

A school-based anxiety prevention program for primary school children in Jerantut, Pahang, Malaysia

Submission date 06/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/05/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/08/2022	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

Background and study aims

The researchers are conducting a study to determine the effectiveness of a school-based anxiety prevention program for primary school children in Jerantut, Pahang, Malaysia. The aim of this study is to find out whether the school-based anxiety prevention program is effective in reducing anxiety symptoms, as well as to improve the participants' worry coping skill and self-esteem.

Who can participate?

Standard 4 and 5 children who are attending selected primary schools in Jerantut, Pahang, Malaysia

What does the study involve?

Participants complete an assessment and are randomly allocated to either the intervention group or the control group. Participants in the intervention group attend four sessions of a school-based anxiety prevention program over 4 weeks. After the participants in the intervention group complete all the sessions, the participants in the control group are offered the same program. Participants in both groups are followed up immediately and three months after the program.

What are the possible benefits and risk of participating?

The possible benefits of participating in the study are the participants will be able to know their current anxiety status and increase their worry coping skill and self-esteem. This possibly may help to reduce the symptoms of anxiety. There are no risks involved in this study.

Where is the study run from?

Primary schools in Jerantut, Pahang, Malaysia in collaboration with Universiti Putra Malaysia

Who is funding the study?

Universiti Putra Malaysia

Who is the main contact?
Prof. Dr Sherina Mohd Sidik

Contact information

Type(s)
Scientific

Contact name
Prof Sherina Mohd Sidik

Contact details
Cancer Resource & Education Centre (CaRE)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial on a school-based anxiety prevention program for primary school children in Jerantut, Pahang, Malaysia

Study objectives
It is hypothesized that the symptoms of anxiety will reduce in the intervention group as compared to the control group. Worry coping skill and self-esteem of the participants are also expected to improve after the intervention. The null hypothesis is there is no significant difference between the intervention and control groups, in terms of reduction of anxiety symptoms and improvement of worry coping skill and self-esteem.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Putra Malaysia, 04/09/2015, ref: UPM/TNCPI/RMC/1.4.18.1 (JKEUPM)/F2

Study design

Parallel two-arm randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Anxiety

Interventions

Current interventions as of 16/01/2019:

The study enrolled twelve primary schools which have not participated in the first phase of this study (An analytical cross-sectional study on associated factors of anxiety among primary school children in Jerantut, Pahang, Malaysia). Method for randomisation is simple randomisation method.

Participants in the intervention group were invited to participate in a 4-weeks school-based anxiety prevention program. The intervention program consists of 4 sessions, with each session implemented on each week.

The control group is a wait-list control group. After the participants in the intervention group completed all the sessions of the school-based anxiety prevention program, the participants in the control group were offered the same program thereafter.

Participants in both groups were followed-up immediately and at three months post intervention.

Previous interventions:

The study enrolled 584 participants who have not participated in the first phase of this study (A cross-sectional study on associated factors of anxiety among primary school children in Jerantut, Pahang, Malaysia). Method for randomisation is simple randomisation method.

Participants in the intervention group were invited to participate in a 4-weeks school-based anxiety prevention program. The intervention program consists of 4 sessions, with each session implemented on each week.

The control group is a wait-list control group. After the participants in the intervention group completed all the sessions of the school-based anxiety prevention program, the participants in the control group were offered the same program thereafter.

Participants in both groups were followed-up immediately and at three months post intervention.

Intervention Type

Behavioural

Primary outcome measure

Anxiety symptoms, measured using the sum score on the short version of Revised Child Anxiety and Depression Scale (RCADS-25) at baseline and follow-up assessments immediately and at three months post intervention

Secondary outcome measures

Worry coping skill and self-esteem, measured using the total score on the Children's Worry Management Scale (CWMS) and the Rosenberg Self-Esteem Scale (RSES) at baseline and follow-up assessments immediately and at three months post intervention

Overall study start date

01/05/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/01/2019:

1. Primary school children who are attending selected primary schools in Jerantut, Pahang, Malaysia
2. Standard 4 and 5 primary school children

Previous inclusion criteria:

1. Primary school children who are attending selected primary schools in Jerantut, Pahang, Malaysia
2. Aged 10-11 years old

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

This study aimed for 12 clusters (mean of participants in each cluster is 55) (6 clusters for intervention and 6 clusters for control group)

Key exclusion criteria

1. Cannot comprehend and write English and Malay language
2. Non Malaysian

Date of first enrolment

06/02/2017

Date of final enrolment

17/07/2017

Locations

Countries of recruitment

Malaysia

Study participating centre

Government Primary School

Jerantut

Pahang

Malaysia

27000

Sponsor information

Organisation

University Putra Malaysia

Sponsor details

c/o Sherina Mohd Sidik

Cancer Resource & Education Centre (CaRE)

Universiti Putra Malaysia

UPM Serdang

Selangor

Malaysia

43400

Sponsor type

University/education

ROR

<https://ror.org/02e91jd64>

Funder(s)

Funder type

University/education

Funder Name

Universiti Putra Malaysia

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a repository. Type of data will be stored is the data gathered from the questionnaire, the process for requesting access is by obtaining permission through email, consent from participants was obtained and ethics approval was obtained from the Ethics Committee for Research involving Human Subjects of Universiti Putra Malaysia (JKEUPM) and Ministry of Education Malaysia.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/01/2019	16/01/2019	No	No
Results article		05/12/2019	16/08/2022	Yes	No