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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

Registration date
09/09/2005

Overall study status
Completed

Last Edited
06/07/2010

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00164203

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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)

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

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