DIGEST II

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The primary objective of this study is to compare the effectiveness of two app-based interventions on diet quality and perceived stress compared to standard care.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional research applied for the first time in human subjects

Summary

ID

NL-OMON57538

Source
Onderzoeksportaal

Brief title
DIGEST II

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Health Holland

Intervention

- Life style intervention

Explanation

N.a.

Outcome measures

Primary outcome

The main study parameters are diet quality and perceived stress levels.

Secondary outcome

The secondary objectives investigate the effect on IBS-related symptoms and the usability of the app-based interventions.

Study description

Background summary

Irritable bowel syndrome (IBS) is a prevalent disorder of the gut-brain interaction affecting 4–6% of the global population. Studies show that 85% of IBS patients indicate certain foods that exacerbate gastrointestinal complaints, and 90% of IBS patients avoid these foods, such as gas-forming vegetables, dairy products, fat-rich items, sparkling soda, apples, and bread. Without professional guidance from a dietician and proper substitutions, this can lead to lower diet quality with possible long-term health consequences. To the best of our knowledge, there is a lack of (digital) support to improve diet quality for this target group and tailored to their perspectives and needs. Therefore, earlier research of the overall project mapped the perspectives and preferences of IBS patients regarding (digital) dietary interventions and guidance and found that they prefer personalized dietary advice and guidance in adjusting their diet (i.e., healthy alternatives for personal trigger foods). This study aims to examine the effect of the developed personalized dietary support app on dietary quality and a personalized stress management app on stress levels, with a secondary aim of assessing its effects on IBS-related symptoms and assessing the usability of these mobile app interventions.

Study objective

The primary objective of this study is to compare the effectiveness of two app-based interventions on diet quality and perceived stress compared to standard care.

Study design

The DIGEST study is a pilot study with a randomized controlled design consisting of three study arms of each 20 participants with a total duration of eight weeks. 60 participants with IBS (based on Rome IV criteria), aged 18 and 65 years, who already identified their trigger

foods, will be recruited online through patient organizations for IBS, Wageningen University & Research, and Maastricht University Medical Center+.

Intervention

One group receives an intervention with a mobile application, which focus on personal dietary support and an informational brochure with general stress management support. The second group receives an intervention with a mobile application which focuses on personal stress management support and an informational brochure with general dietary support. The third group receives standard care, which includes an informational brochure with general dietary support and general stress management support.

Study burden and risks

Participation in this study has practically no adverse effects. The only requirement is that participants make use of the intervention offered. As most participants are expected to enroll due to their need for support with their diet or stress management, the time commitment will be proportionate to the potential benefits they will experience. Participants will also be free to withdraw from the study at any time, for any reason, with no consequences. It is possible that the participant does not receive the desired intervention. That is why, after the study, participants are offered to receive the intervention of their choice.

Contacts

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Trial sites

Trial sites in the Netherlands

Wageningen Universiteit
Target size: 60

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, a potential subject must meet all of the following criteria:

- IBS diagnosis using Rome IV-criteria;
- Between 18 and 65 years old;
- Must have already identified which foods trigger their symptoms after completing an elimination diet;
- In possession of a smartphone that can access the internet (Wi-Fi or internet plan);
- In possession of an e-mail address.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Other gastrointestinal disorders and/or proven food allergies;
- No literacy in Dutch (not able to speak and read Dutch);
- Visually impaired;
- Being pregnant or in the lactation period;
- Participation in another human trial;
- Currently employed at the Division of Human Nutrition and Health;
- Legally incompetent;
- Not willing to sign the informed consent.

Study design

Design

Study phase:	N/A
Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	60
Duration:	2 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
Resultaten worden gepresenteerd in overeenstemming met de CCMO-publicatieverklaring. Resultaten en bevindingen zullen worden gepubliceerd in wetenschappelijke, peer-reviewed tijdschriften en vakbladen. De resultaten van het onderzoek zullen ook worden gepresenteerd op conferenties en bijeenkomsten. Alle gegevens worden anoniem gerapporteerd. Zoals vermeld maakt deze studie deel uit van het IBS-DietSup project.

Ethics review

Approved WMO

Date:	20-05-2025
Application type:	First submission
Review commission:	METC Oost-Nederland

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Research portal	NL-009307