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Psychological flexibility intervention for young people with chronic pain and their parents

Submission date
30/11/2020

Recruitment status
No longer recruiting

Registration date
15/01/2021

Overall study status
Completed

Last Edited
28/09/2021

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study is about individuals and parents with chronic pain. The purpose of this study is to answer whether interventions to increase psychological flexibility (PF) are relevant and potentially beneficial in young people and their parents for the treatment of chronic pain. This research is necessary to improve the understanding of young people and their parents with chronic pain.

Who can participate?
Malaysian young people aged 11 to 18 years with pain for 3 months or longer, and their parents.

What does the study involve?
Participants will be asked to complete a survey which will take about 10 min. Participants (both parents, and young people with pain) will be recruited to join a training program.

Participants will be given a survey form to be answered both before and after the training programme. This form contains 6 sections that will enquire about demographic data, psychological flexibility, responses to child's symptoms, depression, anxiety and stress, functional disability, and child's behavior.

Participation in this study is voluntary and participants may refuse to answer any questions they do not want to answer and may withdraw from it at any time. Refusal to participate or withdrawal will not affect any medical or health benefits to which they are otherwise entitled.

What are the possible benefits and risks of participating?
There may or may not be any benefits to participants. Information obtained from this study will help further research and identify the methods needed for further study, including answering a number of unknowns about the best focus, on parents, young people, or both, on recruitment and retention potential, best mode of treatment delivery, and appropriate measures to use. Participants will not be paid for participating in this study.

All information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study

results, participant identity will not be revealed without expressed consent. Individuals involved in this study, qualified monitors and auditors, and governmental or regulatory authorities may inspect the study data, where appropriate and necessary.

Participation in this study will not affect treatment, and the risk is minimal. Participants are free to decline to answer any of the questions that they feel uncomfortable with.

Where is the study run from?
UCSI University (Malaysia)

When is the study starting and how long is it expected to run for?
From September 2020 to January 2022

Who is funding the study?
UCSI Research Excellence & Innovative Grant (Malaysia)

Who is the main contact?
Ms Lee Sook Huey
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Application of the psychological flexibility model to young people with chronic pain and their parents

Study objectives
1. Psychological flexibility will predict the psychological well-being and functioning of parents and young people with pain
2. Parents and young people with chronic pain in the treatment group with psychological flexibility will show better psychological well-being and functioning as compared to the control group and treatment as usual group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/01/2021, National Medical Research Register (NMRR) (Ministry of Health Malaysia, c/o Institute for Health Management, Block A, Kompleks Institut Kesihatan Negara (NIH), No 1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam, 40170 Shah Alam, Malaysia; +60 (0)3-3362 8888/8205), ref: NMRR NMRR-20-2780-57093

Study design
Cross-sectional study and multicenter interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic pain in young people

Interventions
Study 1 uses a cross-sectional survey to unexplored facets of psychological flexibility (PF), design features, and practical methods for enhancing PF for parents and young people with pain conditions.

An online questionnaire will be disseminated through the internet to recruit 50 Malaysian parents of young people with pain conditions via purposeful sampling. The questionnaire will give brief descriptions of treatment focused on PF and ACT for parents of young people with pain conditions in different modes (such as face to face or online, group or individuals, continuous or intermittent, short or long duration), and parents will state their preference through a ratings scale. Participants will also be allowed to give qualitative responses with optional open-ended questions. The questionnaire will also include items to assess parent's belief on the effectiveness of the proposed program, and motivations and barriers to attending such a program. Demographic predictors of parents' interest to participate in the program will also be assessed (including age group of young people with pain conditions, types of pain conditions, severity of pain conditions, and disability).

Study 2 is a study with pre-test post-test control group design to test the feasibility and effectiveness of the prototype treatment for parents and young people with pain conditions.

Parents and young people (11-18 years old) with pain conditions will be recruited from local hospitals via purposeful sampling. A feasibility study with pre-test post-test control group design will be conducted. Based on Lancaster, Dodd & Williamson’s recommendation of an overall sample size of 30 for a feasibility study, 30 parents will be randomly assigned to one of either:
1. PF-focused parent training program group
2. Comparison group (using a brief motivational interviewing intervention)
3. Treatment as usual group

The program will be delivered by a clinical psychologist with knowledge and experiences in pain psychology. During pre and post-test, parents will complete a demographic questionnaire, measure of parental psychological flexibility (e.g. Parent Psychological Flexibility Questionnaire, Adult Responses to Children’s Symptoms scale), measure of parental psychological stress and well-being (Depression, Anxiety and Stress inventory), and children's psychological well-being and functioning (e.g. Functional Disability Inventory, school attendance, Child Behavior Checklist). Young people will complete the visual analogy scale and the Chronic Pain Acceptance Questionnaire adolescent version (CPAQ-A) during pre-test and post-test.

Intervention Type
Other

Primary outcome measure
1. Parental psychological flexibility measured by the Parent Psychological Flexibility Questionnaire (PPFQ) and Adult Responses to Children’s Symptoms scale (ARCS) at 1 and 14 days
2. Parental psychological stress and well-being measured by the Depression, Anxiety, and Stress inventory (DASS) at 1 and 14 days
3. Children's psychological well-being and functioning measured by the Functional Disability Inventory (FDI), school attendance, and the Child Behavior Checklist) at 1 and 14 days
4. Pain measured by visual analogy scale (VAS) and the Chronic Pain Acceptance Questionnaire adolescent version (CPAQ-A) at 1 and 14 days

Secondary outcome measures
1. Preferred treatment mode (including face to face or online, group or individuals, continuous or intermittent, short or long duration) measured using a rating scale and qualitative responses with optional open-ended questions at 24 h
2. Parent's belief on the effectiveness of the proposed program, and motivations and barriers to attending the program measured by questionnaire at 24 h
3. Demographic predictors of parents' interest to participate in the program (including the age group of young people with pain conditions, types of pain conditions, the severity of pain conditions, and disability) measured by questionnaire at 24 h

Overall study start date
01/09/2020

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Malaysian citizen
2. Young people aged 11 to 18 years with pain conditions, and their parents
3. Pain of ≥3 months duration
4. Able to read and write

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
50 for survey study; 30 for interventional study (10 each group)

Key exclusion criteria
1. Recievingother psychological treatments
2. Acute signs or symptoms
3. Significant levels of depression, anxiety or anger, learning disability, or other difficulties which

would affect the ability to participate in the study
4. Significant medical condition that would compromise the ability to participate in the study
5. Unable to attend the full programme
6. Do not provide informed consent

Date of first enrolment
01/01/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Selayang
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Sponsor information

Organisation
UCSI University

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Sponsor type
University/education

ROR

https://ror.org/019787q29

Funder(s)

Funder type
University/education

Funder Name
UCSI University

Results and Publications

Publication and dissemination plan
Web of Science, Scopus, or MyCite-indexed publications in a peer-reviewed journal.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
Participant data will be included in the study, Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) will be shared. The data will be available beginning 9 months and ending 36 months following article publication. Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.

IPD sharing plan summary
Other