*A personalized lifestyle approach for abdominal pain in Irritable Bowel Syndrome and inflammatory bowel disease: a proof of concept study using Experience Sampling Method (ESM) and a digital food diary (Traqq).'

Published: 17-02-2023
Last updated: 07-04-2024

Apart from its use to provide insight in IBS disease courses and in clinical research, ESM can provide patients with feedback about individual triggers of their symptoms, and thereby function as part of a personalized therapeutic strategy. This is...

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

Summary

ID

NL-OMON53914

Source
ToetsingOnline

Brief title
A personalized lifestyle approach in Irritable Bowel Syndrome.

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable Bowel Syndrome, spastic colon

Research involving

Human

Sponsors and support

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

Intervention

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

Outcome measures

Primary outcome

Primary aim: To study whether insight into personal symptom dynamics and triggers via the ESM tool and Traqq will improve treatment outcomes of any chosen treatment for abdominal pain in patients with IBS and IBD-IBS, as measured by the IBS-SSS over a 12-week time period.

Primary hypothesis: We hypothesize that the IBS-SSS score will decrease at 12 weeks compared to baseline measurement in both treatment arms (standard care and ESM/Traqq) due to regular patient education and provided treatment in daily care, but that the decrease in IBS-SSS score in the ESM/Traqq arm will be greater as compared to standard care in both the IBS and IBD-IBS patients. We compare the difference in IBS-SSS score from baseline in the intervention group with the difference in IBS-SSS score from baseline in the control group. We expect a difference in the IBS-SSS score to be clinically higher, defined as >=50 points difference in IBS-SSS score, in the ESM/Traqq group compared to the standard care group for both IBS and IBD-IBS patients.

Secondary outcome

Secondary aims: To explore whether the following parameters will improve more in the ESM/Traqq group compared to the standard care group, as measured at baseline and at 12 weeks after baseline:

- Quality-of-life (QoL) as measured by EQ-5D-5L
- Overall anxiety, as measured by GAD-7
- GI related anxiety as measured by VSI
- Depressive symptoms as measured by PHQ-9
- Fatigue as measured by MFI-20

Furthermore, both patient groups, i.e. IBS and IBD-IBS, will complete the diagnostic Rome IV criteria for IBS at baseline (as an inclusion criterion) and after 12 weeks. Next to that, as there is a strong overlap between IBS and functional dyspepsia, also the Rome IV criteria for functional dyspepsia will be completed at baseline and after 12 weeks.

At last, to explore whether the information out of the ESM and Traqq applications is useful in the shared decision making for an optimal intervention for the patient.

Secondary hypothesis: We hypothesize that the QoL, general and GI related anxiety, depressive symptoms, overall GI symptoms, and fatigue will improve significantly after symptom dynamics and triggers are more understood and recognized by the patients in the ESM/Traqq group, when compared to the standard care groups, at 12 weeks after baseline. We expect that the

information gained out of the ESM and Traqq applications can help in making the

right choice for a treatment that fits the patients* needs better than in

regular care.

Study description

Background summary

Visceral sensation, including visceral pain is a crucial feedback mechanism, signaling the body to act on potential harm in internal organs. During intestinal inflammation, e.g. due to infections or immune mediated conditions, abdominal pain has potential physiological benefits, following the same reasoning. However, when abdominal pain persists even after the gastrointestinal (GI) infection is cleared or the immune mediated inflammation has attenuated, it hampers patients to resume and participate in daily life activities. This is seen in Irritable Bowel Syndrome (IBS), which may develop secondary to a GI infection, or in Inflammatory Bowel Disease (IBD; Crohn*s disease and Ulcerative Colitis), which are immune mediated inflammatory intestinal diseases. There is similarity between abdominal pain and other GI symptoms experienced by patients with IBS and patients with IBD who are in remission (i.e. in absence of active intestinal inflammation). Therefore, in IBD these chronic GI symptoms may be referred to as IBS in IBD (from now on referred to as IBD-IBS) and are currently treated using the same approaches as IBS. Why some people develop IBS after a GI infection and others don*t, or why some remissive IBD patients develop chronic abdominal pain even when endoscopic remission is reached, is unknown, but disturbances along the gut-brain axis are assumed to play a key role in both disorders. When the affected subjects understand the origin of the symptoms, know its dynamics and triggers, coping improves, GI related anxiety is reduced, and the symptoms become less bothersome in daily life. Therefore, the cornerstone of any treatment of chronic intermitted abdominal pain in IBS and IBD-IBS is patient education, and thereafter selecting a personalized treatment approach that matches the patients* needs and expectations in a process of shared decision making. However, in both IBS and IBD-IBS, physicians struggle with finding the right approach to chronic intermitted abdominal pain, leading to doctor-patient perception gaps. This can partly be explained by the complexity of this symptom and its origin. The type, intensity, localization, duration, evolution, and progression of abdominal pain vary greatly between patients. Different factors may trigger or modulate abdominal pain, such as diet, acute or chronic stress, and feelings of anxiety, worry or depression. This makes the group of people with abdominal pain both in IBS and in IBD-IBS heterogeneous, and inevitably unsuitable for a *one size fits all* approach.

The current study is developed to investigate whether two previously validated digital applications can be used to aid in this process, to unravel the dynamics of abdominal pain and potential triggers in individual patients, to assess the interactions with associated GI symptoms, psychological factors, and diet. The personalized analysis of abdominal pain, associated factors and its triggers can then be used to provide insight into the symptom dynamics for the patient and the treating physician which may aid the selection of the best treatment approach for the specific patient. To measure differences in abdominal pain severity at baseline and at the end of the study, the irritable bowel syndrome symptom severity score (IBS-SSS) is used, since this is the broadest measurement of pain-related aspects among validated questionnaires.

Irritable Bowel Syndrome (IBS)
IBS is a disorder of gut-brain interaction, characterized by chronic recurrent abdominal pain, associated with altered bowel habits (i.e. diarrhoea, constipation or a combination of both), in the absence of an explanatory organic cause. In the Western countries it affects up to 10% of the general population, with a female predominance. To aid diagnosis and allow international comparisons, several international consensus meetings have culminated in the production of the Rome IV diagnostic criteria for IBS. Assessment of symptoms is not only relevant with regards to confirming the diagnosis, but also to the evaluation of the natural disease course over time and to follow treatment efficacy. This assessment is generally based on symptom questionnaires; current guidelines on IBS clinical trials from the regulatory authorities suggest the use of retrospective end-of-day diaries. Currently used assessment methods to evaluate natural disease course over time and follow-up of treatment are mainly retrospective, self-reported questionnaires, based on daily or weekly monitoring. However, those have important limitations. The documentation of patients* past symptoms can be evidently distorted due to recall bias, environment and psychological status, and lack of compliance when done retrospectively, resulting in inaccurate representations of symptom patterns. Due to the lack of any identifiable biological marker, symptom monitoring is cardinal in this patient population as it is the only clinical read-out available for assessing IBS treatment efficacy.

Chronic abdominal symptoms in Inflammatory Bowel Disease (IBD) in remission
The aetiology and evolution of chronic abdominal pain in IBD-IBS are poorly understood, and treatment is often unsatisfactory. There is a paucity of robust evidence on the safety and efficacy of potential interventions for the management of abdominal pain. However, gut-directed psychological therapy and dietary intervention have proven to be promising approaches.
Although recently the main focus in management of IBD was treatment of intestinal inflammation, the quality of life of these patients is affected by several other factors, including chronic abdominal pain, present even when inflammatory remission is achieved, as well as psychosocial wellbeing. In general, the medical perspective is slowly changing and it becomes more important to treat the persistent symptoms after remission is achieved in

general practice.
However, despite the changing perspective in the medical field on the treatment of chronic abdominal pain or IBS-like symptoms in IBD-IBS, the treatment options are limited. A personalized approach for the treatment of these symptoms is needed, but currently lacking in daily clinical practice. A better understanding of the interaction between abdominal pain and psychological, lifestyle and environmental factors is needed to pave the way for personalized approaches.

Experience Sampling Method (ESM)
Experience Sampling Method (ESM), also referred to as Ecological Momentary Assessment (EMA), a symptom assessment method widely used in the field of psychology, but minimally implemented in somatic fields, may overcome these limitations. ESM is an electronic questioning method characterized by repeated, momentary assessments in the subject*s current state and environment. Measurements take place at random moments during regular daily life, for several consecutive days. ESM assessments are completed using a digital device, which emits an auditory signal every time the subject is supposed to complete an assessment. Subjects are allowed only a short time after the auditory signal to respond to the questions and questions always relate to current symptoms. In a study by Vork et al the scores of the developed ESM-based Patient Reported Outcome Measure (PROM) were significantly lower than the end-of-day scores. The difference between the ESM and end-of-week scores was even more pronounced. Furthermore, patients reported less GI related anxiety with ESM compared with the Visceral Sensitivity Index. This further supports the notion that it there is a difference in measuring symptoms of IBS patients during the day compared to at the end of the day, because of the misperception patients have about their complaints and trigger factors. The study showed a good validity and reliability of the developed ESM-based PROM for measuring GI symptoms in an IBS population. The ESM-based PROM has the advantage of a more detailed view on individual symptom patterns, with the option to analyse symptom-symptom and symptom-environment interaction. This can be useful for giving patients more insight in their symptoms and the relation with environmental factors, like stress or diet.

Smartphone-based dietary assessment tool (Traqq)
As said before, nutritional factors can be related to abdominal pain in IBS or IBD-IBS patients. In a study by Lucassen et al a smartphone-based dietary assessment tool (Traqq) was developed and validated. The application can be used to record food and drinks during the day. The data is stored on a secure server. It can be used to collect detailed information about the macro- and micronutrients the patient has eaten. This tool can be perfectly used to get more insight in the patients eating pattern to see whether food is a trigger factor for their symptoms.

Study objective

Apart from its use to provide insight in IBS disease courses and in clinical research, ESM can provide patients with feedback about individual triggers of their symptoms, and thereby function as part of a personalized therapeutic strategy. This is also true for IBD-IBS. Treatment strategies in IBS and IBD-IBS are largely based on reassurance, identification and elimination of triggering factors, and in more severe cases pharmaco- and psychotherapy. The ESM approach has the potential to increase therapeutic efficacy in IBS and will assist patients in disease self-management. The Traqq application can provide more detailed information about the dietary pattern of IBS patients. Traqq in combination with ESM will give an overview of abdominal pain and associated symptoms and psychosocial factors are exposed to during the day. The insight provided using ESM and Traqq may improve patient understanding of their personal symptom dynamics and triggers, as well as the physician*s insight into the symptom patters of the specific patients, which may aid treatment choice and eventually improve the outcome of any treatment provided in daily clinical care.

Study design

This is an unicenter, prospective, proof-of-concept randomized controlled, non-blinded intervention study that focuses on two patient populations, with overlapping symptom patterns and treatment approaches, i.e. patients with IBS and IBD-IBS.

Recruitment procedures are described in paragraph 8.2. Following written informed consent, the eligibility screening is performed and instructions about the study procedures will be given. Hereafter, both groups will independently be randomized into i) an ESM/Traqq arm or ii) a standard care arm. The intervention group and the control group will complete the IBS-SSS, EQ-5D-5L, GAD-7, PHQ-9, VSI, and MFI-20 as well as the Rome IV criteria for IBS and functional dyspepsia at baseline and the intervention group will complete thereafter the ESM and Traqq applications during the first week. After this week, the data will be analysed to identify associations between abdominal pain and psychosocial factors, diet or other GI associated symptoms. The coordinating investigator will contact the participants of the intervention group and will ask how they experienced the ESM/Traqq method and whether they think this helped them to get more insight about the association between abdominal pain and the trigger factors.
About two weeks later, participants will have their second visitation at the outpatient clinic with their treating physician. In the intervention group, but not the control group, the patient and the treating physician will receive the results of the personal data of the patients based on ESM and Traqq. The insight participants and their physicians get from this information, will help them to make changes in lifestyle factors that affect their symptoms or to choose a pharmacological or non-pharmacological treatment. However, the study protocol will not indicate which treatment choice should be made by the patient and their treating physicians. That choice will still be based on shared

