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The effects of art therapy with clay on emotion regulation, stress, and hormone levels in secondary school students

Submission date
04/01/2020

Recruitment status
Suspended

Registration date
08/01/2020

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Serious emotional problems of adolescents have become a pressing issue in Hong Kong (HK). While causes of the problems are inconclusive, effective measures to combat stress and control teen suicide carry vital significance at the present. As the literature shows that art therapy has positive impacts on emotional efficacy, this study aims to specifically investigate the efficacy of art therapy with clay (clay art therapy; CAT) by comparing it with a control group, in improving psychophysiological stress responses, which includes changes in various signs of emotion, interaction between cognition and emotion, and physiological stress response by analyzing salivary cortisol.

Who can participate?
Hong Kong S.4-5 students, aged between 15 and 17 with mild, moderate, or severe depression scores.

What does the study involve?
Students will be randomly allocated to receive either the CAT for six, two-hour weekly sessions, or to receive no additional treatment. The participants in the no treatment group will receive CAT after the study has finished. Some students in the treatment group will also be interviewed about their experience with the CAT after the treatment has finished.

What are the possible benefits and risks of participating?
Participants will be able to receive 6 sessions of free clay art therapy sessions that will be instructed by registered art therapists. During the session, participants can learn different skills and techniques to create clay art pieces, freely express their own thoughts and emotions through art activities, which have possible effects of soothing emotions. Regardless of the group allocation results, both experimental group and waitlist control group participants (subsequently) will receive the free art therapy sessions. The procedure has no known risks.

Where is the study run from?
Hong Kong Baptist University

When is the study starting and how long is it expected to run for?
September 2019 to August 2021

Who is funding the study?
Research Grants Council, University Grants Committee, Hong Kong

Who is the main contact?
Dr Joshua Nan
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A study on the effects of art therapy with clay intervention program on emotion regulation strategies, psychological stress and cortisol rhythm of secondary school students: A randomized controlled trial

Study objectives
The study aims to investigate and compare the effects of clay art therapy program and an active control group on the following aspects of Hong Kong senior secondary students:
1. Improvement in emotion regulation strategies
2. Improvement in positive affective states
3. Alleviation of negative affective states
4. Alleviation of defective symptoms in cognitive processing of affect, which symptoms are exhibited in terms of alexithymia
5. Reduction in physiological stress level

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2018, The Committee on the Use of Human & Animal Subjects in Teaching and Research (HASC) of the HK Baptist University (Hong Kong Baptist University Road, Kowloon Tong, Hong Kong; +852 3411 6461; hkbu_rec@hkbu.edu.hk), ref: HASC/17-18/0681

Study design
Randomized controlled interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
Participants who fulfill the screening test will be randomly assigned to either the clay art intervention group or the waitlist control group on a 1:1 basis with matched demographics. The clay art group will receive six weekly sessions of two-hour art therapy.

The waitlist control group will receive the supplementary art therapy sessions after all the data collection process.

8-10 participants in each arm will be randomly selected to join two separate focus groups that lasts about 45 minutes to 1 hour after completion of all intervention groups. The focus group will be in the format of semi-structured interview that allows the participants have the space to share their experiences in the group process, expand their answers and give complex accounts of their experiences in related to clay art making, art products, interaction with art therapist and other group members.

Randomisation process:
A reference number will be assigned to each participant to conceal any possible personal identification. Participants will be randomly assigned to either clay art group or waitlist control group on 1:1 basis. Allocation sequence will be generated by computer randomization program.

Intervention Type

Behavioural

Primary outcome(s)
Measured at T0 (baseline), T1 (right after intervention) and T2 (2 months after intervention):
1. Salivary cortisol measured using the “Salivette” kits (Starstedt, Ag & Co., Numbrecht, Germany)
2. Emotion regulation measured using the State Difficulties in Emotion Regulation Scale (S-DERS)
3. Emotion measured using the Positive and Negative Affect Schedule (PANAS)
4. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
5. Emotional awareness measured using the Toronto Alexithymia Scale (TAS-20)

Key secondary outcome(s))
Experiences of the intervention measured using focus groups at completion of the intervention

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Hong Kong S.4-5 students, aged between 15 and 17 (this age range may have included children who are newly emigrated from the mainland)
2. Ability to understand and communicate in Cantonese
3. Suitable and able to perform activities in groups during the course of the 6-week program
4. Students with DASS depressive subscale scores in the 9-21 range will be recruited for the current research and scores on the other two subscales (anxiety and stress) will be used as controlled variables during data analysis

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
15 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Diagnosed with mood disorder, anxiety disorder, or any other psychiatric disorder that required medical treatment, or professional intervention during the past 12 months
2. With other medical conditions that are likely to limit group participation during the course of the 6-week program

Date of first enrolment
01/09/2019

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Hong Kong

Study participating centre
Hong Kong Baptist University
Room 1012A, 10/F
AAB Building
Hong Kong Baptist University Road
Kowloon Tong
Hong Kong
Hong Kong
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Sponsor information

Organisation
Hong Kong Baptist University

ROR
https://ror.org/0145fw131

Funder(s)

Funder type
Research council

Funder Name
Research Grants Council, University Grants Committee

Alternative Name(s)
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Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication. Acquired participant level raw data will only be included in results publications /conferences of this study and will not be accessible for the public. All participants will be indicated by a participant code, no identifiable personal information will be stored with the data or published. All datasets will be destroyed within 3 years after the publication of research results.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		07/01/2020	10/01/2020	No	No