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**Project Title: A Randomized Controlled Feasibility Study of Emotional Well-being of Adolescents Undergoing a Mindfulness Training During COVID-19**

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# **A randomized controlled feasibility study of emotional well-being of adolescents undergoing a mindfulness training during the COVID-19 pandemic**

## **Specific Aims**

The COVID-19 pandemic has been significantly affecting people's lives around the globe. Social distancing, self-quarantine, shelter-in-place measures, economic challenges, and COVID-19-caused illness and deaths have the potential to significantly impact mental health and cause stress, anxiety, and depression. Adolescents may be especially vulnerable to this situation, due to their increased vulnerability to the onset of depression and anxiety in general.

One promising approach to reduce anxiety and depression in youth is a neuroscience-based mindfulness intervention Training for Awareness Resilience and Action (TARA) (*Henje Blom et al., 2014*). TARA is usually delivered over 12 weeks by two facilitators in groups of 10-15 adolescents in-person, and it has been shown to reduce symptoms of depression and anxiety in depressed adolescents (*Henje Blom et al., 2016*) and modify brain properties (*Yuan et al., 2020*). The TARA intervention can also be delivered remotely. Other types of therapy delivered remotely, such as internet-based cognitive behavioral therapy, have shown comparable efficiency to face-to-face delivery (*Carlbring et al., 2017*).

The objective of this study is to utilize an individually randomized group treatment, open-label, waitlist-controlled clinical trial to test the feasibility of TARA (delivered partially over Zoom) in improving the self-reported emotional well-being primary outcome (emotional problems measured with the Strengths and Difficulties Questionnaire [SDQ]) in healthy adolescents between the ages of 14 to 18 years old during the COVID-19 pandemic.

Our central hypothesis is that emotional well-being of adolescents in the intervention group will improve stronger (or deteriorate less) than in the control group. We will test this hypothesis in 21 adolescents randomized to the TARA intervention (partially delivered over Zoom) (12 adolescents) or to the waitlist control group (9 adolescents). We will pursue the follow Specific Aim:

***Specific Aim 1. To study changes in emotional well-being in healthy teens with mindfulness training during the COVID-19 pandemic. Hypothesis 1:*** Internalizing emotional problems as measured by the SDQ will decrease in the training group compared to controls.

With respect to expected outcomes, the work proposed here is expected to establish feasibility of remotely delivered TARA intervention in reducing emotional problems of adolescents during the COVID-19 pandemic. The important general positive impact of this study lies in the possibility of offering a neuroscience-based mindfulness intervention remotely to youth living in remote areas and for all youth during pandemic times, in order to help reduce their depression and anxiety, and prevent development of the Major Depressive Disorder, a highly prevalent illness ranked as the #1 leading cause of disability worldwide (*WHO, 2017*) that dramatically increases and often begins during adolescence.

## Research Plan

### **Objectives**

The **primary objective** will be to test the feasibility of a neuroscience-based mindfulness intervention in improving the self-reported emotional well-being in healthy adolescents between the ages of 14 to 18 years old during the COVID-19 pandemic. **Hypothesis:** Internalizing emotional problems will decrease in the training group compared to controls.

### **Design and Outcomes**

The current research study design will utilize an individually randomized group treatment, open-label, waitlist-controlled clinical trial design.

**Primary Outcome:** emotional problems measured with the Strengths and Difficulties Questionnaire (SDQ). The SDQ self-assessment will be done remotely via a Qualtrics questionnaire.

### **Interventions and Duration**

The study will compare a 12-session neuroscience-based mindfulness group intervention Training for Awareness Resilience and Action (TARA) (*Henje Blom et al., 2014*) with a waitlist control group. The intervention duration is 1.5 hours per week for 12 weeks. The first 5 TARA sessions will be conducted in-person. The last 7 session will be delivered over Zoom.

### **Sample Size and Population**

The target population for the current study will be 21 healthy female and male adolescents that are between the ages of 14 to 18 years old who are randomly assigned to the TARA intervention or waitlist control group.

**Inclusion Criteria:** Healthy female and male adolescents, 14-18 years old. Fluency in English. **Exclusion Criteria:** MRI contraindications and pregnancy; Current mindfulness training (e.g. MBSR, MBCT, DBT) and/or practice with a typically sitting meditation or yoga of 20 or more minutes two or more times per week within 60 days prior to study entry.

Recruitment of potentially eligible participants will be primarily performed in the San Francisco Unified School District (SFUSD) using IRB-approved flyers.

### **Data Analyses**

Our hypothesis is that TARA training will improve emotional problems as assessed by the SDQ T-score compared with controls. We will use an analysis of covariance (ANCOVA) accounting for sex and fit by maximum likelihood. Stata (College Station, TX) will be used to perform data analyses.

### **References:**

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