

Psychoeducation versus cognitive-behavioral therapy in bipolar disorder

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/04/2008	Condition category Mental and Behavioural Disorders	<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
Dr Sagar V. Parikh

Contact details
Toronto Western Hospital
Toronto
Canada
M5T 2S8
+1 416-603-5734
sagar_parikh@camh.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-55404

Study information

Scientific Title

Study objectives

To compare the impact of cognitive-behavioral therapy to that of properly structured psycho education on the illness burden and functional outcome of bipolar disorder, in combination with pharmacotherapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Centre for Addiction and Mental Health Research Ethics Board, Toronto, ON, July 9, 2001

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Bipolar Disorder

Interventions

Control group: 6 sessions of group psycho-education (topics include illness recognition, treatment approaches, and monitoring and coping strategies; based on manual by Bauer & McBride, 2002: Life Goals Phase I)

Experimental group: 20 sessions of individual Cognitive Behavioural Therapy for Bipolar Disorder (topics include limited psychoeducation, activity scheduling/behavioural interventions, cognitive techniques, including thought monitoring and challenges to dysfunctional assumptions and other coping techniques; based on manual by Lam et al., 1999: Cognitive Therapy for Bipolar Disorder)

Trial details received: 12 Sept 2005

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Mania and depression

Secondary outcome measures

1. Health care utilization
2. Social and occupational functioning scales
3. Quality of life

Overall study start date

01/04/2002

Completion date

31/03/2005

Eligibility**Key inclusion criteria**

1. Bipolar I and II
2. Currently either in remission or subsyndromally ill (Ham-D-29 <14; CARS-M <12)
3. Age ≥18, either sex
4. Significant symptoms and/or episodes on at least 2 occasions in the past 3 years
5. Grade 6 education able to understand English, and Folstein Minimental Score Exam >26 to ensure cognitive ability to participate
6. On mood-stabilizing medication.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

210

Key exclusion criteria

1. Substance dependence meeting DSM-IV criteria within the last 3 months
2. Acutely high suicidal or homicidal
3. Serious other medical conditions that would render pharmacotherapy or psychotherapy very difficult i.e. cancer, severe diabetes etc.
4. Severe antisocial or borderline personality disorder

Date of first enrolment

01/04/2002

Date of final enrolment

31/03/2005

Locations

Countries of recruitment

Canada

Study participating centre

Toronto Western Hospital

Toronto

Canada

M5T 2S8

Sponsor information

Organisation

University of Toronto (Canada)

Sponsor details

27 King's College Circle

Toronto

Canada

M5S 1A1

Sponsor type

Not defined

ROR

<https://ror.org/03dbr7087>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-55404)

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