

# **Filling the Gap: Development and qualitative process evaluation of a task sharing psycho-social counselling intervention for perinatal depression in Khayelitsha, South Africa.**

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**NYTMEM001**



Thesis presented for the degree of  
**DOCTOR OF PHILOSOPHY**  
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University of Cape Town

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## Preface

This thesis includes published papers, as per general provision 6.7 in the General Rules for the Degree of Doctor of Philosophy (PhD) of the University of Cape Town. I confirm that I have been granted permission by the University of Cape Town's Doctoral Degrees Board to include the following publication(s) in my PhD thesis, and where co-authorships are involved, my co-authors have agreed that I may include the publication(s): The following four co-authored papers are formally included as part of the thesis:

1. Munodawafa\*, M; Mall, S; Lund, C and Schneider, M. Process evaluations of task sharing interventions for perinatal depression in Low and Middle Income Countries (LMIC): A systematic review and qualitative meta-synthesis. *BMC Health services research*. 2018 18(1), 205.
2. Nyatsanza\*, M; Davies, T; Schneider, M and Lund, C. Filling the treatment gap: developing a task sharing counselling intervention for perinatal depression in Khayelitsha. *BMC Psychiatry* 2016 16(1), 164.
3. Munodawafa\*, M; Lund, C and Schneider, M. A process evaluation exploring the lay counsellor experience of delivering a task shared psycho-social intervention for perinatal depression in Khayelitsha, South Africa. *BMC psychiatry* 2017, 17(1):236.
4. Munodawafa\*, M; Lund, C and Schneider, M. A process evaluation exploring the participant's experience of receiving a task shared psycho-social intervention for perinatal depression in Khayelitsha. For submission to *Global Mental Health*.

All papers were submitted to different journals in the style required by the different journals. However for this thesis the referencing has been standardised.

---

\* Nyatsanza is my maiden name and Munodawafa is my married (current) surname.

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To sum up my PhD journey, I will use the quote below;

*“It always seems impossible until it’s done”* – **Nelson Mandela**

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# List of Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
AFFIRM-SA	AFrica Focus on Intervention Research for Mental health, South Africa
ART	Antiretroviral treatment
CBT	Cognitive Behavioural Therapy
CHC	Community Health Centre
CHW	Community Health Worker
CMD	Common Mental Disorders
COREQ	Consolidated Reporting for Qualitative Studies
CPMD	Common Perinatal Mental Disorders
DALY	Disability Adjusted Life Years
EPDS	Edinburg Post Natal Depression Scale
HDRS	Hamilton Depression Rating Scale
HIC	High Income Country
HIV	Human Immunodeficiency Virus
IPT	Interpersonal Therapy
LAMIC	Low and Middle Income Country
LHW	Lady Health Worker
MDD	Major Depressive Disorder
MHC	Mental Health Counsellor
MRC	Medical Research Council
NGO	Non-governmental organisation
NIMH	National Institute of Mental Health
PST	Problem Solving Therapy
PPD	Postpartum Depression

PLWH	People Living With HIV
PRIME	<b>PR</b> ogramme for <b>I</b> mproving <b>M</b> ental health car <b>E</b>
PMHP	Perinatal Mental Health Project
SANCA	South African National Council of Alcoholism and Drug Dependence
THP	Thinking healthy programme
RCT	Randomized Controlled Trial
UCT	University of Cape Town
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

# Abstract

Perinatal depression is a major public health issue which contributes significantly to the global burden of disease, especially in low resource settings in South Africa, where there is a shortage of mental health professionals. New psychological interventions delivered by non-specialists are needed to fill the treatment gap. Task sharing of psycho-social interventions for perinatal depression has been shown to be feasible, acceptable and effective in low and middle-income countries. However; there are limited data on process evaluations of task shared interventions for perinatal depression. This thesis attempts to address this gap by presenting four papers based on a study that undertook a qualitative process evaluation on a task shared psycho-social intervention. The thesis integrates all the papers under one primary aim (a process evaluation) which triangulated data from four sources which were published literature, perspectives of local depressed women, perspectives of the counsellors in the trial and perspective of recipients of the intervention in the trial.

The thesis will be presented in six chapters. The first chapter provides a background with current issues in global mental health, psycho-social interventions, task sharing in low and middle income countries and the United Kingdom (UK) Medical Research Council (MRC) framework for developing and evaluating interventions.

A second chapter presents a systematic review on qualitative evidence of process evaluations of task sharing interventions for perinatal depression in LAMICs in relation to the UK MRC framework for conducting process evaluations. The systematic review reveals a paucity of qualitative evidence of process evaluations together with several crucial factors related to context, implementation and mechanisms of an intervention including: content and understandability, counsellors facilitating trust and motivation to conduct the intervention and participant factors such as motivation to attend the sessions and willingness to learn and change their behaviour.

The third chapter provides information on development of the intervention and determining the feasibility in line with the MRC framework. Qualitative semi-structured interviews were conducted with 26 participants, including service providers and service users at a clinic in Khayelitsha. After the semi-structured interviews, a workshop was conducted with mental health experts on evidence-based psychological

interventions for depression, together with a document review of counselling manuals for community health workers in South Africa. The feasibility study showed that a task sharing counselling intervention was acceptable and feasible for depressed women in Khayelitsha, under the following conditions: (1) respondents preferred a female counsellor and felt that clinic based individual sessions should be provided at least once a month by an experienced Xhosa speaking counsellor from the community; and (2) the content of a counselling intervention should include psycho-education on cognitive and behavioural effects of depression, how to cope with interpersonal problems, and financial stressors. Based on these conditions, the review of manuals and expert consultation, key components of the counselling intervention were identified as: psycho-education, problem solving, healthy thinking and behaviour activation. These were included in the final counselling manual.

The fourth chapter, presents the first of two perspectives of the post-intervention qualitative process evaluations, with lay counsellors. Post intervention qualitative semi-structured interviews were conducted with six counsellors from the AFrica Focus on Intervention Research for Mental Health (AFFIRM-SA) randomized controlled trial on their perceptions of delivering a task shared psycho-social intervention for perinatal depression. These interviews revealed that facilitating factors in the delivery of the intervention included intervention related factors such as: the content of the intervention, ongoing training and supervision, using a counselling manual, conducting counselling sessions in the local language (*isiXhosa*) and fidelity to the manual. Counsellor factors including counsellors' confidence and motivation to conduct the sessions and participant factors included older age, commitment and a desire to be helped. Barriers included contextual factors such as poverty, crime and lack of space to conduct counselling sessions and participant factors such as the nature of the participant's problem, younger age, and avoidance of contact with counsellors. Fidelity ratings and dropout rates varied substantially between counsellors.

The fifth chapter presents the second of two perspectives of post intervention qualitative process evaluation with participants. Stratified purposeful sampling based on non-attendance, partial attendance and complete attendance of the intervention resulted in 34 participants being selected for semi-structured interviews. All interviews were recorded, transcribed and translated. Transcripts were analysed using a framework analysis in NVivo v11. Several factors acted as either barriers or facilitators

of the participants' context, mechanisms of the intervention and the implementation of the intervention. Contextual factors included the nature of problem such as unplanned pregnancy, interpersonal difficulties and location of the counselling. Mechanisms included participant factors such as willingness to learn new skills and change behaviour, counsellor factors such as motivation and empathy and intervention factors such as the content of the intervention. Implementation factors included the perception of the use or inability to use material such as the counselling manual, homework book and relaxation CD. The majority of the participants found the following sessions to be most valuable; "psycho-education for depression", "problem solving" and "healthy thinking", although a few participants did not have good recall of the sessions.

The final chapter presents a discussion of key findings together with their implications for researchers, policy makers and other stakeholders. The chapter concludes with recommendations for future research in order to understand the contextual, participant, counsellor and intervention factors involved in the implementation of task sharing interventions.

# CHAPTER 1

## Introduction

This first chapter highlights current issues in global mental health, psycho-social interventions and task sharing in low and middle income countries. The chapter also discusses the PhD study and how it fits into the larger AFFIRM-SA trial and focuses on the United Kingdom (UK) Medical Research Council (MRC) framework for developing and conducting process evaluations of interventions.

### 1.1 Common Mental Disorders and Perinatal depression

Mental, neurological and substance abuse disorders (MNS) constitute 21.2% of the global disease burden [1]. Previous studies indicated depression as the leading cause of Disability Adjusted Life Years (DALYs) in women globally, accounting for 4.1% of the global burden of disease [2] and anticipated depression to be the leading cause of the global burden of disease by 2020 [3, 4]. In 2010 major depressive disorder was ranked as the 11<sup>th</sup> leading cause of DALYs globally and 10<sup>th</sup> in Southern Sub-Saharan Africa with a 37% increase between 1990 and 2010 [5, 6]. Major depression is the leading cause of Years Lived with Disability (YLD) in 56 countries, the second leading cause in another 56 countries and the third leading cause in 34 countries [1]. Depression is the leading cause of neuro-psychiatric disability with a higher burden in women than men [2, 7] and an even larger burden in women of child bearing age [8, 9]. Low and Middle Income Countries (LAMICS) have a high prevalence of Common Mental Disorders (CMDs) which are associated with premature mortality and severe functional impairment [5, 10-12]. CMDs in LAMICS are exacerbated by socio-economic factors such as poverty, chronic unemployment and violence [12-16]. For poorer households, the economic impact of mental disorders is devastating due to loss of income or cost of treatment [17].

For the purpose of this study *perinatal depression* is defined as occurring during the perinatal period which is between conception and up to one year post-partum [18]. Two systematic reviews of Common Perinatal Mental Disorder (CPMDs) in LAMICS revealed a weighted mean prevalence of 15-20% for perinatal depression in Africa in one study [19] and 11.3% for antenatal depression and 18.3% for post-natal

depression in another study [20]. South African studies have suggested that prevalence of perinatal depression varies within and between provinces. For example, in the Western Cape province of South Africa prevalence of perinatal depression is estimated to be between 22% and 39% [21-23] while it is estimated at 47% in KwaZulu-Natal province [24]. A survey in Khayelitsha in the Western Cape revealed that depressed mood was reported by 39% of a sample of 1062 pregnant women [23]. It is important to note that the different ranges indicated above could be attributed to the varying cut off points of measurement instruments used, period of perinatal depression used, point of measurement and the varying socio-economic and cultural factors which put women in LAMICS at high risk of developing depression [25, 26].

The increased physical and social demands on perinatal women, anxiety about childbirth, combined with chronic stressors such as lack of income, inadequate social support, intimate partner violence and HIV /AIDS contribute to perinatal depression [19, 20, 23, 27, 28]. These findings are consistent with research by Lund and colleagues which reveals that elements of poverty such as low education level, unemployment and lack of household income carry strong links to CMDs which can lead to a cycle of poverty and poor mental health status [7, 16, 17, 28]. Depressed pregnant women are at further risk of obstetric complications such as slow foetal growth, pre-term labour and poor uptake of antenatal care which can lead to increased frequency of infant diarrhoea, delayed psycho-social development and diminished care-giving capacity [23, 29, 30].

Despite depression being treatable, there is a large number of women living with undetected and untreated depression [31, 32]. In South Africa a significant proportion of people with mental health problems who require mental health care do not receive sufficient attention. This is known as the “treatment gap” which is estimated to be more than 75% [16, 19-21, 33, 34]. Multiple barriers exist for the treatment of mental disorders in resource poor settings including centralised services, inadequate resources, large workloads and lack of mental health training for staff in primary healthcare [32]. Inequitable distribution of resources also results in smaller budgets being allocated towards mental health services compared to other conditions[17] .

With this context in mind, there is a need to develop accessible interventions in order to fill the treatment gap for perinatal depression in LAMICS. Psycho-social

interventions for depression are preferred by perinatal women compared to pharmacological treatment due to concerns about safety of taking pharmacological treatment during pregnancy and while breastfeeding [28, 35, 36]. There is evidence that Cognitive Behavioural Therapy (CBT) can be as effective as medication in the treatment for moderate to severe depression in both men and women after eight weeks of intervention [37].

## **1.2 Task sharing**

Task sharing (sometimes referred to as task shifting) has been recommended as a method for reducing the treatment gap and increasing access to care [32, 38]. In this model, specialists provide training, supervision and support of lay health workers to enable them to identify and treat mental disorders [39]. Task sharing has several advantages, such as providing culturally sensitive treatment by local people [40, 41] and increasing access to care and sustainability if provided within the context of a good referral system with quality assurance [3, 39]. If task shared interventions are provided with inadequate training, supervision and support, the strategy can result in inferior service [42]. Task sharing has been shown to be effective for the treatment of depression in women and men in Uganda [43] and for perinatal women in Pakistan [44]. Below, I will illustrate how task sharing has been used for two notable programmes in LAMICS for the treatment of common mental disorders.

### **1.2.1 The Thinking Healthy Programme (THP)**

The THP, developed by Atif Rahman and colleagues in Pakistan [44] is based on Cognitive behavioural therapy (CBT) principles such as cognitive reframing, collaboration, focusing on the here and now and uses behaviour activation and problem solving techniques [44]. The THP offered women 16 home based sessions, which focused on three main areas: the mother's health, the mother-infant relationship and psycho-social support from the family [44]. Rahman and colleagues demonstrated how lay health workers (LHW) can be successfully trained to deliver a healthy thinking intervention for depressed women as part of their routine care [44]. Women who received the intervention experienced better social functioning, less depressive symptoms and less disability compared to women who did not receive the intervention [44]. The THP has been manualised by the World Health Organization (WHO) and has been adopted as the preferred psychological intervention for maternal depression by

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the WHO [45]. The THP followed similar steps to the United Kingdom Medical Research Council (MRC) framework for the development and evaluations of complex interventions [46] which will be explained in a later section. Both quantitative and qualitative methods were used to evaluate the THP intervention. Participants and LHW were interviewed post-intervention and gave feedback on the intervention content and structure which helped the intervention team to make further improvements [44].

### **1.2.2 The Friendship Bench Programme**

Women who experience depression tend to battle with rumination of negative and sometimes irrational thoughts which have been described as *Kufungisisa* in Shona (the terms which best describes depression) [47]. Research on the Friendship Bench (known as *Chigaro Chekupana Mazano in Shona*) in Zimbabwe demonstrates how lay counsellors can be trained to use Problem Solving Therapy (PST) in an effort to reduce the symptoms of depression and CMDs [47]. The Friendship Bench offered people living with HIV (PLWH) six PST sessions while sitting on bench in a secluded area at the clinic. These sessions focused on collaboration for problem identification and exploration of the problem followed by the identification of a solution [47]. Lay health workers were trained to deliver the counselling sessions by clinical psychologists and psychiatrists and complex cases were referred to the psychologist or psychiatrist [48]. The Friendship bench programme was evaluated through qualitative methods and findings reveal that use of local terms contributed to the acceptability and sustainability of the programme [48]. A theory of change approach was used for the development of the Friendship Bench intervention [49].

### **1.3 Theoretical framework for development and evaluation of interventions**

Evaluations of interventions are crucial for sustaining and improving public health interventions [50]. There are several theoretical frameworks for designing and evaluating complex interventions such as theory of change (ToC) and realist evaluation. ToC is an approach used for programme design and evaluation which seeks to understand why and how a programme works [51]. ToC also explicitly hypothesises how a programme will achieve its impact through a causal pathway [52]. ToC is “developed in a collaboration with all relevant stakeholders and it is modified

throughout intervention development and evaluation” [51]. Realist evaluation is an approach which assesses if the basic implementation plan is feasible, durable, valid and sound [53]. ToC and Realist evaluation approaches focus on broad system based interventions and thus are ideal when looking at scaling up interventions. The Medical Research Council framework of the development and evaluation of interventions provides a way to evaluate an intervention prior to scaling it up at a system level. This framework will be explored in the following section.

### 1.3.1. The MRC framework

In 2008, the United Kingdom (UK) Medical Research Council (MRC) published a revised framework for developing, evaluating and implementing complex interventions. The framework proposes a cyclical process with four stages including: intervention development, feasibility and piloting, evaluation and implementation with emphasis on process evaluations which explore the relationship between delivery of the intervention, causal pathways and the local context [46, 54]. These stages are not linear allowing for revisions based on findings from the pilot or modifying the intervention if there is feedback on problems encountered during the implementation stage [46]. In 2015 the MRC further modified this framework to include guidelines on

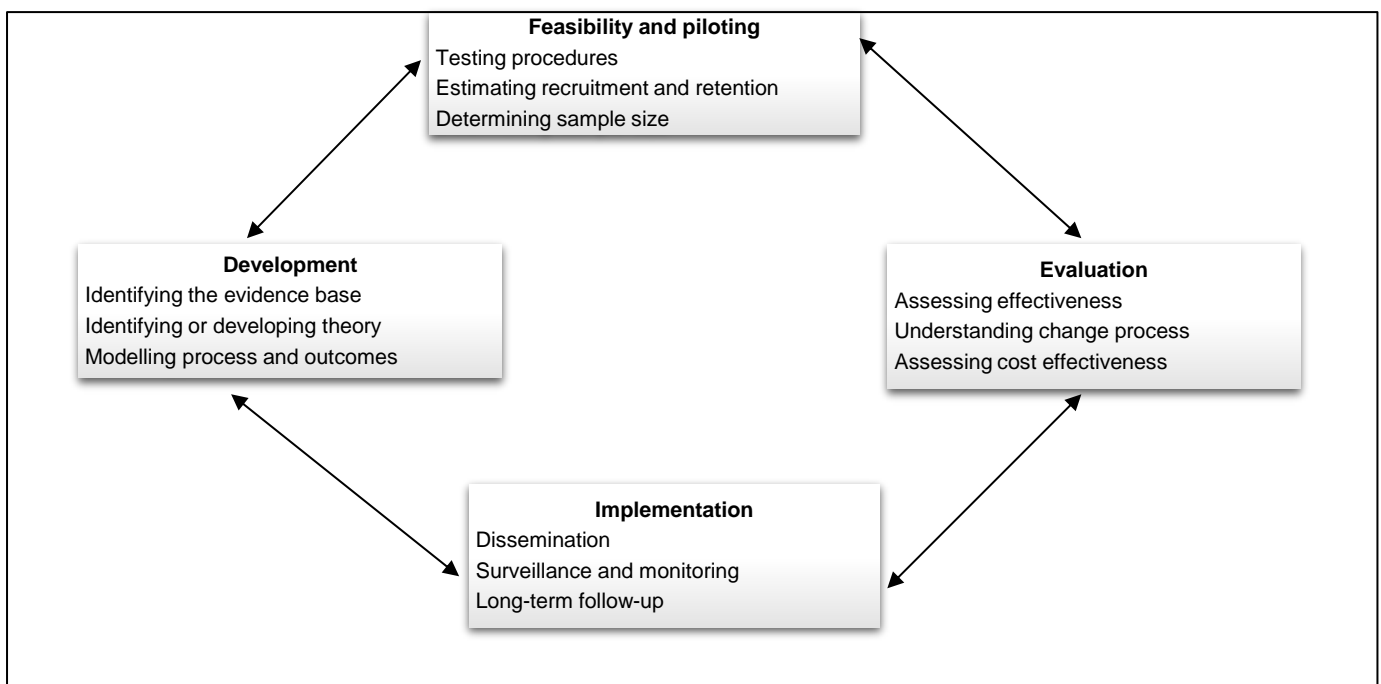


Figure 1: MRC Framework for Intervention Development and Evaluation

conducting process evaluations [54]. The MRC frameworks are the most appropriate for this study because they can be applied to all of the objectives of this PhD. Study one provided a foundation for intervention development through a systematic review focusing on the qualitative evidence of process evaluations from other studies in LAMICS. Study two focused on the feasibility, acceptability and development of the intervention based on theory and results of the feasibility study. Studies three and four looked at implementation and evaluation by conducting post-intervention qualitative process evaluations of the intervention from the perspective of providers and recipients. This PhD does not examine the effectiveness or cost-effectiveness of the intervention, which were examined in the broader AFFIRM-SA trial.

#### **1.4 The context for the PhD study: The AFFIRM-SA Trial**

My study forms part of a larger study within the AFrica Focus on Intervention Research for Mental health (AFFIRM-SA) project which ran a Randomized Controlled Trial (RCT) testing the effectiveness of task sharing for perinatal depression in Khayelitsha (AFFIRM-SA trial) led by the University of Cape Town (UCT) and funded by the National Institute of Mental Health (NIMH, USA) [55, 56]. A brief description of AFFIRM-SA participants, study design and instruments will be given below in order to contextualise my study.

The study was conducted in Khayelitsha, Cape Town. Khayelitsha is one of the largest townships on the eastern outskirts of Cape Town nearly 30 kilometres from central Cape Town with over 500 000 residents, the majority of whom are Xhosa speaking [57, 58]. Townships were developed for Black South Africans through the segregation policies of the apartheid government and have continued to exist as property prices in more expensive suburbs continue to exclude poorer populations [57, 58].

##### **1.4.1 AFFIRM-SA Intervention**

The intervention was conducted in the antenatal phase of the participant's pregnancy and carried on into the postnatal phase if the participants had not completed the sessions before they gave birth. [55, 56, 59]. The intervention, which is the focus of Chapter 3, (published in BMC Psychiatry) [59], was based on Cognitive Behavioural Therapy [60] and Problem Solving Therapy principles [61]. The six AFFIRM-SA counsellors used a structured manual to deliver six sessions and fidelity to the manual

was monitored regularly by a Mental Health counsellor (MHC) a clinical social worker (the PhD candidate), who trained the counsellors and supervised them weekly during the delivery of the intervention [62]. The six sessions were as follows: session one – psycho-education for depression, session two – problem solving, session three – behaviour activation, session four – healthy thinking, session five – psycho-education about birth preparation and lastly session six – termination and evaluation. A table which summarises the intervention is presented in Chapter 3 in the 2016 BMC Psychiatry publication.

#### **1.4.2 Study Design: AFFIRM-SA Trial**

The AFFIRM-SA study was an individual-level RCT with two arms. A total of 425 depressed pregnant women were recruited for both arms of the trial and randomly assigned to both groups resulting in (209 in the intervention group) and (216 in the control group). The intervention group received counselling over a period of three to four months (two sessions per month) as indicated above. Twelve Community Health Workers (CHW) were trained and six were selected to deliver the counselling for the intervention. The control group received enhanced usual care through attending their routine antenatal services as well as a monthly phone call for three months. Two Community Health Workers were trained to conduct the phone calls but with no training in basic counselling and were also supervised by the MHC [55, 56].

#### **1.4.3 Trial Inclusion and exclusion criteria for participants**

For participants to be recruited into the study they needed to be pregnant women in their first and second trimester (below 28 weeks of pregnancy) who screened positive for depression on the Edinburgh Post-natal Depression Scale (EPDS) (score  $\geq 13$ ) [63], were aged 18 years or older, had capacity to give informed consent, lived in Khayelitsha and spoke Xhosa. Pregnant women who were below 18 years, women who did not screen positive for depression on EPDS (score  $< 13$ ), were later than 28 weeks in their pregnancy, did not live in Khayelitsha and/or did not speak Xhosa were excluded from the study [55, 56].

#### **1.4.4 Measurement**

Assessment of the participants was conducted through administering, among a number of other measures, the EPDS and Hamilton Depression Rating Scale (HDRS). A full list of assessment measures can be found in the AFFIRM-SA trial protocol paper [56]. The EPDS is a brief self-reporting instrument which is widely used to detect symptoms of depression in pregnant women. It can also be used in an antenatal setting and can be repeated throughout the perinatal period in order to monitor changes in symptoms [18] (see appendix A). The EPDS has been translated and validated in different cultural settings including among Xhosa speaking pregnant women in South Africa [24].

The HDRS is an instrument for rating depression symptoms by clinicians, which has been modified for the AFFIRM-SA study to detect severity of depression by lay fieldworkers through asking of standard questions; [64] (see appendix B). The HDRS was translated for the purpose of this study and was validated as part of the AFFIRM-SA trial. The HDRS was the primary outcome measure to determine the effectiveness of the intervention. Assessments were conducted at four time points, at baseline, at eight months gestation, and at three and 12 months post-natal.

#### **1.5 Relationship of thesis to AFFIRM-SA**

This thesis presents a sub-study of the AFFIRM-SA RCT [55, 56] described above. However, the sub study only focuses on the intervention group and their counsellors in order to conduct a qualitative process evaluation to evaluate the implementation of the intervention. A large part of the PhD data was drawn from the formative (preparatory) research for the AFFIRM-SA trial which was used to describe the development of a task sharing counselling intervention for depressed pregnant women in Khayelitsha.

#### **1.6 Qualitative research methods**

Qualitative research methods are often used in health services research to understand the participant perspective and to explore the meaning that is given by participants to specific concepts [65, 66]. Qualitative methods can be used to inform research design and to determine data collection, analysis and interpretation of studies. These methods are useful for the development, implementation and evaluation of policy [66, Memory Munodawafa Thesis 2018

67]. The following qualitative methods can be used to understand participant perspectives; ethnography, narrative, phenomenology, grounded theory and the framework approach [65, 66]. Ethnographic approaches include observational studies and are used in Anthropology or Sociology to provide in-depth descriptions of naturally occurring data such as people's culture and beliefs. These generally require immersion by the researcher within the participants' context and, as a result, are prone to observer bias [66, 68]. Phenomenological approaches entail exploring the meaning that is attached to an individual's words or discourse [66]. The above methods were not appropriate for the PhD study as the aim was not about understanding phenomena but rather about describing experiences of providing and receiving the intervention.

The narrative approach is where participants are asked to recount their personal experience or stories as a way of highlighting their plight and emphasising their point of view [65, 66]. Grounded theory includes open coding and sampling until saturation point where information arises from the data itself in order to develop a theory or emergent theme [66, 69-71]. Grounded theory therefore excludes a hypotheses and predetermined sample size which makes it difficult to use when evaluating an intervention [68]. The narrative and grounded approaches were not appropriate for the PhD as the study required some structure as well as a thematic framework based on the MRC framework for process evaluations.

Qualitative approaches make use of individual or focus group interviews to obtain in-depth information on the participant's experience. These interviews can be informal, structured, semi-structured and in-depth depending on the researcher's objectives. Structured interviews allow the researcher to follow a set of questions whereas in-depth interviews allow the participant to go into detailed descriptions of their perspectives [65, 66].

The framework approach starts from a given hypothesis and a set of predetermined themes that are selected specifically to address a research question. However, the use of open ended semi-structured questions allow for nuanced responses. While this approach predetermines a number of the relevant themes, it also allows for themes to evolve as the researcher familiarizes with the data [66, 72]. The framework approach has five distinct phases which are used to summarise and organise data into a thematic framework. The steps are; familiarization, thematic analysis, indexing,

charting, mapping and interpretation [72-74]. When comparing all the methods listed above, it is important to note how labour intensive and time consuming each are and their fit with the research question [65, 68]. The framework approach provided the best analytical approach which was the most appropriate for this study as it provides a very structured research question and facilitated an examination of specific themes.

## **1.7 Assessing the effectiveness of an intervention**

There are different aspects of assessing effectiveness of interventions when conducting randomized controlled trials (RCT). Investigators can either choose to conduct efficacy or effectiveness trials. Efficacy trials examine whether the treatment can work under optimal conditions (explanatory) whereas effectiveness trials focus on whether the intervention works in real world settings (sometimes referred to as pragmatic or management studies) [75]. RCTs tend to examine effectiveness in order to apply findings to future clinical settings due to the need for replication of future studies [75]. The larger AFFIRM-SA study examines the effectiveness and cost effectiveness of a task shared intervention. However, details of the trial results are not included in this thesis and will be published in a separate trial outcome paper. Conducting a process evaluation within an RCT is a good way to look at how the intervention components contribute towards intervention effectiveness. More information on process evaluations is included below.

