

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

Submission date 30/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Can be found at: http://www.camh.net/Research/Studies_and_recruitment/functional_bowel_study.html

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:

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Research Co-ordinator

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Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Desipramine

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/05/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

200

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)

Sponsor details

33 Russell Street

Toronto

Ontario

Canada

M5S 2S1

Sponsor type

Hospital/treatment centre

Website

<http://www.camh.net/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration