The Experience Sampling Method (ESM): Validation of a newly developed real-time Patient-Reported Outcome Measure (PROM) and its Evaluation of triggers for Chronic Abdominal Pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON42980

Source
ToetsingOnline

Brief title
ESM in IBS

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Grunenthal

Intervention

Keyword: Abdominal pain, Experience Sampling Method, Irritable Bowel Syndrome

Outcome measures

Primary outcome

The main study outcome comprehends the psychometric properties (i.e. content validity, cross-cultural adaptation, concurrent validity, internal consistency and test-retest reliability) of the PROM for symptom assessment of abdominal pain.

Secondary outcome

Secondary outcomes are associations between the presence of psychosocial and environmental factors (e.g. as measured by the PROM) and an increase in ESM score for gastrointestinal symptoms from one time point (t-1) to the next (t).

Study description

Background summary

Reliable patient reported outcome measures (PROM*s) for symptom assessment in irritable bowel syndrome are essential in order to investigate natural disease course and potential treatment options aimed at symptom improvement, since biological markers are currently unavailable. Currently used symptom assessment methods, i.e. end-of-day or end-of-week questionnaires, have considerable limitations. The Experience Sampling Method (ESM), an electronic questioning method characterised by random and repeated, momentary assessments in the subject*s current state and environment, might overcome these limitations.

Study objective

The aim of this study is to validate an IBS-specific electronic patient-reported outcome measure, based on the Experience Sampling Method-principle, for symptom assessment in IBS. The objectives, therefore, are to establish the validity and reliability, i.e. psychometric properties, of the developed PROM for the assessment of abdominal pain and other gastrointestinal symptoms, i.e. bloating, flatulence, abdominal rumbling, in IBS patients. An additional objective is to determine specific triggers for the onset of abdominal complaints in irritable bowel syndrome, using the IBS specific ESM tool.

Study design

This is a multicenter, prospective, cross-sectional study, in which five secondary and tertiary referral centers for gastrointestinal diseases are participating.

Study burden and risks

The burden that is associated with participation in this study comprises completing the PROM questionnaire several times a day, which interrupts daily life due to its random character. Furthermore, the burden is limited to completing an end-of-day symptom diary and end-of-week questionnaires. However, participating does not bring along important risks. No direct benefits are expected, since the study does not contain any interventions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of IBS according to Rome IV criteria, age 18-70, ability to understand and speak the concerning language, ability to understand how to use the ESM.

Exclusion criteria

Any organic explanation for the abdominal complaints, a history of abdominal surgery (except for uncomplicated appendectomy, laparoscopic cholecystectomy and hysterectomy), start up of regularly used medication from one month before inclusion until the end of study participation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	24-03-2017
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2016
Application type:	First submission
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
ClinicalTrials.gov	NCTnotyetassigned
CCMO	NL57473.068.16

Study results

Date completed:	01-11-2018
Actual enrolment:	73