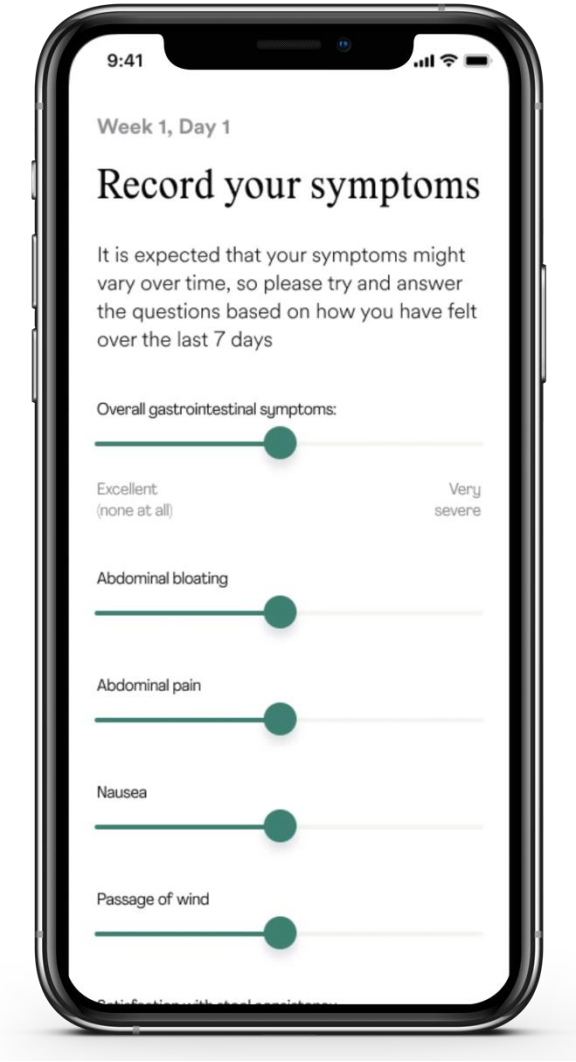
Evaluation Endpoints

PHQ4 for Anxiety and Depression

- Baseline and post-program
- Severity categories: Normal (0-2), Mild (3-5), Moderate (6-8), Severe (9-12)

IBS Symptoms

- Baseline and post-program
- Measured using a 100mm VAS
- >30% change in abdominal pain is considered clinically relevant



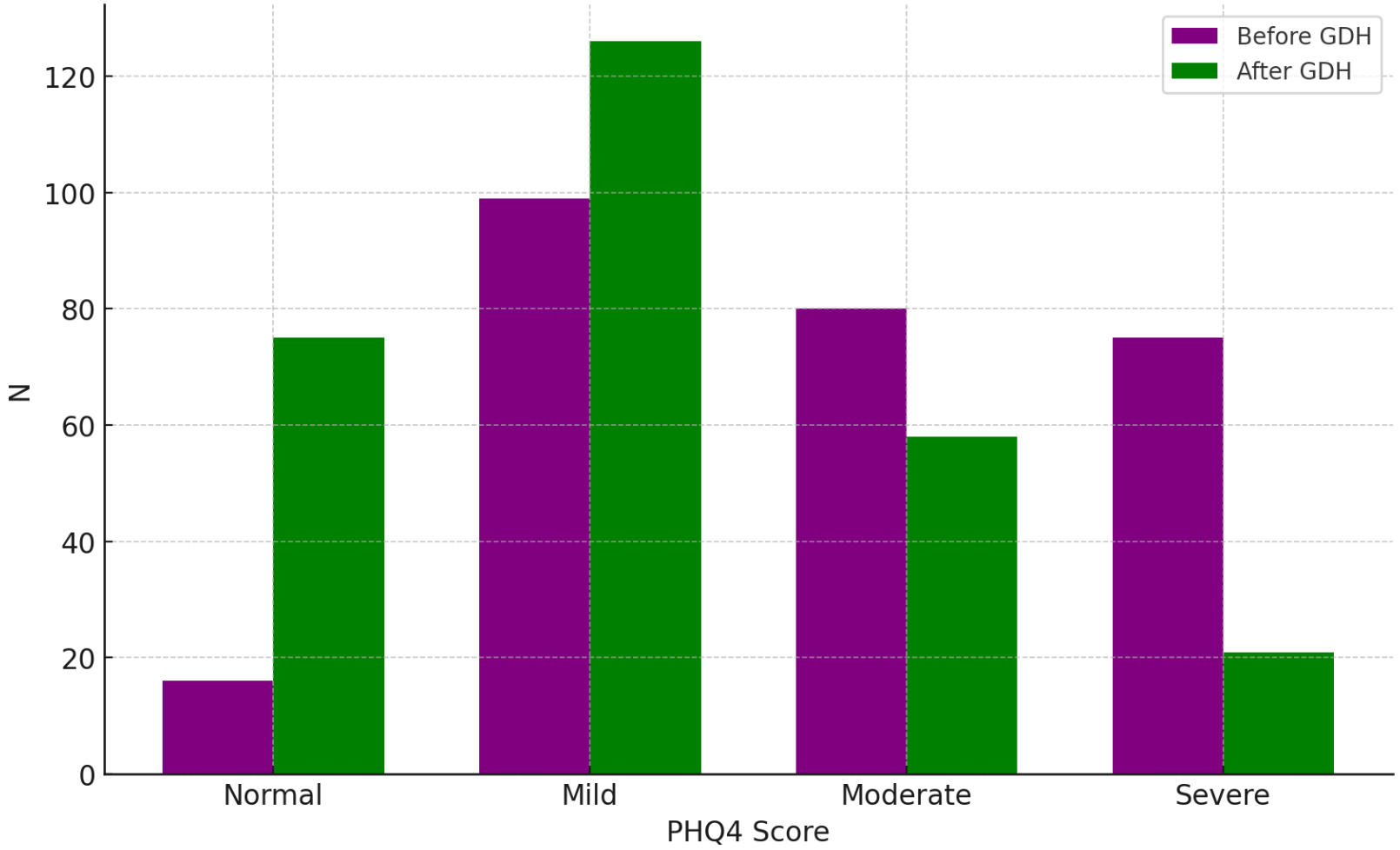
Results

Demographics

Baseline Demographics	
No. of participants	278
Gender F M	 239 (86%) 39 (14%)
Age (mean)	48 years
IBS symptom duration 0-6 months 6-12 months 1-5 years 5+ years	 20 (8%) 24 (9%) 81 (30%) 145 (53%)

Results

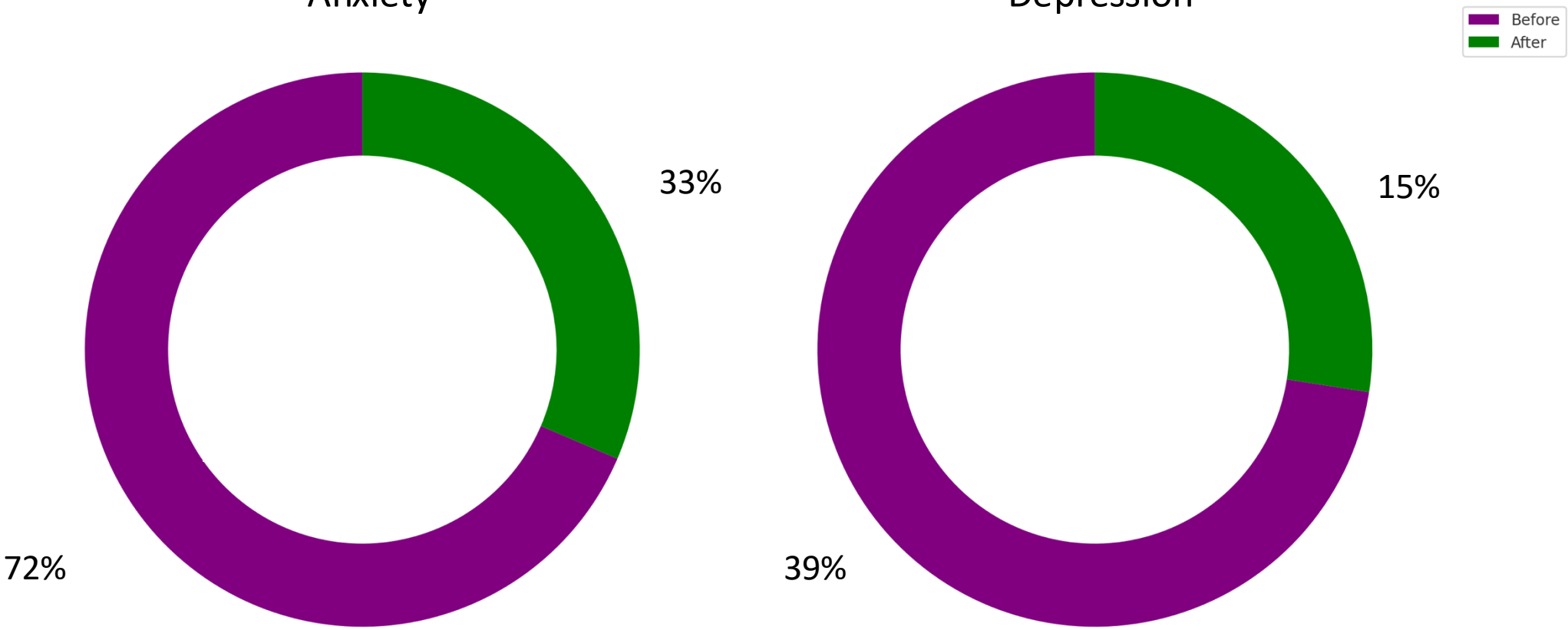
PHQ4



PHQ4 scores from before and after GDH classified into four categories: Normal (0-2), Mild (3-5), Moderate (6-8) and Severe (9-12) (n=278.

Results

PHQ4



Total PHQ4 anxiety and depression scores, represented at percentages, before and after GDH ($p<0.001$).

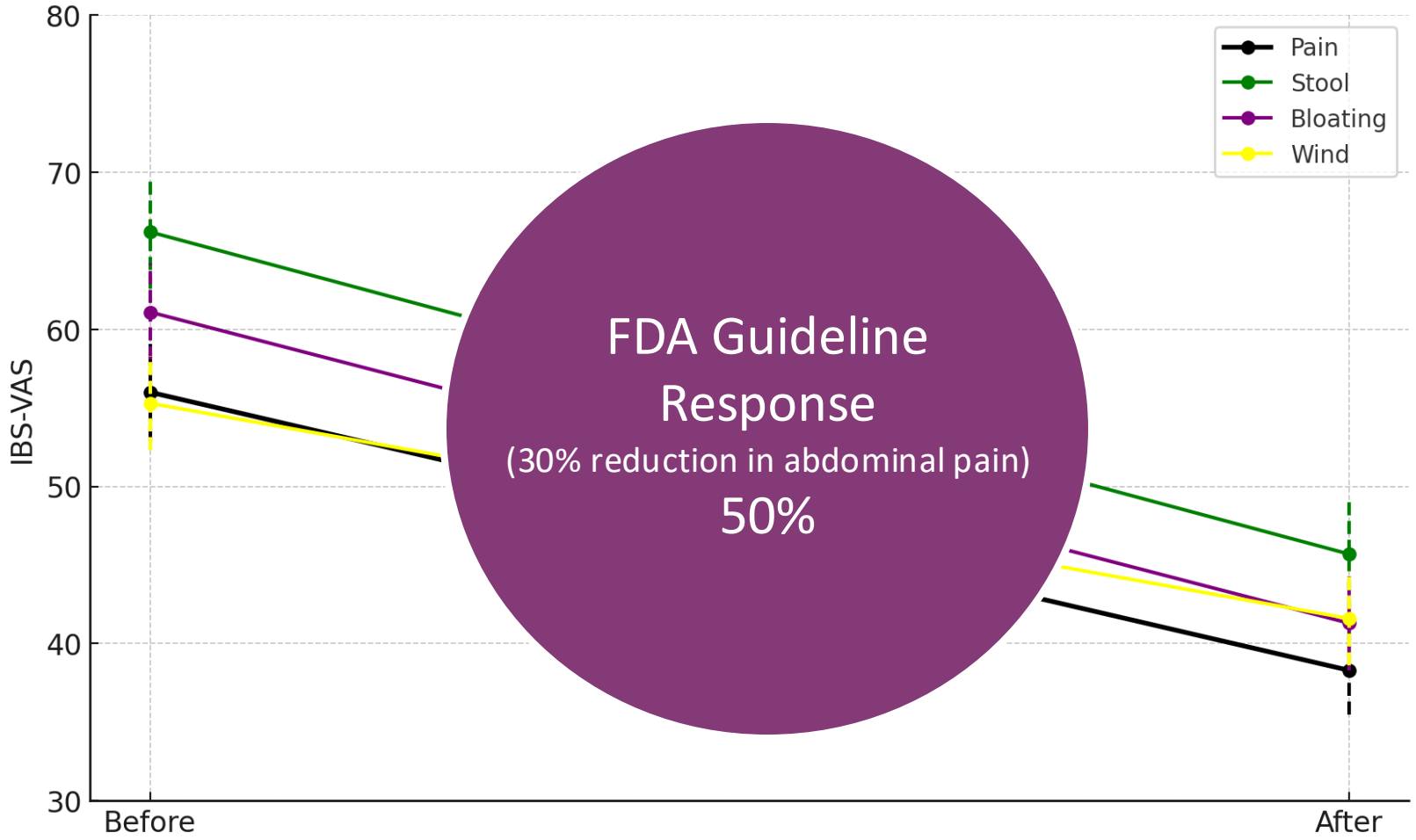
Results

Gastrointestinal Symptoms

	Baseline	Program completion	*P*-value
Abdominal pain	56.0	38.3	<0.001
Abdominal bloating	61.1	41.3	<0.001
Passage of wind	55.3	41.6	<0.001
Satisfaction with stool consistency	66.2	45.7	<0.001
* Paired sample t-tests			

Results

Gastrointestinal symptoms



Median scores in IBS patients from baseline to the end of the GDH program (n=278).

Conclusions

Retrospective Findings

- **Enhanced outcomes:** Nerva has shown significant improvements in both physical and psychological well-being for IBS patients
- **Role of supportive relationships:** Supportive relationships are key to the effective management of IBS
- **Importance of referrals:** Referrals from Primary Care Providers play a crucial role in achieving optimal patient outcomes

Implications

Widescale Implications

- **Advantages of Digitally Delivered GDH:** Nerva provides an accessible, cost-effective, and highly effective therapy for IBS, with the potential for wide-scale implementation.
- **Primary Care Providers:** PCPs are essential in educating patients on the benefits and use of digital therapeutics
- **Future Innovations:** Future work would benefit from establishing response to digitally delivered GDH for other gastrointestinal conditions

Thank you

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