

**Effectiveness of a Culturally Adapted Cognitive Behavioral Intervention to Reduce Psychological Distress Among COVID-19 Survivors**

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## The Study Protocol

The Coronavirus disease (COVID-19) pandemic has an enormous psychological impact worldwide (Luo et al., 2020). Individuals with suspected or confirmed COVID-19 have been defined as one of the most vulnerable groups suffering from psychological distress during the pandemic (Wang et al., 2020). In a study conducted with COVID-19 survivors, it has been found that this group had a significantly increased risk for developing psychiatric conditions such as anxiety and mood disorders, substance use disorders, and insomnia, even when comparing with other respiratory tract infections (Taquet et al., 2021). In addition, these psychiatric conditions remained elevated at the 6-month period for COVID-19 survivors. Therefore, COVID-19 survivors should be considered to be in need of an urgent intervention (Wang et al., 2020).

The proposed study aims to conduct a randomized controlled trial in order to implement culturally adapted cognitive behavioral intervention (CA-CBI) to COVID-19 survivors and evaluate the effectiveness of the intervention in reducing psychological distress for this particular group. Individuals who are 18 years or older, who got infected with COVID-19 and currently recovered, and who have a considerable amount of psychological distress will be included to the study. Individuals who have a severe mental disorder or suicidal risk will be excluded from the study. For screening purposes, an online survey followed by a structured interview will be conducted to identify the eligible participants. 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 revised to the sample of COVID-19 survivors and the problems they are experiencing during the COVID-19 pandemic. Participants in the control group will receive online leaflets including a brief psychoeducation and appropriate referrals to receive free psychosocial support. To test the effectiveness of CA-CBI, all participants will be assessed one week before the intervention (pre-test), one week after the intervention (post-test), and one month after the post-test (follow-up). During the assessment, participants will be asked about psychological distress, symptoms of depression, anxiety, post-traumatic stress and somatization, as well as, questions about their quality of life, psychological flexibility and emotion regulation. The primary outcome is the psychological distress at the follow-up phase. A process evaluation will be conducted in order to assess the treatment fidelity and possible facilitators and barriers during the implementation of online-delivered group CA-CBI.

This project consists of 3 stages:

In the first stage, participants will be reached through social media and online communication channels and will be asked to fill out an online survey for screening purposes. Participants agreeing on the informed consent will be able to answer questions about demographics, COVID-19 related data (infection, recovery, etc.), psychological problems and suicidal risk. Participants who were infected with and recovered from COVID-19 will be able to continue with the Kessler-10 Psychological Distress Scale (K10). Those who score higher than 15 will continue to the suicidality questions. In this part, participants who are detected to have a suicidal risk will see a referral list on the screen where they can receive free psychological help for their suicidal ideations. Also, they will receive the phone number of the research team on the screen in case if they need to obtain more information about the referrals and to reach the research team. Participants who got infected with COVID-19 and recovered, who score a considerable amount of psychological distress ( $K > 15$ ), and who do not have a suicidal risk will be invited to the next stage of the screening procedure. In this

stage, the Structured Clinical Interview for DSM-5 (SCID-5) will be conducted with participants to screen any severe mental disorders. The structured interview will be conducted via Zoom and participants who have no severe psychiatric condition will be asked whether they would like to attend an intervention to decrease their psychological distress. After conducting SCID-5, eligible participants who agree to participate to the intervention will be included to the study and will be given the pre-test assessment one week before the intervention. Pre-test survey will take approximately 20 minutes. It is aimed that 86 participants who meet the inclusion criteria would participate to this phase of the study. The links of the surveys which will be created on Qualtrics will be shared on social media and online 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 second stage, eligible participants who agree to participate to the study will be randomly assigned to intervention (CA-CBI) group or control [enhanced treatment as usual (ETAU)] group. The required sample is identified as 86 participants for this stage. During the intervention, participants in the intervention group will receive online group CA-CBI for 8 weeks. Participants in the control group will receive a brief psychoeducation about their psychological distress as well as a referral list to consult appropriate places due to their psychological distress. In order to test the effectiveness of the CA-CBI for COVID-19 survivors, post-test assessment will be conducted with participants in the intervention and control group one week after the intervention. Participants in the control group will additionally be asked whether they received any psychological support during this process. To be able to observe the long-term effects of the CA-CBI, follow-up assessment will be conducted one month after the post-test. After all measures are completed, participants in the control group will be able to receive the intervention.

In the third stage, a process evaluation will be conducted to assess the treatment fidelity and the feasibility of implementation of the CA-CBI to COVID-19 survivors in an online group format. Interviews will be conducted with 5 completers, 5 drop-outs and 2 facilitators in order to evaluate the possible facilitators and barriers of attending/delivering the online group sessions.

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, SCL-90-R Somatization subscale, WHOQOL BREF) between the baseline and follow-up measure. Mediation analyses will be conducted to explore the mechanisms of change by using the Psychological Flexibility Scale and Emotion Regulation Questionnaire.