### **1.7.1. Process evaluation**

Process evaluations in public health help to explore success and failure of interventions [50]. Process evaluation helps us to understand why and how an intervention works which can help to improve intervention effectiveness by refining the theory behind the intervention [50]. In a way, process evaluation helps to examine the components of the intervention separately in order to identify and refine a component that did not work instead of discarding the whole intervention [76]. The new MRC framework for conducting process evaluations suggests that process evaluations should examine three main factors: (i) context (the wider environment in which the intervention is delivered), (ii) implementation (the content and delivery of the intervention) and (iii) mechanisms (intermediate mechanisms that impact on the

intended effects such as participant responsiveness to the intervention, mediators and unintended pathways and consequences) [54]. Process evaluations can be conducted through qualitative or quantitative methods. Process evaluations within an RCT are useful as they give in-depth information on the relationship between the implementation, mechanisms and context of the intervention which can be linked to the outcomes of the intervention [67].

Qualitative process evaluation can explore service user and service provider perceptions of the intervention [77] in order to develop future interventions that are acceptable and culturally sensitive [41]. It is important for qualitative evaluations to have clear criteria for the appraisal of the quality, such as the Consolidated criteria for reporting qualitative studies (COREQ), a 32 item check list used to examine methodological rigour in qualitative studies, included in the appendices [78]. For this study, qualitative methods were the most appropriate methods to conduct process evaluations to explore participant and provider perceptions of the interventions while examining the context and the responsiveness to the interventions simultaneously. Although qualitative process evaluations provide detailed descriptions of participant and provider perceptions, they lack evidence of how those processes can be linked to the outcomes. The quantitative outcomes of the AFFIRM-SA RCT are beyond the scope of this doctoral study.

### **1.7.2. Manualized interventions**

Developing a manual and a protocol for supervision facilitates quality assessment of an intervention which is an important aspect of delivering the intervention, particularly in the context of task sharing psychological interventions to non-specialist health workers [79]. The use of manuals for task shared interventions is encouraged as it facilitates standardisation of the intervention and fidelity of implementation [80]. Both the THP and the Friendship Bench Intervention described above made use of counselling manuals for the training and implementation of the interventions.

### **1.7.3 Fidelity checking**

The assessment of fidelity is part of the growing field of implementation research theory and frameworks which is crucial for the evaluation of interventions [81-83].

Examining the fidelity of an intervention helps to explain why interventions succeed or fail [84]. Fidelity can be defined as the extent to which an intervention is delivered in the way that is was planned. This can be measured by five components which are; adherence, dose, quality of delivery, participant engagement and programme differentiation [84, 85]. Adherence looks at the extent to which the intervention is delivered according to the prescribed format, dose looks at the number of sessions completed, quality of delivery focuses on the general understanding of the concepts, participant responsiveness examines the extent to which participants are involved in the intervention and program differentiation focuses on the extent to which the program deviates from the prescribed format [84]. A fidelity checklist is a useful tool when assessing intervention fidelity. It can include a list of minimum core intervention components that should be adhered to for an intervention to have a high fidelity rating [86]. Fidelity assessment examines the quality of an intervention and good fidelity is associated with adequate training, supervision and high motivation to deliver the intervention [80]. It is important for task shared interventions to conduct fidelity checks in order to ensure that the counsellors are adhering to the intervention manual. Neither the THP nor the Friendship Bench programme indicated how they assessed implementation fidelity. This study includes a brief fidelity assessment as part of Chapter 4.

## **1.8 Rationale**

The rationale for conducting this research is based on several gaps in knowledge which this study aims to fill:

1. In South Africa and particularly in Khayelitsha we have evidence of a substantial burden of both antenatal [23] and postnatal depression [22] but there is limited evidence on effective interventions for depression. Early identification and intervention for antenatal depression in LAMICS can improve pregnancy outcomes and could also serve as an early indicator for post-natal depression [24, 87]. Going beyond the quantitative analysis of research, there is little evidence on the more experiential and qualitative aspects of how the intervention was delivered and received.
2. Task sharing treatment for maternal depression can be viewed as a culturally

appropriate and low cost method of improving the quality of life of the mother, her child and family members and reducing disability [47]. The combination of high prevalence of mental health disorders in LAMICS, low numbers of mental health service providers [32], and limited research on the task sharing approach as a means to reduce the treatment gap [88] underscores the importance of building up the evidence on the effectiveness of the task sharing approach to find out if lay health workers can deliver effective treatment for depression.

3. Psychological intervention for depression is often preferred to pharmacological intervention during pregnancy [27]. Counselling in various forms (e.g. CBT) has been shown to improve the mother's mental health [27]. Several studies have shown the effectiveness of group interventions [4, 36, 43]. However few studies have used individual counselling. This study adds to the pool of information on individual counselling within resource poor settings.
4. Conducting two components of post-intervention process evaluations, one with service providers and another with service users within a RCT helps to examine implementation and contextual factors associated with the outcomes of the intervention which is crucial for intervention modification prior to scaling up [77]. My study will therefore include a process evaluation of the intervention in order to assess participants' and counsellors' perceptions on components of the intervention that were useful and valuable as indicated in objectives three and four. This study will address the gap in qualitative intervention research through providing more information on the needs of participants and counsellors thus enhancing our understanding of the development of interventions for the improvement of mental health interventions [27]. This thesis contributes to the growing field of task-shared interventions for perinatal depression in an effort to increase access to care and decrease the treatment gap of depressed pregnant women. The following section summarises the thesis aims and objectives. The thesis has one primary aim (a process evaluation) which triangulates data from four sources which were published literature, perspectives of local depressed women, perspective of the counsellors in the trial and recipients of the intervention in the trial.

## 1.9 Study aims and Objectives

This thesis covers four objectives with each objective linked to a publication:

**Objective 1-** To identify the qualitative evidence on process evaluations that have been conducted on task shared psychological interventions for perinatal depression in LAMICS.

**Objective 2-** To explore how a manual based counselling intervention can be developed and to assess if it is acceptable to mothers, lay health workers and nurses.

**Objective 3** – To assess if lay health workers can be trained to deliver the counselling intervention for depressed mothers under the supervision of a mental health specialist in South Africa, focusing on (i) how well counsellors are able to deliver the intervention as intended with fidelity to the manual; and (ii) What the counsellors think about the intervention that they delivered.

**Objective 4** - To explore the experience of the participants who either did not receive the intervention or those with partial or complete attendance to the intervention.

## 1.10 Structure of thesis

**Chapter 1:** Introduction and literature review giving background information on perinatal depression and common mental disorders.

**Chapter 2:** Systematic Review and qualitative meta-synthesis. The review examines qualitative evidence of process evaluations of task sharing interventions for perinatal depression in LAMICs in relation to the UK MRC framework for conducting process evaluations in the form of a systematic review.

**Authors:** Munodawafa, M; Mall, S; Lund, C and Schneider, M. Process evaluations of task sharing interventions for perinatal depression in Low and Middle Income Countries (LMIC):

**Status:** *Published. BMC Health services research. 2018 18(1), 205.*

**Chapter 3:** Filling the treatment gap: developing a task sharing counselling intervention for perinatal depression in Khayelitsha. This study explores the feasibility, acceptability and content of a task sharing counselling intervention as part of the development of a task shared intervention.

**Authors:** Nyatsanza, M; Davies, T; Schneider, M and Lund, C.

**Status:** *Published BMC Psychiatry 2016 16(1), 164.*

**Chapter 4:** A process evaluation exploring the lay counsellor experience of delivering a task shared psycho-social intervention for perinatal depression in Khayelitsha, South Africa. This study presents a post-intervention qualitative process evaluation of lay counsellors.

**Authors:** Munodawafa, M; Lund, C and Schneider, M.

**Status:** *Published: BMC Psychiatry 2017, 17(1):236.*

**Chapter 5:** A process evaluation exploring the participant's experience of receiving a task shared psycho-social intervention for perinatal depression in Khayelitsha, South Africa. This study presents a post-intervention qualitative process evaluation of participants.

**Authors:** Munodawafa, M; Lund, C and Schneider, M.

**Status:** *For submission: Global Mental Health*

**Chapter 6:** Discussion which links all the objectives of the thesis by examining the summary of findings for each paper and makes recommendations for practice, future research and policy.

Table 1: Summary of objectives

Objective covered	Method	Data used	Participants	Analytical approach
<b>Objective 1: To conduct a systematic review</b>	Data base search for and selection of articles	Journal articles on qualitative evaluations of task sharing interventions	N/A	Systematic Review
<b>Objective 2: Development of the intervention</b>	<ol style="list-style-type: none"> <li>1. Qualitative interviews</li> <li>2. Document Review</li> <li>3. Panel Discussion</li> </ol>	Semi-structured interviews in formative research	<ol style="list-style-type: none"> <li>1. Service users : <ul style="list-style-type: none"> <li>• Depressed pregnant women</li> <li>• Depressed mother of young babies</li> </ul> </li> <li>2. Service providers: <ul style="list-style-type: none"> <li>• HIV counsellors</li> <li>• CHWs</li> <li>• Midwives</li> </ul> </li> </ol>	Thematic coding using framework analysis
<b>Objective 3: Lay counsellor experiences and fidelity</b>	Qualitative	<ol style="list-style-type: none"> <li>1. Semi-structured Interviews with counsellors</li> <li>2. Transcribed and translated session recordings</li> </ol>	<ol style="list-style-type: none"> <li>1. 6 AFFIRM-SA Counsellors</li> </ol>	Thematic coding from counsellors' perspective Fidelity rating using a structured fidelity checklist
<b>Objective 4: Participant experiences of intervention</b>	Qualitative	<ol style="list-style-type: none"> <li>1. Semi-structured Interviews with participants</li> </ol>	<ol style="list-style-type: none"> <li>1. Selection of 36 participants selected from the 6 counsellors</li> </ol>	Thematic coding from participants' perspective

### 1.11 Ethical considerations

Ethical approval for the AFFIRM-SA study was granted through the University of Cape Town Health Sciences Human Research Ethics Committee (HREC Reference no: 226/2011 for the main trial and 842/2014 for this specific PhD study), the Western Cape Department of Health and the local Community Health Centre (CHC) heads. All counsellors and AFFIRM-SA study participants gave written informed consent to participate in the study and to have their interviews audio recorded and findings used for publication. Please see attached appendices C to F.

### **1.12. The Candidate's role in the AFFIRM-SA Trial**

The candidate was the Mental Health Counsellor (MHC) on the AFFIRM-SA trial. The candidate was part of the development of the intervention, collated and edited the counselling and training manual in consultation with the AFFIRM-SA team, conducted the training of the counsellors and selected the counsellors for the intervention. The candidate also conducted ongoing supervision and support of the counsellors once they started delivering the intervention. Post-intervention roles included developing the post intervention interview topic guides, developing the fidelity assessment checklist and lastly the candidate conducted the analysis of all the data used in the PhD papers.

# CHAPTER 2

## **Process evaluations of task sharing interventions for perinatal depression in Low and Middle Income Countries (LMIC): A systematic review and qualitative meta-synthesis**

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### **Description of Contribution of the candidate**

This study was designed with the guidance of both supervisors. Memory Munodawafa developed the protocol which was reviewed by all authors; both supervisors and co-author Dr Sumaya Mall. Dr Mall and Memory Munodawafa both screened the abstracts using the inclusion and exclusion criteria. All full text articles were double screened. Memory Munodawafa conducted the data extraction and analysis and wrote the first draft of the paper. All authors reviewed and gave input into the final manuscript prior to submission for publication.

Current status: Published in BMC Health service research journal

## **Abstract**

*Background:* Perinatal depression is common in low and middle income countries (LAMICs). Task sharing interventions have been implemented to treat perinatal depression in these settings, as a way of dealing with staff shortages. Task sharing allows lay health workers to provide services for less complex cases while being trained and supervised by specialists. Randomized controlled trials suggest that these interventions can be effective but there is limited qualitative information exploring barriers and facilitators to their implementation. This systematic review aims to systematically review current qualitative evidence of process evaluations of task sharing interventions for perinatal depression in LAMICs in relation to the United Kingdom (UK) Medical Research Council (MRC) framework for conducting process evaluations.

*Methods:* We searched Medline/ PubMed, PsycINFO, Scopus, Cochrane Library and Web of science for studies from LAMICS using search terms under the broad categories of: (a) “maternal depression” (b) “intervention” (c) “lay counsellor” OR “community health worker” OR “non-specialist” and (d) “LAMICs”. Abstracts were independently reviewed for inclusion by two authors. Full text articles were screened and data for included articles were extracted using a standard data extraction sheet. Qualitative synthesis of qualitative evidence was conducted.

*Results:* 8420 articles were identified from initial searches. Of these, 26 full text articles were screened for eligibility with only three studies meeting the inclusion criteria. Main findings revealed that participants identified the following crucial factors: contextual factors included physical location, accessibility and cultural norms. Implementation factors included acceptability of the intervention and characteristics of the personnel. Mechanisms included counsellor factors such as motivating and facilitating trust; intervention factors such as use of stories and visual aids, and understandability of the content; and participant factors such as shared experience, meeting learning needs, and meeting expectations.

*Conclusions:* While task sharing has been suggested as an effective way of filling the treatment gap for perinatal depression, there is a paucity of qualitative research exploring barriers and facilitators to implementing these interventions. Qualitative process evaluations are crucial for the development of culturally relevant interventions.

Keywords: MRC process evaluation guidelines, perinatal depression, task shared intervention, lay health worker, Low and middle income country.