decision making, just as in the standard care arm, only with the additional data provided.
Furthermore, if the patients are referred to a dietician, psychologist, or both, the digital data obtained in the intervention group can be used to personalize the therapy. After giving informed consent by the participant for the data of ESM and Traqq being sent to the dietician or psychologist they are referred to, the coordinating investigator will send the data digitally to the dietician or psychologist that is needed for the personalized treatment (see E1-E2_Informatiebrief en toestemmingsformulier_Versie 1.0 _22.09.2022).
Participants in the control arm will get a consultation with the gastroenterologist as usual after the same period of time as the intervention group get their consultation. The participants of the control group will be given treatment advice only based on this consultation, the PDSkeuzehulp by shared decision making, according to standard care.
Twelve weeks after the second outpatient visit, independently of the chosen treatment approach, the participants in both study groups will be asked to complete IBS-SSS, EQ-5D-5L, GAD-7, PHQ-9, VSI, MFI-20 and Rome IV criteria for IBS and functional dyspepsia for the second time to evaluate whether there is an effect on 1) reduction of abdominal pain and 2) quality of life, psychological aspects or fatigue of the participants due to the insight provided by ESM and Traqq.
After those twelve weeks, the coordinating investigator will contact the participants of the intervention group and control group by phone for the last time. Participants are asked what treatment they have gotten and what lifestyle modifications they have done to reduce abdominal pain.
To improve compliance for completing the questionnaires by the control group, the participants in the control group will get the opportunity to use the ESM and Traqq applications after the study has been completed. This will not be part of this study but can be beneficial for those individuals who have not got any additional insight about their symptoms by getting the standard care.

Study burden and risks

Participating in this study does not bring along important risks, since subjects only have to complete questionnaires and there are no investigational products involved. Therefore, this is a low-risk study. However, completing the PROM several times a day might be quite burdensome and time-consuming for participants and will intervene with regular daily life. Completing the PROM questionnaires at baseline and at the end of the study will take approximately 10 minutes. For the intervention group, completing the ESM and Traqq applications will take approximately one hour per day. Furthermore, since data are transferred via Internet and partly stored at a participant*s smartphone, there is a need for securing on an individual*s privacy. This is described into more detail in section 9.1 *Handling and storage of data and documents*. The advice for lifestyle modifications, psychological treatments or other treatments are not different from the treatments used in standard care. The only difference is that the treatment chosen would fit the individual better,

because by using ESM/Traqq a detailed analysis is made of the individual triggers. A better, more accurate treatment plan can be made by the general practitioner, but this only contains the currently available treatments. Therefore, there will not be any additional risks according these treatments when participating in this study compared to the standard care.

During the study period, subjects could directly benefit from participation since they receive a personalized intervention strategy. It is possible that completing the ESM questionnaires and food diary makes subjects more aware of their symptom patterns and possible provoking factors in daily life, which might be beneficial. Moreover, a personalized intervention strategy can treat specific trigger factors in daily life of a particular individual. These trigger factors will not be the same for every individual. Therefore, the beneficial effect of the use of this ESM/Traqq method will be that beside of standard diagnostics and therapeutic aims, a more personalized manner is used to relate individual trigger factors to IBS symptoms.

All in all, the risks in this study are not disproportional in association with the benefits. Participants will be informed about the burdens before participating. Participants in the control group will be informed at start of the study about the opportunity to use the ESM and Traqq application afterwards to see if any improvements can be made regarding their symptoms and trigger factors. This will not be part of this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria IBS patients
• A diagnosis of IBS according to Rome IV criteria, as follows:
o Recurrent abdominal pain, on average, at least 1 day per week in the last 3 months, associated with 2 or more of the following criteria:
* Related to defecation;
* Associated with a change in stool frequency;
* Associated with a change in stool form (appearance).
o Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.
• Age between 18 and 70 years;
• Ability to understand and speak the Dutch language
• Ability to understand how to utilize the ESM and Traqq applications.

Inclusion criteria IBD patients
• Patients with IBD diagnosed in accordance with current ECCO guidelines, with IBD- IBS and with chronic abdominal pain, as follows:
o MIAH score <3
o Fecal calprotectin < 150 ug/g
o Fulfilling the Rome IV criteria for IBS.
• Age between 18 and 70 years;
• Ability to understand and speak the Dutch language
• Ability to understand how to utilize the ESM and Traqq applications.

Exclusion criteria

Exclusion criteria IBS patients
• Any organic explanation for the abdominal symptoms;
• A history of abdominal surgery, except for uncomplicated appendectomy, laparoscopic cholecystectomy and hysterectomy is present;
• Pregnant or lactating at the baseline visit.

Exclusion criteria IBD patients

• Uncertainty about the absence of active inflammation
• Uncertainty about other explanatory causes for the GI symptoms, such as bile acid malabsorption, intestinal stenosis, or small intestinal bacterial overgrowth.
• Pregnant or lactating at the baseline visit.

Patients with a clinical relevant depression or anxiety disorder will not be excluded from participation in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2023
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Date:	17-02-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-01-2024

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
CCMO	NL82286.068.22