**AFFIRM Metadata**

The AFrica Focus on Intervention Research for Mental Health (AFFIRM) hub was a research and capacity building project, taking place in six partner countries: Ethiopia, Ghana, Malawi, South Africa, Uganda and Zimbabwe. The aim of the project was to identify and test cost-effective interventions for mental disorders. In South Africa, this was investigated through a randomised controlled trial (RCT), assessing the effectiveness of a task-shared psychosocial intervention for perinatal depression delivered by community health workers.

The primary objectives of the AFFIRM South African trial were to:

1. Determine the effectiveness of a task-sharing psychosocial intervention for perinatal depression, delivered by community health workers
2. Determine the cost-effectiveness of a task-sharing psychosocial intervention for perinatal depression, delivered by community health workers.

The secondary objectives were:

1. To examine factors influencing the implementation of the task-sharing intervention and future scale up, (i) by assessing acceptability, feasibility, sustainability, quality, and safety of the intervention, and (ii) by qualitative exploration of the experience of task-sharing from the perspectives of both primary healthcare workers and patients.
2. To evaluate locally relevant but generalizable measures for evaluating the effectiveness and cost-effectiveness of task sharing care to primary health care.

The study was a two-centre, two-arm, single blind individual-level RCT among 419 pregnant women presenting with depressive symptoms in Khayelitsha, South Africa. Recruitment took place in the Maternity and Obstetric Units at Michael Mapongwana Community Health Centre (CHC) and Site B CHC in Khayelitsha. Four fieldworkers were trained to screen women attending their first antenatal clinic booking, which is typically in the first or second trimester, using the Edinburgh Postnatal Depression Scale (EPDS) (1). The EPDS is a 10-item Likert-scale questionnaire assessing a range of depressive symptoms, such as anhedonia, somatic symptoms and suicide ideation. Women who scored 13 or above on the scale, and fulfilled the following eligibility criteria were enrolled into the study:

* Lives in Khayelitsha
* Speaks isiXhosa
* Aged 18 years or older
* Presented for their first antenatal visit no later than 28 weeks gestation
* Was able to give informed consent
* Did not require urgent medical care
* Did not suffer from a severe mental disorder (diagnosis of schizophrenia, bipolar mood disorder, or experiencing acute psychotic symptoms at the time of screening)

Participants were then randomised into either a psychosocial intervention (PSI) or enhanced usual antenatal care (three monthly phone calls during the course of the pregnancy). All participants received the same usual antenatal care from the clinics.

* The intervention group was given a series of 6 – 8 sessions of basic counselling, presented in the form of structured manual-based sessions. A participant attending at least 6 sessions was considered as having completed the counselling course.
* The control group received enhanced usual care, which consisted of three phone calls over 3 months from a community health worker trained to conduct the phone calls but not in basic counselling.

The randomisation was stratified by site, and on an individual basis. A list of 60 randomisation entities was generated per clinic by the centralized data management system (30 intervention, 30 control). A participant enrolled was assigned an entity that was available. Once all randomisation entities for a clinic were used, then another list of 60 entities was created.

All participants conducted a baseline assessment after enrolment. Assessments were repeated at one month before their expected date of delivery, and three months and 12 months after giving birth. The full sample was recruited by October 2014, and the study completed by May 2016. Data from baseline and follow-ups, as well as reports from sessions were collected through a mobile application, called Mobenzi. All assessments covered socio-demographic and socioeconomic questions, as well as the primary and secondary outcome measures.

The primary outcome, depressive symptoms, was assessed using the Hamilton Depression Rating Scale (HDRS) *(2)*. The HDRS is a 17-item questionnaire, with scores ranging from 0 to 54; a higher score suggests more severe depressive symptoms. The HDRS has been used as a clinical outcome in depression trials, including as a primary outcome in a trial assessing a cognitive behavioural therapy intervention for perinatal depression in Pakistan (3). The HDRS was originally devised to be completed by a mental health specialist, but was subsequently modified and adapted for use by non-clinicians (4-6). Potts’ version was adapted, translated into isiXhosa and validated for the RCT (7).

Secondary outcomes covered a range of mental health, health-related and socio-economic measures including intimate partner violence, HIV status, depression diagnosis and suicidal behaviours (using the Mini International Neuropsychiatric Interview 6.0 , Major Depressive Episode and Suicidality modules (8)), functional impairment (using the 12-item WHO Disability Assessment Schedule 2.0 (9, 10) and a locally developed tool called the Functioning Assessment Instrument (11)), alcohol use (using the Alcohol Use Disorder identification Test (12)), social support (using the Multidimensional Scale of Perceived Social Support (13, 14)) and food insecurity (using the Household Food Insecurity Access Scale (15)). The 3-month and 12-month postnatal assessments also included child health and development measures, namely infant height and weight, head circumference, adherence to child immunization, and prevalence of diarrheal disease and respiratory tract infections. Finally, a set of 14 questions was asked at the end of each session or phone call, to monitor change in depressive symptoms, suicidal risk, alcohol use and partner violence (currently in a separate data file).

All sections in the assessments were translated into isiXhosa and back-translated to English. More information on the design and data collection methods is published in Lund et al. 2014 (16).

The data are available in SPSS, Stata or CSV files, and either in long or wide format. To access the data, please contact Prof Crick Lund: crick.lund@kcl.ac.uk

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