## 2.1 Background

Perinatal depression is a significant public health issue in both high income (HIC) and low and middle income countries (LAMICs) [19, 27]. Perinatal depression which refers to the experience of depression during pregnancy and up to one year post-partum can be associated with adverse consequences for both mother and baby [89]. In LAMICs, where resources are few, and access to mental health professionals is limited, [32, 38, 90, 91] prevalence of perinatal depression is estimated to be 15.9% [19]. The experience of perinatal depression in LAMICS is exacerbated by poverty, unemployment, HIV/AIDS, and intimate partner violence.

LAMICS have a “treatment gap” where up to 75% of people who need mental health treatment do not always receive optimal care [33, 34]. Research suggests that task sharing is a successful means of addressing this “treatment gap” for perinatal depression in resource poor settings [8, 92]. Task sharing is an approach to mental health service provision whereby non-specialist health workers provide care for less complex cases under the training and supervision of a specialist. This shares the burden of care [32] while providing locally relevant interventions to people from the same community and cultural background who speak the same language [40, 93].

Although the line between efficacy (whether the treatment works under ideal circumstances) and effectiveness (whether the treatment works in real world situations) [75] in relation to task sharing for mental health in LAMICS has been somewhat blurred, many trials have proceeded to effectiveness evaluations without necessarily demonstrating efficacy. Several studies have suggested that task sharing has benefits and results from a Cochrane review indicate that non-specialist workers can be trained to deliver psychological interventions with training and supervision in order to improve the symptoms of perinatal depression in mothers [94]. Task sharing has also been shown to be effective for the treatment of perinatal depression in Pakistan and for depression in men and women in Uganda [43, 95]. There is a need for both process evaluations and in-depth qualitative analyses of task shared interventions to develop a better understanding of factors contributing to their sustainability. Providing qualitative evidence on interventions is crucial for gaining insight into the participants’ and service providers’ views on the development of acceptable interventions [96].

The new United Kingdom (UK) Medical Research Council (MRC) framework for process evaluations provides guidelines for conducting process evaluations in order to assess the quality of implementation and fidelity to the intervention [54]. The framework further recommends examining the relationship between three main factors: implementation, context and mechanisms [54]. Implementation includes examining the resources provided for the intervention and their appropriateness, such as counsellor training, supervision, manuals, dose and reach (the total number of sessions and participants reached) [54]. The context includes examining the external environmental or community (such as rural or urban setting and common cultural or religious practices), and service structure factors such as acceptance by local Primary Health Centre [97]. Mechanisms refer to participant responses to the intervention and the aspects of the intervention that lead to change in the participant's behaviour including counsellor motivation to conduct the intervention and participants' motivation to attend sessions [54]. In this study we understand mechanisms to include both the mechanisms of the intervention and the mechanisms of implementation (which are important to consider in the context of task sharing). The context, implementation and mechanisms can be used to examine factors that affect the intervention [54].

There have been previous qualitative studies on task sharing for mental health care in LAMICS without a clear process evaluation which highlight important factors that affect the intervention's acceptability and feasibility. These include: service providers' level of confidence, distress experienced by participants, fidelity to the intervention, acceptability of the intervention, costs and policy alignment and adequate incentives [98]. Several barriers to task shared interventions have been noted including poor adherence, low acceptability of talk therapy, stigma of mental health interventions and burnout due to increased workload for service providers [93]. Synthesising themes across these various studies is useful to evaluate the appropriateness, acceptability and effectiveness of interventions [99, 100]. Qualitative studies can provide nuanced detailed understandings regarding the process of delivering interventions which are not accessible through quantitative data. Within the context of task sharing, qualitative studies can complement quantitative studies because most studies do not report qualitative data from trials, and this is an important area to highlight for future research [101].

To our knowledge no systematic review has been conducted to synthesise qualitative evidence on process evaluations of task shared intervention for perinatal depression in LAMICs. This review seeks to answer two main questions: (i) to what extent are qualitative process evaluations conducted on task shared interventions for perinatal depression in LAMICs; and (ii) what is the best way to synthesize emergent themes from the process evaluations with the MRC framework for conducting process evaluations [54]?

## **2.2 Methods**

The full protocol is registered on the PROSPERO database URL ([http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42015025190](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015025190))

### **2.2.1 Search strategy**

Five electronic databases were searched between September and December 2015 - Medline/ PubMed, PsycINFO, Scopus, Cochrane Library and Web of science. The search terms included four concepts (a) “maternal depression” (b) “intervention” (c) “lay counsellor” which were expanded by using “community health worker” OR “non-specialist” and (d) “LAMICs” as determined by the World Bank Country classification. These phrases were adapted for use in each database. The terms “task sharing” and “process evaluation” were excluded from searches since they restricted the number of abstracts identified. In PubMed the following search terms were used, and adapted for use in other databases:

(((((perinatal) OR prenatal) OR antenatal) OR postnatal) OR postpartum) OR postpartum AND depression AND (((((community health workers) OR community health aides) OR village health workers) OR health personnel) OR fieldworkers AND counselling OR psycho-social intervention\*AND developing countries.

A full description of the search strategy is included as additional file 1. The inclusion and exclusion criteria are presented in Table 3.

Table 2: Inclusion and Exclusion criteria

	<i>Inclusion Criteria</i>	<i>Exclusion Criteria</i>
<b>Publication Type</b>	<ul style="list-style-type: none"> <li>Qualitative evidence of process evaluations of psycho-social treatment interventions for antenatal or postnatal depression</li> </ul>	<ul style="list-style-type: none"> <li>Quantitative studies which do not have a qualitative component</li> </ul>
<b>Study Design</b>	<ul style="list-style-type: none"> <li>Studies which evaluate effectiveness of both pharmacological and psycho-social intervention</li> </ul>	<ul style="list-style-type: none"> <li>Studies that only evaluate pharmacological interventions</li> </ul>
<b>Condition of Interest</b>	<ul style="list-style-type: none"> <li>Antenatal OR Post-natal OR Perinatal depression</li> </ul>	<ul style="list-style-type: none"> <li>Studies of other conditions which are not perinatal depression</li> </ul>
<b>Type of intervention</b>	<ul style="list-style-type: none"> <li>Psycho-social counselling or psychoeducation</li> </ul>	<ul style="list-style-type: none"> <li>Studies that do not include counselling or psychoeducation</li> </ul>
<b>Time point</b>	<ul style="list-style-type: none"> <li>Post-intervention evaluation</li> </ul>	<ul style="list-style-type: none"> <li>Pre-intervention evaluation</li> </ul>
<b>Study Population</b>	<ul style="list-style-type: none"> <li>Group and individual intervention by non-specialists</li> </ul>	<ul style="list-style-type: none"> <li>Studies where intervention is conducted by mental health specialists</li> </ul>
<b>Intervention Location</b>	<ul style="list-style-type: none"> <li>Studies in LAMICS</li> </ul>	<ul style="list-style-type: none"> <li>Studies in HICs</li> </ul>
<b>Language</b>	<ul style="list-style-type: none"> <li>Studies in English</li> </ul>	<ul style="list-style-type: none"> <li>Studies not in English</li> </ul>

Abstracts identified were imported into Endnote and duplicates were removed. MM (primary reviewer) and SM (secondary reviewer) independently reviewed the abstracts for each paper using the eligibility criteria described in Table 3. Upon initial screening, the majority of the articles were excluded for the following reasons; not an intervention study, a review paper not intervention and treatment other than counselling. Once full-text articles had been retrieved, MM and SM independently reviewed the studies again and the following criteria were used to further exclude papers such as: studies that do not employ a qualitative methodology, were not process evaluations nor task shared interventions and did not target perinatal depression. MM and SM had several face to face discussions to reach consensus on studies. In cases where studies provided limited information on the intervention, the authors were contacted to provide further information.

### **2.2.2 Quality Appraisal**

The review used the 2009 Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement which ensures that the study reported fits the reporting standards of systematic reviews, assesses the quality, structure and whether there is a clear explanation of the objectives, methods and results [102]. The PRISMA Statement is included as appendix C. Data were extracted using a standard data extraction table which included the following: date of publication, setting of the study (hospital/ clinic/community), study design, number of participants, age range, measures used, validity of measures, quality assessment and main process evaluation findings. This table is provided in D. The quality of the included studies was assessed by both reviewers independently using the Critical Appraisal Skills Programme (CASP) checklist which examines risk of bias, and whether the study design, recruitment strategy, data collection and analysis were appropriate for the study [103]. The CASP checklist is provided in appendix E.

### **2.2.3 Data Analysis and meta-synthesis**

Data analysis was conducted using thematic analysis. The reviewers followed the 3 steps set out by Thomas and Harden [104]: (i) free coding of data (ii) organising coded data into descriptive themes and lastly, (iii) generating analytical themes. The reviewers read the full text articles and conducted free coding of data by reading each line of text and organising the free codes into hierarchical groups of descriptive themes based on their similarities or differences [104]. Meta-synthesis involved interpreting, integrating and inferring the process evaluation elements from all the included studies identified and generating hypotheses based on these findings after discussion and consensus among the reviewers [100]. Emerging themes were integrated into the MRC Framework of context, implementation and mechanisms and further classified into sub-themes where applicable.

### **2.2.4 Results**

The database search identified 8420 articles which were screened per the process outlined in figure 1 and 7703 articles were excluded for the reasons set out above.

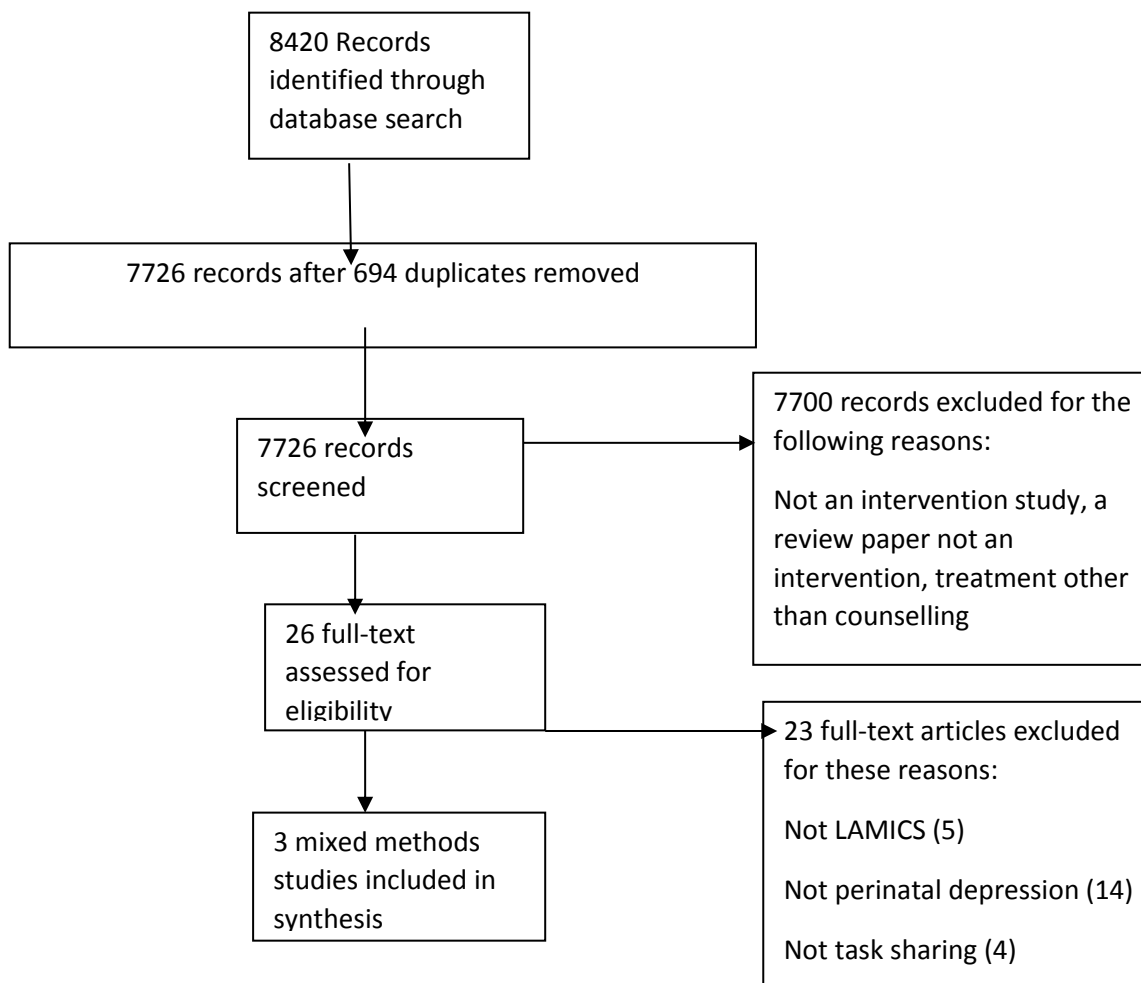


Figure 2: Flow diagram of study selection

## 2.2.5 Description of the studies

We screened 26 full text articles and three studies were selected for final inclusion in this review. All studies were written in English. The studies included were the Thinking healthy Programme (THP) from Pakistan [44], The Ekjut trial of Participatory Learning Action Groups (PLAG) in India [105] and the Interpersonal Therapy (IPT) trial in China [106]. The THP and Ekjut studies were designed as cluster Randomized Controlled Trials (RCT) [44, 105] and the IPT study was an individual level RCT [106]. Depression was measured by three different scales, the IPT study used the Edinburgh Postnatal Depression Scale (EPDS) [63] with a cut off score of 13 and above, the THP recipients were diagnosed by a trained psychiatrist using the Schedules for the Assessment of Neuropsychiatry (SCAN) [107]. The Ekjut study used the Kessler 10 (K10) [108] with cut offs between 16 and 50 to assess for depression in the second and third year of

the study due to difficulty selecting a contextually appropriate scale and did not use depression as part of their initial screening criteria. Findings reported in this current paper are for the intervention groups of the RCTs only.

All three RCTs indicated that the intervention was effective as measured by various outcome measures. The Ekjut study was focused on reducing neonatal deaths and noted a 45% reduction in neonatal mortality in the last two years of the intervention along with a 57% reduction in moderate depression in their third year [109]. The THP reported a reduction in maternal depression at six months postnatal with (23%), 97 out of 418 mothers compared to (53%), 211 out of 400 mothers meeting the criteria for major depression [95]. The IPT focused on preventing postpartum depression (PPD) and reported improved psychological wellbeing, improved interpersonal relationships and fewer symptoms of depression in the intervention compared to the control group at 6 weeks postnatal [110]. The number of women in the intervention group who scored above 13 in the EPDS reduced from 15 to 9 post intervention and the control group reported an increase of women who scored above 13, from 11 to 17 [106]. The studies are summarised in Table 3.

Table 3: Description of included studies

<b>Country, Author, Date</b>	<b>Study design</b>	<b>Intervention</b>	<b>Depression Assessment Instrument</b>	<b>Personnel</b>	<b>Duration</b>	<b>Format</b>	<b>Location</b>	<b>Evaluation Objective</b>	<b>Data collection method</b>
<b>Pakistan (Rahman, 2007)</b>	Cluster RCT	Cognitive Behavioural Therapy	Schedules of Clinical Assessment in Neuropsychiatry	Lady health workers	16 sessions	Individual	Home/Community	To develop and evaluate some processes of intervention delivery	4 Focus group discussions 30 In-depth interviews
<b>India (Rath et al., 2010)</b>	Cluster RCT	Participatory learning and action cycle (psychoeducation)	Kessler 10	Female Community health workers	20 monthly group meetings 9 under 2 hours)	Group	Home/Community	Process evaluation of the intervention	244 Focus groups Document reviews Analysis of evaluation forms
<b>China (Gao et al., 2012)</b>	Individual RCT	Interpersonal Psychotherapy	Edinburg Post-natal Depression Scale	Midwives	3 sessions (2, 90 minute sessions and 1 follow up phone call	Group	Hospital	Post intervention process and outcome evaluations	83 Program satisfaction questionnaires 20 outcome evaluations

### **2.2.5.1 Recipients and provider characteristics**

IPT recipients were middle class first time mothers under the age of 35 with uncomplicated pregnancies, PPD symptoms and no family history of psychiatric illness [106]. THP recipients were purposefully selected depressed mothers of low socio-economic status aged 17 – 40 in their perinatal period [111]. The Ekjut study participants were a purposefully sampled group of pregnant women and mothers aged 15-49 who had received the intervention and all group facilitators who provided the intervention [105].

### **2.2.5.2 Recruitment, training and supervision of personnel**

The IPT study indicated that personnel received intensive training and supervision on the intervention without giving further details regarding the nature of training and supervision [106]. In the Ekjut study, the personnel received five days of training on participatory communication, how to discuss basic health problems and two days of additional training after six months [105] (no additional information is given on the supervision of the personnel). The THP used Lady Health Workers (LHW) of varying ages and experience who had completed secondary schooling to provide counselling after a two-day workshop and one day refresher training three months after the first training. [44]. Supervision comprised half a day a month in group format and included the discussion of challenges, and brainstorming solutions. Personnel were supervised by a mental health professional and a public health expert [44].

### **2.2.5.3 Content of the intervention**

The content of the interventions were CBT for the THP [44], IPT for the IPT study [106], psychoeducation, and problem solving therapy (PST) through participatory stories and problem solving games for the Ekjut study. [105] The Ekjut study emphasised collective problem solving and planning and the intervention was divided into four phases: identify and prioritise problems, plan strategies, implement strategies and assess impact. The intervention was conducted over 20 meetings [105]. Group participants organised meetings in the community where they shared lessons learnt with community members to obtain support for implementing strategies to address their problems in pregnancy and childbirth [105]. The THP used CBT techniques of active listening, collaboration with family, guided discovery and homework applied in

LHWs' routine work of maternal and child health education [44]. The IPT study intervention used lectures and videos as the main methods of delivery [106]. IPT content included psycho-education on the transition to motherhood, obstacles to communication, communication skills, information about PPD, developing social support, identifying potential interpersonal conflict after delivery, and skills for resolving interpersonal conflict.

#### **2.2.5.4 The duration of the intervention**

The duration of the intervention varied for all three studies; for example, the Ekjut study continued for 3 years and conducted 20 monthly group meetings each lasting under two hours [105]. There is no indication of whether the sessions were antenatal or postnatal and if any women dropped out of the intervention. The THP and IPT studies conducted the interventions both in the antenatal and postnatal phases. The IPT study conducted two group antenatal classes of two hours, and a follow up phone call two weeks after delivery [106]. The THP study conducted a total of 16 sessions during the perinatal period - four weekly individual sessions in the last month of pregnancy, three sessions in the first postnatal month and nine sessions thereafter [44]. None of the studies indicated if and how implementation fidelity was monitored [50].

### **2.3. Thematic analysis of study findings**

#### **2.3.1 Context**

Contextual factors included physical location and accessibility as well as upholding cultural norms. The THP and Ekjut studies were conducted in rural areas within the community [44, 105] while the IPT study was conducted at a regional teaching hospital without further information being provided on the context [106]. According to the Ekjut team, several challenges arose from the rural context of the trial including: physical isolation of villages, difficulties building rapport with marginalised individuals and dealing with dominant group members and cancellations of meetings during festivals. As part of the context, the theme of upholding cultural norms for increasing the acceptability of the interventions was apparent in all three studies. The THP study explored socio-cultural aspects of depression from participants' point of view and

aspects of delivering the intervention from LHWs' point of view [44]. The THP study also referred to the importance of respecting participants' wishes to observe "chilla" (indoor confinement for 40 days post-delivery) thus not allowing women to do outdoor activities at this stage [44]. The IPT study helped participants understand more about the Chinese post-partum practice of "doing the month" which is a 30 day post-partum period designed to strengthen the mother's self-esteem. This includes a set of practises such as rest and seclusion, avoiding bathing or washing hair and not touching cold water [106, 112]. The Ekjut study made use of culturally appropriate materials during the meetings [105].

The THP study used the qualitative feedback from interviews with participants, lay workers and primary healthcare staff to further develop their intervention [44]. A number of changes were incorporated into the THP development, such as setting out the steps more clearly, integrating the intervention into the daily work of LHW, encouraging the family to participate in the intervention, calling LHW "trainers" instead of "therapists" and replacing the word "depression" with "mental distress" to avoid stigmatising the women [44]. There was no indication of the contextual challenges that were encountered by the IPT study.

### **2.3.2 Implementation**

Implementation factors included acceptability of the intervention and characteristics of the personnel delivering the intervention.

#### **2.3.2.1. Acceptability of the intervention**

Several factors aided the acceptability of the intervention delivered in all three studies. These include characteristics of the personnel (see below for further details), training and supervision of the personnel (discussed above), and the content and duration of the intervention. All these can be heavily influenced by the context of the intervention, such as the cultural practises of 'chilla' and 'doing the month' described above.

#### **2.3.2.2. Characteristics of personnel**

The Ekjut and the THP studies used lay health workers [44, 105] and the IPT study used midwives [106]. The THP and Ekjut studies emphasised the recruitment of respected women in the community [44, 105] and the Ekjut study also consulted local

leaders for input on selection criteria during the formative part of the study [105]. No additional information is given on the recruitment and selection of the midwives for the IPT study.

## **2.4 Mechanisms**

### **2.4.1 Counsellor Factors**

#### *Motivation to conduct the sessions*

Most of the THP lady health workers felt that the programme gave their work structure, made them more effective and that it was not a burden to their work. This motivated them to deliver the intervention [44]. The Ekjut facilitators reported feeling motivated and felt that the structured content of the intervention contributed to confidence building.

#### *Facilitating trust*

The Ekjut study participants indicated that being from the same community and flexibility in content and scheduling facilitated communication and trust within the counsellors. Facilitators felt that trust had been developed when participants started practising what they had learnt from the groups [105]. The THP study noted that trust was built through participants working together with the LHWs [44]. The IPT did not look at the issue of trust.

### **2.4.2 Intervention factors**

All three studies reported positive feedback about the intervention from both the recipients and the personnel delivering the intervention.

#### *Use of stories and visual aids*

All the interventions described both collaboration between the participant and counsellor and the use of visual aids as important aspects of the intervention. These visual aids help to include illiterate individuals by making them active participants of the intervention. The Ekjut study engaged in educational problem solving, storytelling and use of picture cards, games and role plays [105]. Similarly, the THP study used

materials such as a health calendar and health corner activities to monitor and encourage healthy behaviour among recipients [44]. The IPT study made use of a lecture and video presentations [106].

#### *Understandability of content*

Most LHW felt that the intervention was useful and they were able to understand the concepts and explain them to participants [44]. The THP study did not have further information on the specific aspects of the intervention that were helpful to the participants. The IPT study participants were motivated to attend the programme and indicated that it helped them to understand and change their attitude on the Chinese practise of “doing the month” [106].

#### **2.4.3 Participant Factors**

THP study participants rated the intervention as either useful or somewhat useful to them (48% and 47% respectively) [44]. IPT study participants revealed that they learnt more about postpartum depression, the transition into motherhood and communication skills which helped them to form better interpersonal relationships [106]. Ekjut study participants felt that a shared experience through using stories helped them to problem solve and learn more from each other [105]. From the IPT study participants, 61.4% indicated that the programme met their learning needs and 47% indicated that the programme met their expectations [106]. Most IPT participants also indicated that the programme helped them to establish or improve their relationships and all participants generally indicated that the programme enhanced their perceived social support.

#### **2.5 Discussion**

This review highlighted evidence from the qualitative process evaluations using the MRC framework to examine the context, implementation and mechanisms of the interventions from three studies. The few articles included in this review highlight the paucity of evidence on qualitative data from process evaluations on task sharing interventions for perinatal depression in LAMICs.

The context of implementation highlighted cultural aspects of the participants for all

three studies in terms of access to the intervention and intervention delivery [54]. The rural communities in Pakistan [44] (THP) and India [105] (Ekjut) used communal methods of intervention delivery such as inclusion of family members and other community members. The same two studies also made use of stories or illustrations to include illiterate participants and to reduce the stigma associated with depression. Both the THP and Ekjut studies emphasise the importance of observing important cultural practices in order to provide culturally sensitive interventions which concurs with Chowdhary and colleagues who suggest that cultural sensitivity improves the acceptability of interventions [93]. It is important to note that the IPT study only collected their evaluation data from interviews with clients whereas the THP and Ekjut studies also included interviews with people who did not participate in the intervention [44, 105].

When looking at implementation the three studies highlight common evidence based task sharing interventions in mental health which are CBT, IPT and psycho-education. The training and supervision of the interventions varied, depending on the contextual factors. There is little information provided about the supervision of facilitators for the Ekjut and IPT studies but the THP study gives details of intensive supervision process which included discussion of problems and brainstorming solutions. The duration of the interventions varied across the studies with the IPT study providing only three sessions while the THP and Ekjut studies delivered 16 and 20 sessions respectively. None of the three studies indicate how implementation fidelity was monitored, examining the fidelity to the intervention can help researcher to see if the intervention is implemented in the way it was intended [50].

Regarding the mechanisms of the intervention all three studies reported positive feedback about the intervention from the recipients of the intervention. Several factors appeared to contribute to the perceived effectiveness of the interventions. Intervention related factors such as the content and understandability, counsellor factors such as facilitating trust and motivation to conduct the intervention and participant factors such as motivation to attend the sessions and willingness to learn and change their behaviour, in terms of how they look after their children and relate to other people.

The factor of trust was emphasised in the Ekjut and THP studies. Trust was fostered through aspects such as combining participants and lay health workers from the same community and using cultural inclusion. Most of the THP health workers felt that the

programme gave their work structure, made them more effective and that it was not a burden to their work [44]. The Ekjut facilitators reported feeling motivated to help change behaviour of participants and also felt that trust had been developed when participants started practising what they had learnt from the groups [105]. These findings show that motivation to deliver or attend an intervention can be seen as provider and participant mechanisms. We can see that participants view intervention positively when personnel delivering the intervention speak the same language, and that the intervention is educational and uses some form of imagery consistent with local cultural meanings [93]. Process evaluations are helpful because they can help to increase the acceptability of an intervention. For example, the THP study made several changes based on the feedback from their qualitative interviews from their formative work such as ensuring that the terminology was appropriate.

Overall, the systematic review highlights qualitative evidence on task shared interventions which can be linked to the MRC framework categories of context, implementation and mechanisms. Understanding how the three factors relate to intervention delivery is the key to developing future interventions which are culturally appropriate and feasible in LAMICS. The context of the interventions determines the type of personnel and activities that are deemed appropriate as seen in all three studies. Counsellor factors such as motivation to deliver the intervention and facilitating trust help to encourage intervention recipients and intervention factors such as the use of visual aids and understandability of the content facilitate learning in participants and help meet their learning needs and expectations. All these factors make interventions culturally appropriate [93].

## **2.6 Recommendations**

For policy makers, we recommend the use of task sharing psychosocial interventions that are culturally adapted through paying attention to the needs of providers and recipients alike. It is also important to pay attention to duration of training and mechanisms such as trust which is built over time. Therefore it is important to invest sufficient time in training, supervision and delivery of interventions.

For researchers, it is important to publish more comprehensive qualitative process evaluations following the MRC guidelines in order to aid the development of future

interventions. There is limited information specifically focusing on training, supervision and monitoring of fidelity of interventions from the selected studies. This information would be helpful for the replication of the study in other LAMICS. Gaining an in-depth understanding of participant and provider perspectives is useful for the development and evaluation of interventions and applying the MRC framework in process evaluations could yield more effective information.

For lay counsellors we recommend that they be open to discussing the challenges or facilitators that they experienced when delivering interventions as this information is crucial for implementation research. For depressed women in the communities we recommend that additional support and training as peer educators be conducted in line with the recent peer-delivered THP study in Pakistan and India [113].

## **2.7 Limitations**

It is important to be aware of the possibility of publication bias for all identified studies, since we did not include unpublished studies and studies which were not in English. This aspect could limit the potential number of studies included in the review. It would have been helpful to know which aspects of the intervention LHW and participants found to be useful to help us understand the mechanisms involved in the effectiveness of the interventions. We contacted authors of the THP and IPT studies requesting more information on fidelity to the intervention, and training and supervision of personnel. The authors responded however the information that they provided did not shed any new light on these areas as this information was not included in their analyses. We also checked the reference lists of included studies for additional sources of information however no additional information was obtained.

## **2.8 Conclusion**

This review highlights qualitative evidence of process evaluations for task shared interventions for perinatal depression in LAMICS from three studies. There are common mechanisms which can be recommended for successful implementation of interventions, including counsellor factors, intervention factors, and participant factors. More qualitative and comprehensive process evaluations of task shared interventions for perinatal depression are necessary to help us to understand what works and what

does not work when implementing a task shared intervention both at the level of the client-provider interaction and the services and systems level. A more comprehensive application of the MRC framework for process evaluations of complex interventions would provide further information, such as fidelity to the implementation of the intervention.

# CHAPTER 3

**Title: Filling the treatment gap: developing a task sharing counselling intervention for perinatal depression in Khayelitsha, South Africa.**

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## **Description of the candidate's contribution**

This study was designed with the guidance of both supervisors. Thandi Davies conducted the formative interviews with study participants. Memory Munodawafa analysed the data and developed the first draft of the paper. All other co-authors were involved in critically revising the manuscript and all authors approved the final draft before publication.

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\*1 Nyatsanza is my maiden name and Munodawafa is my married (current) surname, at the time of submitting the publication I was still using my maiden name.

## **Abstract**

*Background:* Perinatal depression is a major public health issue especially in low income settings in South Africa, where there is a shortage of mental health professionals. New psychological interventions delivered by non-specialists are needed to fill the treatment gap. This paper describes the process of developing a manual based task sharing counselling intervention for perinatal depression in Khayelitsha.

*Methods:* Qualitative semi-structured interviews were conducted with 26 participants, including service providers and service users at a clinic in Khayelitsha in order to explore the feasibility, acceptability and content of a task sharing counselling intervention. The interviews were recorded, translated and transcribed. Themes were identified using the framework analysis approach and were coded and analysed using NVivo v10. After the semi-structured interviews, a workshop was conducted with mental health experts on evidence-based psychological interventions for depression, together with a document review of counselling manuals for community health workers in South Africa.

*Results:* The findings indicate that a task sharing counselling intervention was acceptable and feasible for depressed women in Khayelitsha, under the following conditions: (1) respondents preferred a female counsellor and felt that a clinic based individual sessions should be provided at least once a month by an experienced Xhosa speaking counsellor from the community; and (2) the content of a counselling intervention should include psycho-education on cognitive and behavioural effects of depression, how to cope with interpersonal problems, and financial stressors. Based on these conditions, the review of manuals and expert consultation, key components of the counselling intervention were identified as: psycho-education, problem solving, healthy thinking and behaviour activation. These were included in the final counselling manual.

*Conclusion:* The development of task sharing counselling interventions for perinatal depression should be informed by the views and needs of local service users and service providers. The study illustrates the manner in which these views can be

incorporated for the development of evidence-based psychological interventions, within a task sharing framework in low and middle-income countries.

### 3.1 Background

Common Mental Disorders (CMDs) are highly prevalent in Low and Middle Income Countries (LAMICs) and are known to cause disability and premature mortality [5, 10, 11]. Women in the perinatal period are highly vulnerable to depression and suicide [27, 40] and depressed pregnant women are at risk of experiencing various obstetric and neonatal complications, such as spontaneous pre-term labour and low birth weight [23, 29, 30]. Impaired mother-infant relationships and poor uptake of antenatal care together with adverse child development outcomes (including increased frequency of infant diarrhoea and delayed psycho-social development) are also common in depressed mothers, partly due to diminished care-giving capacity [23, 29, 30]. The perinatal period is defined as the period between conception up to one year post-partum [18, 40]. In LAMICs the estimated prevalence rate for Common Perinatal Mental Disorders (CPMD) is one in six pregnant women and one in five postnatal women [114]. Global rates for perinatal depression vary enormously as indicated by a review of 40 countries showing perinatal depression ranges from 0% to 73.5% [25]. Two systematic reviews in LAMICs show weighted mean prevalence rates of 11.3% and 15.6% for antenatal depression [19, 20] and 18.3% and 19.8% for postnatal depression [19, 20]. At a local level, a survey of mothers in Khayelitsha revealed a postnatal depression prevalence rate of 34.7%, a figure three times higher than samples used as comparisons in high income countries (HIC) [22]. A more recent study, also in Khayelitsha, found 39% of a sample of 1062 mothers to have depressed mood during pregnancy [23].

A systematic review identified positive associations between common contextual factors in LAMICs such as low education level, chronic unemployment, low household income, poverty, intimate partner violence, rejection of paternity, and HIV/AIDS and CPMDs [13-15, 19, 20, 23, 115]. The factors linked to low socio-economic status and CMDs can lead to a vicious cycle of poverty and poor mental health. This is exacerbated during pregnancy when some women experience increased physical and social demands such as anxiety about childbirth and lack of income or food security for the unborn child [27, 28, 115]. This cycle of poverty and ill-health can also have an intergenerational impact on infants and children of depressed mothers [23, 44, 116].

### **3.1.1 The Treatment Gap and Task Sharing**

Despite depression being treatable, a significant number of depressed women in South Africa live with undetected and untreated depression, and form part of a “treatment gap” which is estimated to be more than 75% of those requiring a service and not receiving one [33, 34]. LAMICs have the least number of mental health specialists [32], highlighting a need for innovative strategies to reduce the treatment gap. Task sharing (also known as task shifting) is a method of making more efficient use of the available resources by training general health workers, including community health workers (CHWs) to deliver interventions which would normally be rendered by specialists [38, 116]. Task sharing antenatal counselling for depressed women could potentially help improve depressed women’s mood, which in turn can prevent suicide, reduce negative obstetric complications and improve infant outcomes [40]. Task sharing is also a way of providing locally relevant treatment by people from the same community, culture and language thereby making the intervention more culturally appropriate [40, 93]. In this model, CHWs do not replace the specialists, but they can help to support less complex cases in order to reduce the number of people needing specialist care [32, 38]. If a task sharing intervention is provided in the context of a good referral system and quality assurance, this could lead to sustainable narrowing of the treatment gap in vulnerable communities [3, 39].

### **3.1.2 Evidence of task shared counselling in LAMICs**

Task sharing has been shown to be effective in a range of countries; for example, in Chile for depression [4] and in India for people living with schizophrenia [79]. It is crucial for task sharing interventions to be adapted from a pool of evidence-based interventions. There are a number of evidence-based counselling techniques which have been adapted and used in the task sharing context.

#### **3.1.2.1. Cognitive Behavioural Therapy**

Cognitive Behavioural Therapy (CBT) suggests that when an individual is depressed or distressed they experience cognitive errors in thinking such as having rigid, distorted judgement about themselves or other people [60]. CBT further suggests that if clients are taught to monitor their negative mood, thoughts and behaviour, they can learn to alter these [60], through techniques like healthy thinking and behaviour

activation. CBT has been found to be effective in LAMICs by motivating poverty stricken women to become active and change unhealthy thinking patterns, thereby reducing their depressive symptoms [44]. The Thinking Healthy programme in Pakistan, developed by Atif Rahman and colleagues, demonstrated how lady health workers can be successfully trained to deliver an intervention for depressed women [95].

### **3.1.2.2. Problem Solving Therapy**

Problem Solving Therapy (PST) is brief structured therapy which focuses on interpersonal problems in the present social context through collaborative identification, exploration of problems, and identification and implementation of solutions [47]. Research from Zimbabwe on the Friendship Bench (known as *Chigaro Chekupana Mazano* in Shona) indicates how PST can be used to reduce symptoms of depression and CMDs through providing a safe space for people to come and talk about their problems to a trained CHW counsellor [47].

### **3.1.2.3. Interpersonal therapy**

Interpersonal therapy (IPT) is an intervention which focuses on four main interpersonal problem areas, namely grief, role transitions, interpersonal or role disputes and interpersonal deficits that are believed to be at the root of depressive symptoms [117]. Understanding the root of interpersonal stress can help an individual to come up with new ways of responding to their situations as well as reduce the triggers for depressive symptoms. Task shared group IPT has been shown to be feasible and acceptable in South Africa [118] with HIV positive women and been successful in reducing depressive symptoms of men and women in Uganda [43].

## **3.2 The purpose of this study**

The purpose of this study is to describe the development of a task sharing counselling intervention for perinatal depression in Khayelitsha, South Africa as part of the AFrica Focus on Intervention Research for Mental health, South Africa randomized controlled trial (RCT) (AFFIRM-SA) [54-56] In 2000, the UK Medical Research Council (MRC) published a framework for developing, evaluating and implementing complex interventions which was revised in 2008, and again in 2015. The 2008 revised MRC

framework proposes a cyclical process with 4 stages including: development, feasibility, evaluation and implementation [46]. The focus of this study is on development and feasibility of the intervention. The final two stages of the intervention development, which look at implementation and evaluation of the intervention will be reported as part of the AFFIRM. (RCT)(AFFIRM-SA)[54-56].

### **3.3 Methods**

#### **3.3.1 Setting**

The study was conducted in Khayelitsha, Cape Town. Khayelitsha is one of the largest townships on the eastern outskirts of Cape Town, nearly 30 kilometres from the city centre, with over 500 000 residents, the majority of whom are Xhosa-speaking [57, 58]. Townships were developed for Black South Africans through the segregation policies of the apartheid government in (1948-1994). The majority of Xhosa-speaking people living in townships such as Khayelitsha, migrated from the Eastern Cape and live in informal settlements in order to seek employment [57]. High unemployment, violence, crime, substance abuse and intolerable living conditions such as inadequate sanitation and overcrowding are rampant [57, 58, 119]. Some of the township's inhabitants live in corrugated iron shacks without running water and electricity although some live in formal housing [58].

#### **3.3.2 Study design**

The study design used a triangulation of methods by synthesising findings obtained from qualitative formative research, an expert panel discussion and a review of existing counselling manuals, in order to develop the intervention. The semi-structured interviews in the formative research provided information on the feasibility of the intervention and information on the needs and experiences of the participants that should be addressed in the intervention manual. The document review and expert consultations provided information for the structure and content of the manual.

##### **3.3.2.1 Sampling and recruitment**

Consecutive sampling was used for service users by recruiting every participant who met the inclusion criteria. Screening and recruitment of service users was voluntary

and was conducted at a local antenatal and well-baby clinic Community Health Centre (CHC) in Khayelitsha. After agreeing to participate in the study through signing the consent form, users were screened using the Edinburgh Postnatal Depression Scale (EPDS). The EPDS screens for symptoms of Major Depressive Disorder (MDD) based on answers given by the respondent regarding their symptoms over the past 7 days. The EPDS has been translated and validated in isiXhosa with an optimal cut-off score of 12/13 [24]. Users who scored 13 or more on the EPDS were assessed using the Major depression module of the Mini Neuropsychiatric Interview (MINI) v 6.0 [120]. The women who were diagnosed with a major episode of depression on the MINI were interviewed for this study. Recruited users were asked to give further consent for the interview to be recorded and all user interviews were conducted in isiXhosa by a trained field worker, transcribed and then translated into English. Users who were not recruited were given information on organisations and services available in the area such as social services.

Sampling of service providers was purposive and voluntary with the aim being to recruit HIV counsellors, midwives and CHWs to explore their knowledge of depression, and ability to deliver the proposed intervention. Selected participants gave written informed consent for participating and for allowing the interview to be recorded. All the service provider interviews were conducted in English by a researcher from AFFIRM.

### **3.3.3 Semi-Structured interviews**

The semi-structured interviews assessed participants' views on the feasibility, acceptability and content of a task shared counselling intervention for perinatal depression in Khayelitsha. Tables 4 and 5 below provide a list of some of the questions asked in the interviews with service users and service providers please see appendices H and I for the full schedules. The interview schedules were developed by the AFFIRM team, informed by the relevant literature on psychological interventions for CPMD in LAMICs.

Table 4: Service user interview questions

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(Not the complete interview)

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**Symptoms of depression**

1. Do you think you have depression? Why do you think you have depression?
2. How do these feelings that you have change your daily life?
3. Think about a days when these feelings are really bad. Can you tell me what makes it really bad?

**Strategies for dealing with depression**

4. Can you describe a day you feel better and not so depressed... What makes it better?
5. Was there anything you did yourself?

**Counselling as an intervention**

6. The word/name counselling involves somebody helping you, listening to you talking about your problems, and helping you to find some solution to those problems. It does not mean the counsellor will fix your problems for you, but they can help you find ways to solve some of your own problems by giving you new skills that you can use. This counselling is not the same as HIV counselling.
7. Do you think that counselling could help you with your feelings of depression?
8. In what way could it help you?

**Logistics of counselling**

9. If mental health services are closer to where people live, will it help them to use the services? If you could see a counsellor to help you with depression, would you rather see that person at the clinic or at home? Is distance or transport that make it easy or difficult or money or maybe cost of services or getting someone to go with you?
10. If someone came to your house what will your family think? What will the community think?

**Characteristics of the Counsellor**

11. If you could choose, would you want to see a nurse, a community health worker, or an HIV counsellor to get counselling for depression?
  12. If you could see a counsellor to help you with depression, would you rather see that person at the clinic or at home?
  13. If you could choose, what type of person would you choose to give you counselling?
  14. What age should they be?
  15. What culture should they be from?
  16. Where should they come from?
  17. What qualification or training should they have?
  18. What language should they speak?
  19. How many times in a month would you like to see the person?
  20. Would it be best done individually or in a group with other people who are depressed? Please explain.
  21. What do you think some of the problems to getting this help might be?
-

Table 5: service provider interview questions

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(Not the complete interview)

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#### **Counselling Experience and Support**

1. Can you explain to me what your understanding of depression is and how you would know if a person has depression?
2. What typical symptoms do people have who are depressed and how do these symptoms affect their lives? How long do these symptoms usually last?
3. How common is depression in Khayelitsha? Are pregnant women and mothers more likely to be depressed than other people? If so, why?
4. What do you think would be the best way to help pregnant women and mothers with depression in Khayelitsha?
5. What kind of support do you think depressed pregnant women and mothers need?
6. Would you say it would be better to have a CHW or HIV counsellor to do the counselling to the mothers?
7. Do you know what mental health counsellors are? What do mental health counsellors do?
8. Do you have any counselling experience? If so, describe this experience.
9. What skills would you like to learn if you were to provide counselling to depressed pregnant women or mothers of young infants in Khayelitsha?
10. What kind of support and supervision would you need in order to do counselling for depressed mothers in their homes? How often would you like to meet with a supervisor/manager?

#### **Characteristics of the Counsellor**

1. Would you say it would be better to have a CHW or HIV counsellor to do the counselling to the mothers?
2. What kind of counsellor is acceptable to depressed mothers or pregnant women? (Gender, age, qualification, culture, race, locality, relationship/ community relations).
3. Tell me about your current work - Which organisation you work for?
4. How often do you see your supervisor and how do you report to your supervisor?
5. If you were working with pregnant women and mothers who are depressed, how many home visits do you think you could manage, over a period of 6 months? [*If the person struggles to think about 6 months ask about 1 month or even 1 week and then multiply this by 6 for months and by 26 for weeks.*]
6. When in the day and week do you think such home visits would be possible for you?

#### **Logistics of Counselling**

1. Do you visit patients at their homes? And if yes, how often do you do this? What kind of work do you normally do with patients?
2. How comfortable do you/would you feel visiting patients at home – how acceptable is it? (Probe for issues of confidentiality, safety, etc.)
3. What limitations/obstacles do you see in delivering a counselling programme to depressed patients at their homes?
4. What are the potential benefits of counselling women in their homes or clinics that you wouldn't get if you counselled them at the clinic?

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### **3.3.4 Data Analysis**

All interview transcripts were uploaded into NVivo v10 and texts were analysed using an *a priori* framework developed from the interview topic guides set out in Tables 5 and 6. The framework approach is a five step process including familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation [73]. Further codes were added to the *a priori* themes based on the emergent themes from the interviews. The first author generated themes and coded the data independently

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and circulated findings to the rest of the team who then reached consensus on the final coded data after collapsing and reorganising the themes. Of particular interest was the type of feelings experienced by the women and the activities they use to cope with these feelings. These assisted in identifying key activities to be included in the intervention.

### **3.3.5 Panel Discussion and Intervention Development**

Once the interviews were analysed, a 2-stage panel discussion was held over one day. The panel comprised of local South African mental health experts with experience in the field of task sharing, intervention development and delivery of maternal mental health care. In the first stage, the preliminary findings from the semi-structured interviews were presented to the panel. In the second stage, the expert panel discussed the adaptation of evidence-based techniques to fit the local context (as presented in the interview data) for delivery by CHWs. The discussion and recommendations made by the panel were incorporated into the development of the proposed intervention and training manual.

### **3.3.6 Manual Development**

Balaji and colleagues suggest that in the context of task sharing psycho-social interventions it is important to develop a manual as well as a protocol for supervision to promote fidelity and a high quality intervention [79]. The third part of the intervention development was thus the development of the manual through a review of other manuals used to train community health workers in counselling in South Africa and other LAMICs. These manuals included The Perinatal Mental Health Project (PMHP) basic counselling skills guide [121], the Lifeline/Childline basic counselling skills participant manual [122], the STRIVE Booklet by the South African National Council of Alcoholism and Drug Dependence (SANCA) [123], the Thinking Healthy manual [124], the PRogramme for Improving Mental Health carE (PRIME) psychosocial group intervention for maternal depression [125] and a CBT manual for medication adherence and depression (CBT-AD) in HIV-infected patients, a version adapted for South Africa by Safren and colleagues [126]. These were reviewed in light of the interview findings and expert panel recommendations, and subsequently the core components of the AFFIRM perinatal counselling manual were drafted.

### 3.4 Ethical Approval

All study participants gave written informed consent to participate in the study and to have their interviews recorded and findings used for publication please see appendices F and G for consent forms. Ethical approval for the AFFIRM SA study was granted through the University of Cape Town Health Sciences Human Research Ethics Committee (HREC Reference no: 226/2011 and 842/2014), the Provincial Department of Health and the local CHC head.

### 3.5 Results

Table 6: Frequency of themes

Theme	Services users	Service providers	Total	Percentage
Counselling as an intervention				
Counselling acceptable	12/12	N/A	12/12	100
Counselling as advice	4/12	N/A	4/12	33
Clinic visits preferred	6/12	3/14	9/26	35
Individual sessions preferred	7/12	N/A	7/12	58
Group sessions preferred	5/12	N/A	5/12	42
Barriers to counselling	4/12	8/14	12/26	46
Middle aged, Xhosa woman,	11/12	5/14	16/26	62
Willingness to counsel & positive attitude	N/A	2/14	2/14	14
CHWs recommended	6/12	8/14	14/26	54
Already had counselling training	N/A	4/14	4/14	29
No skills for counselling	N/A	2/14	2/14	14
Avoidance	9/12	N/A	9/12	34
Aggression and withdrawal	6/12	8/14	14/26	54
Exacerbating factors				
Financial Stressors	5/12	6/14	11/26	42
Anxiety	7/12	5/14	12/26	46
Coping strategies	11/12	N/A	11/12	92

A number of themes emerged from the analysis of the user and provider interviews, as set out in Table 6 above.

#### 3.5.1 Phase 1: Assessing Participant Views

##### Samples

The overall sample size for semi-structured interviews was 26 participants including seven depressed pregnant women, five depressed mothers of young children, four CHWs, four HIV counsellors, and six midwives the CHC in Khayelitsha.

### 3.5.1.1. Counselling as an intervention

Counselling was perceived by all users (12, 100%) as an acceptable form of intervention for perinatal depression within the community. This was reflected in users reporting benefits from talking about their problems or using forms of informal counselling

*It's going out from the house to meet a family friend and talk and share our problems and, that's how I get better. I see that I am a person to other people.*  
(Pregnant Woman 4)

Counselling also seemed to be associated with advice giving and guidance with problem solving in relation to suicidal ideation. Although all service users felt that counselling was acceptable and feasible, some (4, 33%) expressed fears about sharing problems which could be a barrier to counselling.

*I can't go next door to ask for a nappy, if they give me today what about tomorrow. I can't go there tomorrow. I can't make my problems hers.* (Pregnant Woman 7)

In addition to the above service users' reservations, nearly half of all participants, users and providers, (12, 46%) felt that counselling might not be easily taken up.

*Sometimes it won't be easy to go for counselling. And also for us it is a cultural thing. Most of the people they don't value the counselling. What I notice is that people go for counselling when they have a problem. We don't go when there is no problem... Normally there is this thing of we go when things went very, very bad, it is when you will go for help.* (Community Health Worker 4)

We sought to incorporate the views on counselling into our intervention development, by taking note of the participants' concerns around expectations in counselling and reservations about using the service once it was available in order to make our intervention locally relevant.

### 3.5.1.2. Characteristics of preferred counsellor

Although all mothers and pregnant women felt that they could attend counselling sessions at the clinic, (7, 58%) of all users preferred individual sessions conducted at least once a month, by a middle aged Xhosa speaking female counsellor from the community who had practical experience in terms of “knowing what she was doing” as opposed to education level. Under half of service users (5, 42%) seemed to prefer group sessions. Midwives had the following recommendations.

*I would say preferably a woman, because I think they will be more comfortable and be able to open up if they are speaking to a woman. Um, with race it, it really doesn't matter as long as our women understand what she is saying and they can be able to communicate. At least there mustn't be any communication barrier. (Midwife 1)*

When asked if they could add counselling to their current work, (3, 50%) of midwives seemed unwilling to take on additional roles and recommended that CHWs take on the task sharing role because they have a more flexible workload and job description. One midwife felt that her workload was already high and also raised an important point of how she does not like to work in psychiatry because of previous family trauma.

*There are always changes within the maternity setting, there are always things that are being added, just an addition of work, but no staff.... I don't like psychiatry, but I do like psychiatric patients, but I just don't want to be there! But I do have a background of psychiatry at home, with my aunt, which really affected me in a way that I don't want to work in psychiatry. (Midwife 1)*

Two CHWs (2, 14%) expressed feeling helpless when seeing depressed women and felt that they did not have the necessary skills to provide counselling. These CHWs did feel however that they would be able to counsel depressed women if they were provided with adequate training and supervision. All HIV counsellors (4, 100%) mentioned that they had been trained in basic counselling, but this might not enough to counsel depressed women as indicated below.

*We had some basic training for emotional counselling in our HIV counselling*  
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*training. If we think someone is depressed, we refer them...* (HIV Counsellor 2)

### **3.5.1.3. Clinic versus Home visits**

The study results present conflicting views on location of the proposed counselling, women in this particular community showed a preference for individual clinic based counselling sessions. This would encourage them to leave their homes which in some cases exacerbated their depressive symptoms. A number of participants, both users and providers indicated a preference for clinic based visits (9, 35%) with reasons such as stigma of being HIV positive, issues of confidentiality and leaving the source of depression; expressed in the following quotes.

*People like to look at other people, they will wonder why the counsellor is at my house.* (Mother 1)

And

*You get away from the family, which is often the problem. It is easier to open up, and you get away from the problem.* (HIV Community Health worker 1)

Although clinic visits seemed to be preferred by most, some providers (3, 21%) raised important points to consider such as lack of space and long waiting periods at the clinics.

*The mothers would have to wait too long at the clinic. If they get hungry or tired, they sometimes just give up and go home. So we need to be able to refer them straight to a psychologist.* (HIV Community Health Worker 3)

After discussing clinic visit possibilities and challenges, we explored the possibility of doing home visits. This brought up several issues for consideration related to counsellors conducting home based visits.

*Transport will be another obstacle because they are far, some of the mothers stay in shacks, where there are no proper streets, and you know mos [colloquial expression], crime is also another thing there. So safety will also be another thing to look at...* (Midwife 2)

### 3.5.2 Intervention Content

The content of the intervention manual was drawn from the descriptions of users' symptoms of depression in relation to their context.

A few users (2, 16%) described a cycle of irritability, aggression, social withdrawal and isolation or aggression and conflict which could exacerbate the depression and cause maladaptive functioning if the individual is increasingly isolated.

*People are scared to talk to me, because they say I am always angry, sitting alone in the room. It affects me. I'm always at home I don't go anywhere. I'm not in the mood for anything not even for washing, nothing...I don't like to be with people; when my child does something wrong; even if it's small I shout at him and make it a big a thing. Even when I regret it, I don't know how to say sorry. (Mother 4)*

Financial stressors such as lack of income and lack of social support also exacerbated the users' depression as indicated by nearly half (11, 46 %) of both service users and providers. This was reflected in one mother's quote.

*When I am short of stuff the baby needs. Not having the money to go buy them and not getting support. Then I have those thoughts if only I did not have it... It's when the father does not support you. You see yourself alone. (Mother 2)*

Another major exacerbating factor was that of anxiety as reported by nearly half of all participants, both users and providers (12, 46%), and of particular note was anxiety about HIV testing due to partner infidelity.

*What made me worry was that, when you are pregnant you must have the HIV test. I was worried about that.... What made me worry is that, my husband before was adulterous. (Mother 3)*

### 3.5.3 Coping strategies

In order to assess what activities would be acceptable to the users if an intervention was developed, users were questioned on things they do themselves in order to deal

with their depression. Most servicer users (11, 92%) were able to identify their coping strategies as indicated in the following narratives.

*That feeling ends when I listen to music. (Mother 1)*

*If I go jogging at least the brain has some peace of mind. ...For now I tell myself that I will never try to kill myself again. These are small things; maybe god has many things in store for me. (Mother 2)*

We sought to incorporate these above examples and other activities into our behaviour activation session of our intervention, thereby building on strategies that local mothers already employ to deal with depression.

### **3.5.4 Phase 2: Intervention development**

The purpose of the workshop was to use the findings from the formative study together with evidence from other studies on perinatal depression to develop an intervention. We needed to decide on content of the intervention, the number of sessions, location of the intervention and who would deliver the intervention. All the above findings were presented to a panel of mental health experts and outcomes from the workshop are explored below.

#### *3.5.4.1. The task shared intervention*

In order to develop the intervention, we looked at recurring themes from the semi-structured interviews, together with feedback from other projects and linked these themes to evidence-based techniques such as psycho-education, problem solving, behaviour activation and healthy thinking. The panel recommended that six to eight individual counselling sessions would be ideal to show an effect since some of the concepts are complex and may require revisiting in a subsequent session. A homework component was seen as important and would also require a number of sessions to ensure adequate discussion on completed homework tasks.

