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Psychoeducation versus cognitive-behavioral therapy in bipolar disorder

Submission date	Recruitment status	[ ] Prospectively registered
26/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2008	Mental and Behavioural Disorders	[ ] 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-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

Study type(s)
Not Specified

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(s)
Mania and depression

Key secondary outcome(s))
1. Health care utilization
2. Social and occupational functioning scales
3. Quality of life

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration