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

Submission date 27/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/06/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/10/2021	**Condition category** Digestive System	[_] Individual participant data [_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/11/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
60

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
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3500 BN

Sponsor information

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

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Sponsor type
Research organisation

Website
http://www.nivel.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration