Effectiveness of a Culturally Adapted Cognitive Behavioral Intervention to Reduce Psychological Distress and Improving Well-Being Among University Students During the COVID-19 Pandemic

[NCT ID not yet assigned]

21.03.2021

The Study Protocol

The proposed project aims to conduct a study in which a culturally adapted cognitive behavioral intervention (CA-CBI) will be implemented in an online group format to prevent the expected psychological problems, reduce psychological distress and increase the well-being of the university students and effectiveness of this intervention will be measured. In this regard, a survey study and a diagnostic interview will be conducted to detect the distress and whether the individual has any psychological problem severe enough to meet the diagnostic criteria (for screening purposes; the ones who do not have a considerable amount of distress and who have a diagnosis would not be included in the study), depression, anxiety, traumatic stress and well-being levels of the participants in addition to the COVID-19 related factors and demographic variables. In the intervention part, CA-CBI will be implemented in a group format on Zoom which is an online platform with HIPAA compliance. For this purpose, the CA-CBI manual will be adapted to the sample of university students and the problems they are experiencing during the COVID-19 pandemic. Then, psychological problems and the well-being of the participants will be measured three times (one week before the intervention, one week after the intervention and one month after the post-measurement) to evaluate the efficacy, and a process evaluation will be made to evaluate the feasibility of the intervention.

This project consists of 4 stages. In the first stage, the CA-CBI manual will be adapted for the sample of university students and the problems they are experiencing during the COVID-19 pandemic. For this purpose, the four steps of the DIME (design, implementation, monitoring and evaluation) methodology will be followed: a) Free-listing interviews, b) Key-informant interviews, c) Focus group interviews, and d) Cognitive interviews.

In the second stage, two surveys and a diagnostic interview will be conducted on the internet to learn about demographics, COVID-19 related data (precautions, exposure, etc.), psychological problems and the well-being. The first survey and diagnostic interview will be done by the screening purposes. They will first fill the Kessler Psychological Distress Scale (K10) as a first step of screening. The ones who score higher than 15 will and have no suicidality continue to the next screening phase which is conducting Structured Clinical Interview for DSM-5 (SCID-5). After conducting SCID-5, the ones who do not have a diagnosis for any type of psychiatric disorders according to DSM-5 will be included to the study and have the pre-test. Pre-test survey will take 20-25 minutes. The sample will consist the adult university students living in Turkey. It is aimed that 100 participants who meet the inclusion criteria would participate to this phase of the study (The data collection will stop when the aimed number of participants meeting the inclusion criteria is achieved). The links of the surveys which will be created on Qualtrics will be shared on social media and communication platforms. On these links, participants will first see the information about the study, and after giving consent to participate in the study, they will be able to complete the questionnaires.

In the third stage, the 8-week online group CA-CBI and its efficacy measurement will be conducted to test whether the CA-CBI works for the university students experiencing distress during the COVID-19 pandemic. Only the participants who meet the inclusion criteria, pass the screening procedure and approve to be part of the intervention will take place in this stage. The aimed participant number for this stage is 100. Participants will be randomly

assigned to the care as usual and care as usual/intervention groups. Control (care as usual) group will receive information about the freely available support options. Two other measurements will be taken about psychological problems and well-being at one week after the intervention (post-test) and one month after the post-test (follow-up). After all the measures are completed, the control group will be able to receive the intervention.

In the fourth stage, a process evaluation will be conducted to evaluate the feasibility of delivering CA-CBI to university students in an online group format. The process evaluation will consist of interviews in which participants will be asked about the facilitators and the barriers of attending/delivering the sessions. The participants of this process will be 5 completers, 5 drop-outs and 2 facilitators who apply CA-CBI.

The data will be analyzed by using a statistical package called IBM SPSS 26.0. The effectiveness of the intervention will be tested by comparing the changes in the scores of primary outcome measure (K10) and secondary outcome measures (PHQ-9, GAD-7, PCL-5, WHO-5) between the baseline and follow-up measure. Mediation analyses will be conducted to explore the mechanisms of change by using the Dispositional Hope Scale, Emotion Regulation Questionnaire and Acceptance and Action Questionnaire-II.