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Effect of stimulated laughter therapy through virtual meetings in mothers during the COVID-19 pandemic

Submission date
06/08/2021

Recruitment status
No longer recruiting

Registration date
10/08/2021

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Mental and Behavioural Disorders

[ ] 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 impact of the COVID-19 pandemic has radically changed our routines. The global population is suffering from long confinement and the consequent adverse psychological conditions such as depression and anxiety. COVID-19-related changes increase parental care demand and burnout, possibly leading to potential child maltreatment. The aim of this study is to develop and apply stimulated laughter therapy (SLT) to mothers caring for young children during the pandemic and examine its effectiveness at reducing their levels of depression, anxiety and parental stress.

Who can participate?
Mothers caring for children aged under 6 years during the pandemic

What does the study involve?
Participants are randomly allocated to the experimental group who receive four sessions of SLT or a control group who watch a 50-minute entertainment TV show. The SLT program consists of various stimulated laughter techniques followed by facial stretching, such as laughter with clapping, singing, and dancing. Each session is about 50 minutes long. SLT is provided through a virtual meeting method using Zoom (https://zoom.us).

What are the possible benefits and risks of participating?
Participants who complete the study are compensated with 17.33 USD (20,000 KRW). There is minimal risk involved.

Where is the study run from?
Gwangju University (South Korea)

When is the study starting and how long is it expected to run for?
February 2021 to June 2021

Who is funding the study?
1. Chung-Ang University (South Korea)
2. Gwangju University (South Korea)

Who is the main contact?
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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
Effect of stimulated laughter therapy through virtual meetings in mothers during the COVID-19 pandemic in South Korea: a mixed-method randomised controlled trial

Study objectives
The purpose of this study is to develop and apply stimulated laughter therapy (SLT) to mothers caring for young children during the pandemic and examine its effectiveness in reducing their levels of depression, anxiety, and parental stress. The specific aims of this study were:

1. To examine the effects after applying SLT in the participants' levels of depression, state/trait anxiety, and parental stress
2. To understand the participants' perceived changes and feedback related with SLT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2021, the institutional research board of Chung-Ang University (84 Heuk-seok ro, Dong-jak gu, Seoul, 06974, South Korea; +82 (0)2 820 6236; rsch@cau.ac.kr), ref: 1041078-202103-HRSB-064-01

Study design
Mixed-method randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Depression, anxiety and parental stress

Interventions
One research assistant (RA), not involved in this study, randomly divides 22 participants into an experimental group (n=11) and a control group (n=11) using a research randomizer site (http://www.randomizer.org). Since the study applies the double-blind method, both researchers and participants are blinded to the allocation.

Participants are randomised to the experimental group who receive four sessions of SLT or a control group who watch a 50-minute entertainment TV show.

The SLT in this study consists of four sessions and is performed twice per week for 2 weeks. It is based on a previous meta-analysis (Kang, 2017) reporting that four-session programs showed a higher effect size than three sessions. The number of sessions per week is considered more important at enhancing the program outcome than the duration of the sessions. Each session of SLT consists of four stages — introduction, implement, wrap-up, and evaluation. The program consists of various stimulated laughter techniques followed by facial stretching, such as laughter with clapping, singing, and dancing. Each session is about 50 minutes long.

Intervention Type

Behavioural

Primary outcome measure
1. Depression measured using the Center of Epidemiologic Studies Depression Scale (CES-D) at baseline and right after the intervention
2. State and trait anxiety measured with State-Trait Anxiety Inventory at baseline and right after the intervention
3. Parental stress assessed using the Korean Parenting Stress Scale at baseline and right after the intervention

Secondary outcome measures
Experimental group participants' experiences of the intervention, assessed using a semi-structured questionnaire in an exit phone interview after the intervention

Overall study start date
15/02/2021

Completion date
15/06/2021

Eligibility

Key inclusion criteria
1. Women with at least one child aged under 6 years
2. No psychiatric symptoms and medication histories at the time of intervention
3. Able to use Zoom at home

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
70

Total final enrolment
22

Key exclusion criteria
Those with psychiatric symptoms and medication histories at the time of intervention

Date of first enrolment
07/05/2021

Date of final enrolment
04/06/2021

Locations

Countries of recruitment
Korea, South

Study participating centre
Gwangju University
Department of Nursing
Hyodeok-ro 227, Nam-gu
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Sponsor information

Organisation
Chung-Ang University

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Sponsor type
University/education

Website
http://neweng.cau.ac.kr/

ROR
https://ror.org/01r024a98

Funder(s)

Funder type
University/education

Funder Name

Chung-Ang University

Alternative Name(s)
CAU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Funder Name
Gwangju University

Alternative Name(s)
Kwangju University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this wasn't approved by the institutional review board. The data are all anonymized and stored in the corresponding author’s computer. The researchers are going to destroy this data after 3 years as approved by the institutional review board.

IPD sharing plan summary
Stored in repository