

The feelings club: Evaluating a school-based intervention for children at risk for depression and anxiety disorders

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/07/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00164203

Secondary identifying numbers

MCT-68787

Study information

Scientific Title

Evaluating a school-based intervention for children at risk for depression and anxiety disorders: a randomised controlled trial

Study objectives

Hypothesis 1a: Children in the intervention condition will show greater symptom reduction relative to children in the control condition (primary outcome: anxiety symptoms)

Hypothesis 1b: Children in the intervention condition will show fewer symptoms during follow-up relative to children in the control condition

Hypothesis 2: Children with anxious or depressive symptoms treated in the school setting using CBT have a lower risk of developing internalising disorders within 1 year of treatment than children in a control condition

Hypothesis 3: Self-esteem, anxiety and depression-related impairment, and academic functioning will improve more in intervention participants than in controls

Hypothesis 4: School characteristics, child age, and attitudes of participating personnel are predictive of treatment response

Ethics approval required

Old ethics approval format

Ethics approval(s)

Centre for Addiction and Mental Health Ethics Board approved on the 5th August 2004

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Depression and anxiety in children

Interventions

In partnership with the school system, we will evaluate and disseminate a preventive, cognitive behavioural intervention (CBT) for children at risk for anxiety or depression. Participants will be randomly assigned to either CBT or an after school program of equal duration (control condition). When there are a sufficient number of suitable participants within a school, both CBT and control conditions will be provided in the same school. These children will participate once a week in the 12-session 'Feelings Club' program (Wilansky & Manassis, 2003), administered for one hour immediately after school. There will be 6 to 10 participants in each 'Feelings Club' group. The control group will also be labeled 'Feelings Club', but the content will differ. Instead of learning CBT techniques, these children will participate in a series of enjoyable after-school activities and games once a week for one hour x 12 weeks. There will also be 6 to 10 participants in each of these groups.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Reduction of anxious symptoms. Childrens score on the standardised self-report inventory: MASC. Measured immediately post-intervention and again one year after that (i.e. 15 months after start).

Secondary outcome measures

All are measured immediately post-intervention and again one year after that (i.e. 15 months after start)

1. Reduction of depressive symptoms - will be assessed using CDI
2. The emergence of disorder - will be ascertained using ADIS
3. Self-esteem - will be assessed using Harter Childrens Self-Concept Scales
4. Impairment - will be assessed using the Children Global Assessment Scale
5. Academic functioning - will be assessed using information from the childrens report cards, obtained with parental permission

Overall study start date

01/10/2004

Completion date

30/09/2008

Eligibility

Key inclusion criteria

Screening 'gold standard' self-report inventories include: Multidimensional Anxiety Scale for Children (MASC; March, 1998) and Childrens Depression Inventory (CDI; Kovacs, 1983). Children 5 - 11 years old, either sex, with t-score elevations >60 on either the total score or at least 4 subscales of either instrument will be considered eligible for study.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

140

Key exclusion criteria

1. Already meet criteria for disorder on the ADIS
2. Are unable to complete the inventories due to intellectual impairment or weak English skills (limiting the benefits of cognitive behavioral therapy)
3. Are already engaged in ongoing psychiatric or psychological treatment that could confound study intervention effects
4. Elevated 'externalising' scores on the CBCL (t-score greater than 60), as these children may be difficult to manage in CBT groups, and may obtain more benefit from other interventions

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2008

Locations**Countries of recruitment**

Canada

Study participating centre

Hospital for Sick Children

Toronto

Canada

M5G 1X8

Sponsor information**Organisation**

The Centre for Addiction and Mental Health (Toronto) (Canada)

Sponsor details

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Sponsor type

Research organisation

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-68787)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No