

Statistical Analysis Plan

Research Study

Unique Protocol ID: UOG/ORIC/2022/393

Brief Title: Cognitive Behavioral Couple Therapy for Perinatal Distress

Official Title: The Effectiveness of Psychopharmacological Intervention Versus Cognitive Behavioural Couple Therapy and Their Combination in Perinatal Distressed Couples: A Randomized Clinical Trial

Registration: NCT06001021

Initial Registration: 26th June, 2023.

Initial Approval and Public Release Date: 13th August, 2023.

Statistical Analysis

Mean difference for the impact of intervention across five intervention arms (psychopharmacological intervention; cognitive behavioural couple therapy; cognitive behavioural couple therapy along with Zikr; combined (Psychopharmacological Medication and Cognitive Behavioral Couple Therapy); combined (Psychopharmacological Medication and Cognitive Behavioral Couple Therapy along with Zikr), and two control arms (placebo comparator, and no intervention) is measured separately in the test scores for perinatal distress, dyadic coping, social support, wellbeing, and four domains of quality of life (i.e., physical, psychological, social, and environmental aspects) via ANCOVA after controlling for baseline pre-test scores for perinatal distress (depression and anxiety) in SPSS-24.

Mean difference for the impact of intervention across five intervention arms (psychopharmacological intervention; cognitive behavioural couple therapy; cognitive behavioural couple therapy along with Zikr; combined (Psychopharmacological Medication and Cognitive Behavioral Couple Therapy); combined (Psychopharmacological Medication and Cognitive Behavioral Couple Therapy along with Zikr), and two control arms (placebo comparator, and no intervention) is measured separately in the test scores for perinatal distress, dyadic coping, social support, wellbeing, and four domains of quality of life (i.e., physical, psychological, social, and environmental aspects) via ANCOVA after controlling for baseline pre-test scores for perinatal distress (depression and anxiety) and monthly income covariates in SPSS-24.