

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	<input type="checkbox"/> Prospectively registered
Registration date 10/08/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/08/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Dr Sihyun Park
sh8379@cau.ac.kr

Contact information

Type(s)

Scientific

Contact name

Dr Sihyun Park

Contact details

Department of Nursing, Red-Cross College of Nursing
84 Heuk-seok ro, Dong-jak gu
Seoul
Korea, South
06974
+82 (0)2 820 5737
sh8379@cau.ac.kr

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Gwangju

Korea, South

61743

Sponsor information

Organisation

Chung-Ang University

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

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