ISRCTN17004079 https://doi.org/10.1186/ISRCTN17004079

Investigating pelvic floor training as a treatment for severe bloating in gastrointestinal disorders

Submission date
30/12/2020

Recruitment status
No longer recruiting

Registration date
08/01/2021

Overall study status
Completed

Last Edited
21/09/2021

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The cause of bloating, one of the most common and bothersome complaints in patients with functional gastrointestinal disorders (FGIDs), is complicated and partially understood.

The aim of this study is to investigate, in patients with severe bloating, the relationship between the defecation pattern, the severity of bloating, and the abdominal size changes, and the effectiveness of biofeedback treatment on bloating. Biofeedback training involves using electrical sensors to train

Who can participate?
Patients with FGIDs reporting bloating as their main complaint.

What does the study involve?
Participants will undergo a measurement of abdominal size (girth) using a belt around the abdomen. Participants will also be provided with dietary management with NICE advice with the addition of a lactose-free diet for two weeks. Over the two week period, participants will be asked complete a daily diary to assess their bowel function and to record girth at fasting (before eating) and two hours after lunch.

After two weeks of following diet changes, participants will be asked to fill in a questionnaire on the improvement of their bloating and abdominal girth measurements two hours after a meal.

Patients who do not report fair or major improvement at two weeks will undergo a standardized test. This will be the balloon expulsion test (BET) which uses a balloon to simulate a bowel movement and is scored as successful if the balloon is evacuated within two minutes.

Furthermore, participants will be invited to take part in biofeedback training provided at single center located in Verona, Northern Italy. This training has been previously validated for constipation due to dyssynergic defecation (DD) and will be provided by a registered nurse. The aim of this training is to improve the effort used during defecation with the purpose of relieving

bloating. To confirm the diagnosis of outlet dysfunction, all the subjects allocated to biofeedback training will undergo an evaluation of pelvic floor muscle function on straining using electromyography (EMG) testing. EMG testing uses electrodes to stimulate the pelvic muscle to measure electrical activity.

Clinical visits will occur 1, 3, and 6 months after treatment. During these visits, patients will be required to answer the questionnaires on their bloating that were completed after two weeks, and undergo physiological testing (BET and EMG evaluation).

What are the possible benefits and risks of participating?
There is a possible beneficial effect of biofeedback training on bloating. There are no anticipated risks for taking part in this study.

Where is the study run from?
University of Salerno (Italy)

When is the study starting and how long is it expected to run for?
From December 2015 to June 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Paola Iovino
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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
Studio FgiD

Study information

Scientific Title
Investigating pelvic floor biofeedback as a treatment for severe bloating in functional gastrointestinal disorders with outlet dysfunction

Study objectives
1. Bloating and abdominal distension could be secondary to impaired gas or non-gas emptying possibly due to disordered defecation
2. Pelvic floor biofeedback is an effective treatment for severe bloating in functional gastrointestinal disorders with outlet dysfunction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2013, revision approved 13/06/2019, Ethical Commitee-Azienda Sanitaria Locale Napoli 3 Sud (Via Marconi 66, Torre del Greco, Napoli, 80049, Italy), ref: n°3/2013, revised approval ref: 0089264

Study design
Multicenter observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Bloating treatment in functional gastrointestinal disorders

Interventions
All patients are screened for the severity of bloating that is their main complaint and diagnosed according to Rome III criteria for FGIDs. If the bloating is > 24 mm on 0-100 mm-VAS scale they undergo a girth measurement abdominal girth measured by a belt around the abdomen at standardized sites and start 2 weeks of dietary management with NICE advice with the addition of lactose-free diet and complete a daily diary to assess bowel function as well as record girth measurements at fasting and 2 hours after lunch.

After two weeks at the first visit, participants will be asked to fill in a questionnaire on the subjective improvement of bloating on a 5-point Likert scale (worse to major improvement), a further assessment of abdominal bloating (using a 0-100 visual analogue scale), and abdominal girth measurements 2 h after a meal. Patients who did not report fair or major improvement /cure will undergo a standardized balloon expulsion test (BET) which will be scored as either successful or failed if the balloon could not be evacuated within 2 min. Furthermore, they will invited to take part in a biofeedback protocol to improve the defecation effort with the purpose of ameliorating bloating that was provided at single center located in Verona, Northern Italy. To confirm the diagnosis of outlet dysfunction, all the subjects allocated to biofeedback will undergo a basal evaluation of pelvic floor muscle function on straining by pelvic floor electromyography (EMG) testing according to a previously described protocol. A registered nurse provided the BT previously validated for constipation due to dyssynergic defecation (DD). Clinical visits were scheduled at 1, 3, and 6 months post-treatment. During these visits patients will be required to answer a question on subjective perception of symptom improvement on a 5-point Likert scale (worse, no improvement, mild, fair, and major improvement/cure), will be assessed for bloating on the (0-100) VAS, and undergo physiological testing (BET and EMG evaluation).

Intervention Type
Behavioural

Primary outcome measure
1. Response to diet intervention or pelvic floor biofeedback treatment (BT) measured using patient response to the question: “Compared to the interval preceding the treatment (diet intervention or biofeedback) how would you score your bloating improvement: worse (0), no improvement (1), mild (2), fair (3), or major improvement/cure (4)?", where all patients reporting fair or major improvement/cure will be considered as responding, measured at 2 weeks , and 1, 3, and 6 months after BT

Secondary outcome measures
1. Effect of diet intervention on bloating severity measured using a 0-100 visual analogue scale (VAS), and abdominal girth (using a belt around the abdomen at standardized sites) at baseline and 2 weeks
2. Effect of diet intervention and pelvic floor biofeedback treatment (BT) on quality of life changes measured using the Short Form 36 (SF36) at 2 weeks and after BT

3. Effect of pelvic floor biofeedback treatment (BT) on bloating severity measured using a 0-100 visual analogue scale (VAS), balloon expulsion test (BET), and electromyography (EMG) testing on straining at 2 weeks (before BT), and then 1, 3, and 6 months after BT

Overall study start date
01/10/2015

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years
2. Able to understand and the willingness to comply with the study procedures
3. Average daily abdominal bloating score ≥24 on a 100-mm VAS with/without visible abdominal distension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180 patients

Total final enrolment
180

Key exclusion criteria
1. Pregnancy
2. Serious, or unstable medical condition
3. Insulin-dependent diabetes mellitus
4. Major psychiatric diagnosis
5. Endocrine diseases
6. History of eating disorders
7. History of drug or alcohol abuse
8. Previous abdominal surgery, except appendectomy or cholecystectomy

Date of first enrolment
01/03/2017

Date of final enrolment

30/06/2018

Locations

Countries of recruitment
Italy

Study participating centre
Gastrointestinal Unit, University Hospital "San Giovanni di Dio e Ruggi D'Aragona"
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/09/2021	21/09/2021	Yes	No