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Multicentre trial of combined cognitive behavioural therapy and antidepressant treatment in functional bowel disorders

Submission date 30/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/01/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/11/2009	**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

Protocol serial number
MCT-63138

Study information

Scientific Title

Cognitive behavioural therapy and antidepressant treatment in functional bowel disorders: a multicentre randomised, parallel, three arm trial studying behavioural and medication impact

Study objectives
Combination therapy (cognitive behavioural therapy [CBT] plus desipramine) is superior to monotherapy (CBT or desipramine) for functional bowel disorders in women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Centre for Addiction and Mental Health Research Ethics Board (CAMH REB), Toronto Academic Health Sciences Council (TAHSC) (Canada) approved on the 7th March 2006

Primary study design
Interventional

Study design
Randomised parallel three arm trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional bowel disorders

Interventions
Group 1: cognitive behaviour therapy (CBT), once a week for 12 weeks
Group 2: desipramine, up to 150 mg/day for 12 weeks
Group 3: combined CBT plus desipramine: CBT once a week and desipramine administered weekly up to 150 mg/day for 12 weeks

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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Desipramine

Primary outcome(s)
Composite measure consisting of:
1. Satisfaction with treatment
2. Global well being
3. Pain ratings
4. Health related quality of life

Points two to four above will be measured at pre-treatment, post-treatment, three month follow up and six month follow up.

Key secondary outcome(s)
Four outcomes of composite measure will be analysed separately as secondary variables:
1. Satisfaction with treatment: post-treatment, three month follow up, six month follow up
2. Global well being: pre-treatment, post-treatment, three month follow up, six month follow up
3. Pain ratings: pre-treatment, end of treatment, three month follow up, six month follow up
4. Health related quality of life: post-treatment, three month follow up, six month follow up

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Literate, female patients aged 18 to 65 years
2. Symptoms present at least two days per week for greater than six months
3. Diagnosis of painful functional bowel disorder (later subcategorised using Rome II Criteria as irritable bowel syndrome [IBS], functional abdominal pain syndrome, painful constipation or unspecified functional bowel disorder [FBD])
4. Moderate (MFBD) or severe (SFBD) functional bowel disorder (FBD) based on the Functional Bowel Disorder Severity Index (FBDSI) that we developed. SFBD is defined as a score more than 110, and MFBD as a score between 36 and 110. Patients with mild symptoms (less than 36) will be excluded, since the proposed treatments would not be cost-effective nor clinically needed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. No evidence for lactose intolerance explaining the symptoms
2. Absence of heart disease, cardiac arrhythmias, glaucoma, urinary retention, pregnancy, alcohol consumption more than 3 oz/day that would preclude participation or prevent data assessment, or systemic or gastrointestinal diseases or previous surgery that would interfere with the interpretation of symptoms or physiology (active thyroid disease, scleroderma, vasculitis, IBD, ischaemic bowel, gastrointestinal bypass or resection, malabsorption syndromes)
3. No history of bipolar disorder requiring hospitalisation, schizophrenia, substance abuse /dependency, or suicide attempts. Other psychiatric disorders may be excluded if they preclude successful participation in the study.
4. Ability and willingness to discontinue anticholinergic medication, calcium channel blockers or 5-hydroxytryptamine (5HT) receptor acting agents for the duration of the study
5. Discontinuance of all antidepressant medications for at least one month
6. Patients who have previously used Desipramine for more than one week
7. Use of an acceptable method of birth control (birth control pill, condoms, foam and barrier, intrauterine device [IUD], sterilisation) throughout the study (if receiving anti- depressant treatment)

Date of first enrolment
01/05/2006

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Canada

Study participating centre
Social Equity & Health Research
Toronto, Ontario
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Sponsor information

Organisation
The Centre for Addiction and Mental Health (Centre de toxicomanie et de santé mentale) (Canada)

ROR
https://ror.org/03e71c577

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63138)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes