

Stimulating self-management in irritable bowel syndrome through web-based interactive technology

Submission date 27/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/10/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

NL954 (NTR980)

Study information

Scientific Title

Stimulating self-management in irritable bowel syndrome through web-based interactive technology

Acronym

PDS self-management

Study objectives

Immediate, situational feedback is more effective than standard care alone, which, according to the Dutch Irritable Bowel Syndrome (IBS) Guideline of General Practice (Dutch College of General Practitioners [NHG], 2001), includes education, dietary advice and reassurance about the benign course of the disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee (Medisch Ethische Toetsingscommissie Academisch Ziekenhuis Maastricht) on the 21st December 2005 (ref: MEC 05-085).

Study design

Randomised, active controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Self-management of irritable bowel syndrome

Interventions

Standard care (control condition) and four daily electronic diaries during five weeks following ABA design (experimental condition):

1. One week baseline
2. A psychologist on four daily diaries
3. One week follow-up

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

IBS-severity, measured by:

1. IBS Rome III criteria list

2. Abdominal pain
3. Secondary gastrointestinal complaints (diarrhoea, constipation, flatulence, belching, abdominal rumbling and distension)

All administered at baseline and at 12 weeks; all except (1), which is also measured at five weeks.

Key secondary outcome(s)

1. Quality of life (IBS Quality of Life)
2. Daily functioning (12-item Short Form health survey [SF-12])
3. Cognitions (Cognitive Scale - Functional Bowel Disorders)
4. Pain attributes (Pain Cognition Scale)

All administered at baseline (0 weeks), 5 weeks, and 12 weeks.

Completion date

01/05/2008

Eligibility

Key inclusion criteria

1. IBS for at least three months
2. Age between 18 and 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Sufficient command of Dutch language
2. No visual handicap
3. Concomitant or previous psychotherapeutic treatment

Date of first enrolment

01/11/2006

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Netherlands Institute for Health Services Research (NIVEL)

Utrecht

Netherlands

3500 BN

Sponsor information

Organisation

Netherlands Institute for Health Services Research (NIVEL) (The Netherlands)

ROR

<https://ror.org/015xq7480>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Digestive Diseases Foundation (Maag-Lever en Darm Stichting) (MLDS) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration