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

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| **Submission date**<br>30/01/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/01/2007 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>17/11/2009 | **Condition category**<br>Digestive System | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Brenda B Toner

**Contact details**
Social Equity & Health Research
Centre for Addiction & Mental Health
455 Spadina Ave, Suite 300
Toronto, Ontario
Canada
M5S 2G8
+1 416 535 8501 ext. 7607
brenda_toner@camh.net

## 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

## Study design
Randomised parallel three arm trial

## Primary study design
Interventional

## 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

Contact for public queries:
Adrienne Amato
Research Co-ordinator
Social Equity & Health Research
Centre for Addiction & Mental Health
455 Spadina Ave, Suite 300
Toronto, Ontario M5S 2G8
Canada
Tel: +1 416 979 4296
Fax: +1 416 979 6811
Email: adrienne_amato@camh.net

## 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
Canada
M5S 2G8

## 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 |