

C O V E R P A G E

Official Title: Group Therapy in Primary Care for Women with Depression or Anxiety in Petropolis

NCT number: Not yet assigned

Date: July 12, 2018

Group Therapy in Primary Care for Women with Depression or Anxiety in Petropolis

This is a randomized controlled trial comparing two groups: 1) Enhanced usual care and 2) Enhanced usual care plus group psychological intervention. In both groups a “stepped care” approach was used to the management of anxiety and depression among women seen in primary care.

Study Setting

The study was conducted in 10 of 34 Family Health Units in deprived areas of Petrópolis, Rio de Janeiro, Brazil. Patients in the clinics typically shared low socioeconomic status, low levels of educational attainment, and high rates of unemployment and under-employment. The study was conducted between 2006 and 2010.

Interventions

Given the high levels of anxiety and depression and the enormous unmet need for mental health services in Petrópolis, we decided to have two active arms of the study and to not exclude any patients identified with mental health problems from treatment. Patients positive for common mental disorders (anxiety and depression) were randomized to enhanced primary care vs. enhanced primary care plus group psychological intervention.

Mental health care was delivered in the in the primary care clinic by the patients' Family Health Team (doctor and nurse); a psychiatrist from the matrix team (Author SF) provided supervision for all services.

All patients received enhanced primary care, which included: (1) The nurses and doctors from the Family Health Teams were trained by mental health professionals on clinical aspects of depression and anxiety, including diagnosis, appropriate medication interventions, psycho-education, and cognitive and problem solving therapy. (2) Given the high co-occurrence of anxiety and depression, the intervention was adapted from the

Chilean model to include anxiety as one of its targets (3) All providers received weekly group or individual consultation with a matrix support mental health professional, either psychiatrist or psychologist

Patients in the intervention arm received enhanced primary care plus a 9-session group intervention (seven sessions weekly then two sessions every 15 days). The intervention included two psycho-educational sessions with information about depression and anxiety disorders, two sessions on the development of pleasant activities including relaxation exercises, two sessions on solving problems therapy, one session on the problem of overcoming negative thoughts and emotions, one session on relapse prevention, and a final closure and review session which included a small party. The patients from the intervention arm also received additional outreach from the Family Health Teams, including home delivery of psychotropic medication when needed and active outreach and engagement by community workers if patients missed group sessions.

Procedures

Recruitment was restricted to women for two reasons: they are the most frequent attenders of primary care units and the group of higher risk for anxiety and depressive disorders^(X) A two-stage screening process was used to identify female patients with current depressive and/or anxious disorders. All women age 18-65 attending the units for any reason were initially eligible for screening. Exclusion criteria assessed prior to screening were: cognitive impairment sufficient to preclude informed consent, pregnancy, treatment with antidepressants and neuroleptics for two months before the screening, psychoses, alcohol or drug dependence, bipolar disorder, or severe suicidal risk.

Patients were screened with the General Health Questionnaire-12, with a cutoff point of 4/5 indicating a positive finding. To confirm, a second administration of the GHQ-12 was conducted fifteen days later for those who scored positive in the first screening. All women who were positive at both screenings were evaluated by psychiatry interns with the Mini (. Patients were invited to take part in the study if they presented a positive

diagnosis for anxiety, depression, or both disorders according to the MINI and did not fulfill exclusion criteria.

Randomization and follow up

Patients who provided informed consent were randomized either to enhanced primary care or to enhanced primary care + comprehensive stepped-care group treatment program. The same doctors and nurses, trained on treating anxiety and depression, led both arms of the study. Patients from control group were informed that they had depression or anxiety disorders and that they should come to the unit for consultation with their doctors and nurses on a treatment as usual basis, including prescription of psychotropic medication, Community health workers did not follow up on patients in the enhanced primary care arm if they did not show up for appointments.

Follow up assessments were held at 4 (F1) and 8 (F2) months after the beginning of the intervention. Dropout rates from enrollment to the first follow-up were 5% and to the second-follow up were 13%.

Measurement

The following measures were administered in Portuguese: Beck Depression Inventory, Beck Anxiety Inventory and the World Health Organization Quality of Life Assessment-Brief Version. A general questionnaire to collect socio demographic and personal information was also administered.

Analysis

Using data from the Beck Depression and Anxiety Inventories, we analyzed three ways in which intervention and control group patients could demonstrate differences in anxiety and depression symptoms: (1) *remission*, as the percentage of patients who were negative for depression and anxiety before and after treatment, (2) *reduction in severity level*, the percentage of patients that had a reduction in the level of severity of the disorder they presented, and (3) secondary outcome of improvement in quality of life (World Health Organization Quality of Life Assessment-Brief Version). Analysis of repeated measures (baseline and two follow-ups) for each one of the outcomes were conducted using SPSS software.

Recruitment

