**TITLE PAGE**

**Evaluating feasibility and acceptability of a group WHO trans diagnostic intervention for women with common mental disorders in rural Pakistan: a cluster randomised controlled feasibility trial**

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**Abstract 342 words (400 max)**

**Aims:** The aim of this feasibility trial was to evaluate the feasibility and acceptability of the locally adapted PM+ Group intervention for women in Swat, Pakistan.

**Methods:**

This mixed-methods study incorporated a quantitative component consisting of a two arm cluster randomised controlled feasibility trial, and qualitative evaluation of the acceptability of the PM+ group to a range of stakeholder groups. For the quantitative component, on average from each of the twenty LHW catchment area (20 clusters), 6 women were screened and recruited for the trial with score of > 2 on the General Health Questionnaire (GHQ-12) and score of > 16 on the WHO Disability Assessment Schedule (WHODAS). These LHW clusters were randomised on a 1:1 allocation ratio using a permuted-block randomisation method to the PM+ Group intervention or Enhanced Usual Care. The PM+ Group intervention consisted of 5 weekly sessions of 3 hours duration delivered by local non-specialist females under supervision. The primary outcome was individual psychological distress, measured by levels of anxiety and depression on the Hospital Anxiety and Depression Scale at 7th week after baseline. Secondary outcomes include symptoms of depression, post-traumatic stress disorder, general psychological profile, levels of functioning and generalized psychological distress. Intervention acceptability was explored through in-depth interviews.

**Results:**

Lay-helpers with no prior mental health experience were trained to successfully deliver intervention sessions in the community settings under supervision. There was good intervention uptake, with PM+ Group considered useful by the participants as well as their families. The outcome evaluation, which was not powered to identify significant results, indicated significant improvements in depression, anxiety, general psychological profile and functioning and smaller levels of positive improvement in levels of PTSD symptoms and generalized psychological distress.

**Conclusion:**

This feasibility trial showed good acceptance in the local settings with feasible delivery by non-specialists under supervision by local females. The feasibility trial give way for further adaptation and exploration of the outcomes through larger-scale implementation and definitive RCTs of the intervention in the local challenging settings.

**Trail registration:** Australian New Zealand Clinical Trials Registry: ACTRN12615000210572 (<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=368082>). Registered 5th March 2015.