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VP3: Vancouver primary prevention project (anxiety disorders prevention in school children)

Submission date	Recruitment status	[ ] Prospectively registered
24/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/01/2021	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00247754

Secondary identifying numbers
MCT-53658

Study information

Scientific Title
VP3: Vancouver primary prevention project (anxiety disorders prevention in school children)

Acronym
VP3

Study objectives
1. A cognitive behavior therapy (CBT) oriented intervention as delivered by school personnel will be superior to an attention control procedure in reducing anxiety symptoms in at-risk children
2. Children who have parental involvement will post stronger and more enduring treatment gains

Ethics approval required
Old ethics approval format

Ethics approval(s)
Behavioural Research Ethics Board, University of British Columbia, Vancouver, British Columbia, Canada (12 November, 2004).

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
Anxiety disorders

Interventions
Cognitive behavior therapy (CBT) or an attention control procedure (storytelling)

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Anxiety symptoms

Secondary outcome measures
1. Extension to other school systems within BC (outside Vancouver)
2. Modification of protocol to minority populations/foreign language
3. Upward and downward modification (age range) of protocol

Overall study start date
01/04/2002

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Anxiety disorder symptoms (identified by a score of 56 or higher on the Multidimensional Anxiety Scale for Children [MASC]; and teacher report, and/or parent recommendation) as the primary presenting problem
2. Aged 5 - 11 years old, either sex
3. An enrolled child must have at least 2 of these criteria:
a. Fluency in English
b. Parent willingness to sign consent form and to complete required assessments
c. Student willingness to participate (child assent) in 10-week affective education program and completion of required assessments

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
281

Total final enrolment
1039

Key exclusion criteria
1. Any condition which prevents the subject from participating in 10 consecutive weeks of involvement in the group
2. Special education services provided (e.g. substantial learning disabled, enrollment in other special needs program or receiving private therapeutic services)
3. Organic mental disorder or mental retardation
4. Commencement of psychotropic medication within the past 3 months. Currently medicated children will be accepted in to the study providing they (and their treating physicians) agree to keep their doses constant throughout the course of the study.

Date of first enrolment
01/04/2002

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Canada

Study participating centre
University of British Columbia
Vancouver
Canada
V6T 1Z4

Sponsor information

Organisation
University of British Columbia (Canada)

Sponsor details
2075 Wesbrook Mall
Vancouver
Canada
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Sponsor type
Not defined

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-53658)

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	01/01/2014	07/01/2021	Yes	No