Face-to-face versus online hypnotherapy for the treatment of Irritable Bowel Syndrome, according to a non-inferiority design. Three-armed randomized controlled trial. (FORTITUDE)

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Primary objective:To compare the efficacy of online hypnotherapy versus face-to-face according to a non-inferiority design for the treatment of IBS.Hypothesis: Hypnotherapy delivered in the form of online exercises has non-inferior efficacy to face-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON55898

Source
ToetsingOnline

Brief title
FORTITUDE

Condition

- Gastrointestinal signs and symptoms

Synonym
Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Hypnotherapy, Irritable Bowel Syndrome, Psychoeducation, Self-help instruments

Outcome measures

Primary outcome

According to FDA recommendation:

1. Abdominal pain response rate after 12 weeks of treatment.

a. A responder is defined as a patient who experiences at least a 30 percent decrease in the weekly average of worst daily abdominal pain (measured daily, on an 11 point NRS) compared to baseline weekly average in at least 50 percent of the weeks in which the treatment in given.

Secondary outcome

- Degree of relief response rate after 12 weeks of treatment, according to EMA recommendation: *A responder is defined as a patient who experiences a weekly relief of 1 or 2 (on a 7 point NRS) in at least 50 percent of the weeks in which treatment is given.*
- Response rate directly after completion of the 12-week treatment period
- Improvement of symptom severity as determined by the IBS-SSS by 50 points or more
- Longitudinal change in IBS-SSS at baseline (run-in), t=12 weeks, t=16 weeks, t=6 months follow-up and t=1 year follow-up
- Cost-utility, as determined by calculations incorporating total treatment

costs and changes in EQ-5D-5L (QALYs gained) and MCQ/PCQ results (savings from

reduced medical resource use and increased work productivity respectively)

- Quality of life, as determined by the EQ-5D-5L and IBS-QoL (change from

baseline)

- Use of OTC and rescue medication

- Adherence to therapy

- Response rates in relation to patient expectation prior to the start of

treatment

- Response rates in relation to comorbid anxiety and/or depression- Number and severity of adverse events

Study description

Background summary

Psychological therapies are effective in reducing irritable bowel syndrome (IBS) symptom severity and increasing quality of life and are recommended for the management of IBS by guidelines. Evidence appears strongest for the efficacy of hypnotherapy as psychological treatment. However, therapist-led interventions are time consuming and relatively costly. Approaches based on e-health are cost saving and appear more attractive to patients as no visits to a therapist are necessary. Therefore, we plan to conduct a multicentre randomised controlled trial to examine whether the effectiveness of online hypnotherapy is non-inferior compared to individual face-to-face hypnotherapy delivered by a therapist, according to current FDA guidelines. Online psychoeducation will be used as control condition. In addition, we hypothesize that treatment with online hypnotherapy is a more cost-effective therapy than face-to-face hypnotherapy in IBS patients. and more cost saving.

Study objective

Primary objective:
To compare the efficacy of online hypnotherapy versus face-to-face according to a non-inferiority design for the treatment of IBS.
Hypothesis: Hypnotherapy delivered in the form of online exercises has non-inferior efficacy to face-to-face hypnotherapy delivered by a

hypnotherapist for the treatment of IBS.

Secondary objectives:
1. To compare the efficacy of hypnotherapy vs. online psychoeducation
2. To evaluate the cost-effectiveness of face-to-face hypnotherapy as compared to online exercises of hypnotherapy
3. To evaluate the effect of treatment after discontinuation
4. To evaluate the effect of treatment on quality of life
5. To evaluate the use of OTC and rescue medication
6. To evaluate the adherence to therapy
7. To evaluate the response rates in relation to patient expectation prior to the start of treatment
8. To evaluate the response rates in relation to comorbid anxiety and/or depression

Study design

A randomised controlled clinical trial with three parallel study arms (online psychoeducation, face-to-face hypnotherapy and online hypnotherapy) for 12 weeks with a follow up of 1 year.

Intervention

Group 1 will receive 12 weeks treatment with online psychoeducation, group 2 will receive 12 weeks treatment with individual face-to-face hypnotherapy (6 individual, bi-weekly sessions), group 3 will receive 12 weeks treatment with online hypnotherapy.

Study burden and risks

Subjects may be confronted with certain inconveniences. There are three (digital) visits (screening visit, randomisation visit and post-treatment visit). The screening will take up to 1 hour, including different questionnaires and a pregnancy test for women of fertile age. During the run-in period patients are asked to report their daily symptom scores with the use of an electronic diary (mobile phone application), this takes approximately 30 seconds each day. A similar smartphone application has previously been developed for IBS trials by investigators from the study group (PERSUADE study, NL 56000.068.16 / METC 162009), completion of the questionnaire does not result in substantial interference with everyday life. During the treatment period, participants are asked to report daily symptom scores using the same mobile phone application as during the run-in period, and complete three questionnaires electronically each week. Participants in the online psychoeducation group will be requested to use the online instrument for 15-30 minutes per day for 5 days a week. Participants randomized to face-to-face hypnotherapy will receive treatment that is delivered in a series of 6,

bi-weekly 45-minute sessions in which patients receive protocol-based structured hypnotherapy. In addition, these participants are asked to exercise at home, for 15-30 minutes per day for 5 days a week, using a CD or other electronic data storage equipment provided by their therapist. Participants in the online hypnotherapy group will be requested to do home-work exercises using the online instrument for 15-30 minutes per day for 5 days a week.
During the post-treatment measurement and follow-up participants several questionnaires have to be completed at several time-points. In total, to complete all the questionnaires during the study period take several hours.
Participants in each group may experience relief of IBS symptoms. We don*t expect any side effects. Side effects of hypnotherapy can occur in participants with any psychiatric condition, we will screen for anxiety and depression with the GAD-7 and PHQ-9 questionnaires during the screening visit, subjects which scores corresponds with moderate anxiety and depression are excluded from the study.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 16-75 years
- A diagnosis of IBS according to the Rome IV criteria
- In the presence of alarm symptoms, such as rectal blood loss, weight loss, anemia, first onset of symptoms above 50 years of age, patients will be first referred for further investigation by their treating physician to exclude organic disorders, conform current Dutch guidelines for IBS.(15)
- Women in fertile age must use contraception or be postmenopausal for at least two years.

Exclusion criteria

- Insufficient command of the Dutch language
- No access to internet
- Evidence of current anxiety and/or depression disorder as defined by a score >=10 on the GAD-7 and/or PHQ-9 questionnaire, supported by a detailed interview by the investigator. In this case it is conceivable that the IBS symptoms are strongly related to psychopathology for which different treatment might be more appropriate.
- History of ulcerative colitis, Crohn*s disease, coeliac disease or significant liver disease
- Major surgery to the lower gastrointestinal tract, such as partial or total colectomy, small bowel resection or partial or total gastrectomy
- Past or present radiotherapy to the abdomen
- Current pregnancy or lactation
- Using of psychoactive medication in case there*s no stable dose for at least 3 months prior to inclusion
- Use of over-the-counter or prescription antidiarrheals, analgesics and laxatives in case there*s no stable dose during the study period
- Hypnotherapy treatment received in the last 3 months prior to inclusion
- Using more than 20 units of alcohol per week
- Using drugs of abuse

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-07-2019
Enrollment:	282
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-09-2019
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-03-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-01-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	clinicaltrials.gov registratie under review
CCMO	NL67607.068.18