A booklet was recommended as a way of engaging with the participants although concerns were raised about illiterate participants. These concerns were addressed by looking at previous studies in Khayelitsha, which found education levels of 26% with

completed secondary schooling in a sample of 1069 women [23] and 54.1% primary school education and 45.9% grade 8 or higher in a sample of 98 women [127]. These findings helped us to anticipate recruiting participants with a primary school level of education. If participants were illiterate, they would be encouraged to discuss alternative options of doing the homework such as discussing their ideas with the counsellors, or asking someone at home to assist them with it thus making the exercises inclusive of other family members. The booklet would be used for homework, scheduling appointments, keeping logs of questions, thoughts and activities. A resource list with local places the participant can go to for help in the community would be included in the booklet.

In order to provide guided self-help in a non-judgemental manner, there has to be rapport, trust and therapeutic elements which can be fostered in consecutive sessions in the task shared intervention [128]. The order of sessions was important and it was necessary to make psycho-education about depression the first session since it would educate the participant on the symptoms of depression and build rapport with the counsellor. The second session on problem solving was included in order to assist participants to address everyday problems such as employment, housing, conflict with partners and HIV diagnosis - common factors associated with perinatal depression [14, 23]. This second session includes steps on how to look for alternative solutions to one's problems [47, 117].

Behaviour activation was included as the third session to help participants who avoided places that they used to enjoy going to or who slept all day because of their depression. Behaviour activation sessions can assist these participants to come up with plans for activities that they would like to do more frequently as a way of combating their depression [129]. The CHW can encourage participants to continue or take up various activities such as exercise or listening to music when feeling depressed to make them feel better as a suggested strategy by participants in the formative findings. The fourth sessions is about healthy thinking which is in line with CBT and the Thinking Healthy programme developed by Atif Rahman and colleagues in Pakistan [44]. Some of the respondents indicated using healthy thinking as a way of coping with their depression, a strategy which has been shown to be effective in combatting depression [95]. Healthy thinking is especially beneficial to participants

who could be feeling ashamed of themselves and stuck in unhealthy patterns of self-blame and suicidal thoughts due to partner infidelity .These feelings were reflected upon by some of the participants in the interviews.

A birth preparation session was included as the fifth session in order to help allay anxiety of dealing with a new baby through educating the participant on bonding with their baby, preparing for labour and what to take with them to the hospital. The sixth and final session focuses on termination and evaluation in order to bring all the sessions together and help the participant to evaluate each session and discuss what helped her the most and what was not helpful.

Table 7 below provides a summary of the content and structure of the intervention.

Table 7: Features of the intervention

Features of the intervention	Description
<b>Theoretical basis</b>	Psycho-education, Cognitive Behavioural Therapy techniques, such as healthy thinking adapted from the Thinking Healthy programme by Atif Rahman, and Behaviour Activation.
<b>Structure of the intervention</b>	Manual based individual therapy and psycho-social support provided over 6-8 clinic based sessions. Session 1: Psycho-education on depression Session 2: Problem solving Session 3: Behaviour Activation Session 4: Healthy thinking Session 5: Psycho-education on birth preparation and Relaxation. Session 6: Termination and evaluation
<b>Structure of the sessions</b>	3 step process in all the sessions Step 1: Introduction – greeting and follow up on issues from previous meeting or session, or homework discussion. Step 2: Exploration – discussion of purpose of the session and topic, probing and clarification of issues Step 3: Termination - homework, follow up date and termination
<b>Tools</b>	Counselling manual, voice recorder, relaxation CD, activity workbook and resource list for participants.

#### 3.5.4.2. *AFFIRM counselling manual*

The AFFIRM manual was developed in order to facilitate the training of the CHWs and standardise the delivery of the task shared counselling. The manual is divided into 4 sections. The first section is intended for trainees and covers basic counselling and information about depression. The second section is intended for trainers and includes training activities, such as vignettes and self-reflection exercises for the trainees. The third section is for the counsellors to use post-training and contains a step-by-step guide on how to run the sessions. The fourth section is a participant activity work book

for the counsellors' reference which will be printed separately and given to participants. The manual was translated into Xhosa and formed the basis of a 5-day training for CHWs prior to the start of the pilot phase of the AFFIRM-SA trial. Twelve counsellors from a local NGO were trained using the AFFIRM manual six were selected for the project. The training was conducted in Xhosa by the AFFIRM mental health counsellor (MN) who is a qualified clinical social worker. The training covered assessment of depression and all the six sessions in detail with role plays to enable the CHWs to practice.

#### *3.5.4.3. The delivery of the Intervention*

The counselling sessions are conducted at the clinic initially to allow participant to speak comfortably depending on the availability of space and the participant's needs. Subsequently, home visits are conducted when necessary. In addition to the initial 5-day training, on-going weekly supervision, training, debriefing and support is provided for the CHWs throughout the course of the intervention. Supervision is offered weekly on a group basis and bi-weekly on an individual basis, in order to monitor progress during the sessions, detect adverse events, discuss the difficult cases and provide guidance for counselling sessions. The counsellors are encouraged to improve their counselling skills, adhere to the intervention and ethical practice through regular supervision sessions including feedback from fidelity checks. Counselling for the counsellors is also be provided on request by an external organisation to offer emotional support for the counsellors to prevent burnout.

### **3.6 Discussion**

This study set out to describe the development of a task shared counselling intervention for perinatal depression in Khayelitsha. In order to develop the intervention it was necessary to explore whether task sharing counselling for perinatal depression was feasible and acceptable to potential service users and providers. Such participation is believed to be a key ingredient in helping with service user recovery [115]. This formative work is in line with the MRC guidelines for intervention development [46]. The findings confirm through the narratives provided by participants that untreated depression is common in resource scarce communities underscoring the reality of the treatment gap [33, 34]. This is consistent with other findings that

highlight staff shortages [32], poverty, low levels of education and other responsibilities which could also prevent women from getting the help that they need.

There were no major differences identified between perceptions of service users and providers on the proposed intervention. We found that task shared counselling for perinatal depression in Khayelitsha was acceptable and feasible provided that certain conditions were met: (1) respondents preferred a female counsellor and felt that a clinic based individual sessions should be provided at least once a month by an experienced Xhosa speaking counsellor from the community; (2) the content of a counselling intervention should include psycho-education on cognitive and behavioural effects of depression, how to cope with interpersonal problems and financial stressors. We were able to incorporate these conditions into our intervention development in order to make it locally relevant [40, 93] and to increase the uptake of our intervention.

Clinic based sessions were preferred in order to avoid neighbours thinking participants were too sick to attend the clinic, possibly due to HIV related stigma linked to home based care services for the frail, although there was some acknowledgement that home based services may improve accessibility [32] for example by allowing CHWs to conduct follow up home visits if participants missed clinic appointments. Participants seemed to associate the age and practical experience of the counsellor with a better prospect of advice-giving compared to a younger counsellor who might not have gone through some of the issues they could be experiencing. We therefore had to take all potential barriers and preferences into consideration for the intervention as well as the safety concerns for CHWs doing home visits. A way to overcome these safety issues is by pairing CHWs when conducting home visits and possibly providing them with transport.

Other potential barriers to counselling uptake included difficulty sharing problems with others for fear of being laughed at and fear of burdening other people. Problem perception could also influence uptake of counselling since some individuals could minimise the extent of their problem and refuse the counselling sessions. All the themes brought up in the interviews were taken into account during the intervention development panel discussion and intervention and training manual development. The

wide range of themes called for an eclectic approach [130], which could help women to understand the effect that depression has on their current situation, understand that there are ways of looking at their situations differently, and start taking steps towards changing their situations. Complex elements of the intervention would need to be explained and taught to the counsellors in a clear and understandable manner. The step-by-step guide in the manual that was developed provides the counsellors with instructions on how to conduct the sessions in order to ensure quality and standardised delivery of the intervention [79, 80]. The advantage of an eclectic approach is that it could help the participant to master a range of responses to different situations as opposed to a unitary model of therapy [130]. Some service users also indicated that depression affects their care giving capacity which is consistent with findings from previous epidemiological research on perinatal depression in Khayelitsha [23]. Our intervention aims to teach participants new ways of responding to their situations through PST and CBT techniques such as healthy thinking and behaviour activation, similar to the Friendship Bench intervention in Zimbabwe [47] and the Thinking Healthy programme in Pakistan [44].

For us to identify the best cadre to deliver the intervention, we had to consider motivation for counselling, and it is important to note how previous trauma can affect one's motivation to work in different fields and how such an individual should be given the option to work in their preferred field which is not always the case when resources are scarce. Although nurses are probably in a good position to deliver the training, their workload is high and they might not be able to incorporate new training into their schedules. Motivation for working in mental health counselling and empathy towards depressed mothers are also important qualities that should be considered when looking at the training and selection of potential service providers. Higher fidelity is likely if those delivering the intervention are adequately trained and supervised and highly motivated to deliver the intervention [80]. Given the interest and motivation displayed by the CHWs interviewed in this formative research, and the agreement by the expert panel that this cadre was best placed to deliver the intervention, we decided to recruit and train CHWs as the counsellors.

### **3.7 Limitations**

We are aware that the sample size was small and could have yielded a limited range of responses, however; the sample size was appropriate as the study was formative and qualitative in nature. We are also aware that the participants may have had limited experience of counselling and therefore may not have been able to identify all the possible elements that might be included in a counselling intervention. The study could have also explored indigenous healing systems that local women use to cope with adversity in order to incorporate these into our intervention development.

### **3.8 Conclusion**

The key elements of the study included qualitative formative research, expert consultation and review of other manuals, all of which proved to be crucial for the development of the intervention. The development and adaptation of task sharing counselling interventions for perinatal depression should be informed by the views and needs of local service users and service providers to determine the acceptable content and form of such an intervention. The study illustrates the manner in which evidence-based psychological interventions can be adapted for use by community health workers within a task sharing framework in low and middle income countries.

# CHAPTER 4

**Title: A process evaluation exploring the lay counsellor experience of delivering a task shared psycho-social intervention for perinatal depression in Khayelitsha, South Africa.**

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## **Description of the candidate's contribution**

This study was designed with the guidance of the supervisors. Memory Munodawafa analysed the data with Dr Marguerite Schneider as a second coder and Memory Munodawafa developed the first draft of the paper. All other co-authors were involved in critically revising the manuscript and all authors approved the final draft before publication.

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## **Abstract**

*Background:* Task sharing of psycho-social interventions for perinatal depression has been shown to be feasible, acceptable and effective in low and middle-income countries. This study conducted a process evaluation exploring the perceptions of counsellors who delivered a task shared psycho-social counselling intervention for perinatal depression in Khayelitsha, Cape Town together with independent fidelity ratings.

*Methods:* Post intervention qualitative semi-structured interviews were conducted with six counsellors from the AFrica Focus on Intervention Research for Mental health (AFFIRM-SA) randomized controlled trial on their perceptions of delivering a task shared psycho-social intervention for perinatal depression. Themes were identified using the framework approach and were coded and analysed using NVivo v11. These interviews were supplemented with fidelity ratings for each counsellor and supervision notes.

*Results:* Facilitating factors in the delivery of the intervention included intervention related factors such as: the content of the intervention, ongoing training and supervision, using a counselling manual, conducting counselling sessions in the local language (*isiXhosa*) and fidelity to the manual; counsellor factors included counsellors' confidence and motivation to conduct the sessions; participant factors included older age, commitment and a desire to be helped. Barriers included contextual factors such as poverty, crime and lack of space to conduct counselling sessions and participant factors such as the nature of the participant's problem, young age, and avoidance of contact with counsellors. Fidelity ratings and dropout rates varied substantially between counsellors.

*Conclusion:* These findings show that a variety of intervention, counsellor, participant and contextual factors need to be considered in the delivery of task sharing counselling interventions. Careful attention needs to be paid to ongoing supervision and quality of care if lay counsellors are to deliver good quality task shared counselling interventions in under-resourced communities.

**Trial Registration:** Clinical Trials (ClinicalTrials.gov): NCT01977326, registered on 24/10/2013; Pan African Clinical Trials Registry (www.pactr.org): PACTR201403000676264, registered on 11/10/2013.

## 4.1 Background

Common perinatal mental disorders (CPMD) are highly prevalent in Low and Middle Income Countries (LAMICS) with an estimated prevalence of one in six women [19]. Untreated perinatal depression can lead to unresponsive caregiving and have severe foetal and obstetric complications such as spontaneous pre-term labour, low birth weight and adverse child development outcomes [23, 29, 30]. CPMD is also associated with poorer quality of life as a result of impairment of maternal day-to-day functioning [131], and is exacerbated by poor socio-economic circumstances such as inadequate housing, intimate partner violence and lack of social support in LAMICS [40, 132]. In South Africa an estimated 75% of people requiring mental healthcare do not receive any due to inaccessible services and staff shortages; a figure often referred to as the 'treatment gap' [33, 34].

A systematic review of psycho-social interventions for CPMDs delivered by non-specialists found them to be beneficial to recipients compared to recipients that did not receive any treatment at all [133]. Psycho-social intervention such as Cognitive Behavioural Therapy (CBT), Problem Solving Therapy (PST), psycho-education and Interpersonal Therapy (IPT) have been increasingly found to be feasible and effective within High Income countries and LAMICS [40, 59]. CBT is structured therapy designed to help individuals to change unhealthy thinking patterns to healthy thinking patterns [60]. PST helps individuals to explore and identify effective solutions to problems, as well as develop sustainable problem solving skills [47, 61]. IPT focuses on interpersonal relationships and how an individual can identify the root of interpersonal stress so that they can reduce triggers to their distress and come up with alternative ways to respond to situations [38].

Task sharing can be an effective way to reduce the large treatment gap through the use of lay counsellors such as Community Health Workers (CHWs) to deliver psycho-social interventions previously designated for specialists [4, 32, 38, 79]. Task sharing is a culturally sensitive way to increase access to care within the community by CHWs who share the same language and culture [40]. Task sharing should be provided within parameters of adequate training and supervision from a specialist [4, 32, 38, 79] which leads to capacity building and furthers their motivation to continue working [134]. There is evidence of the feasibility and acceptability of task shared interventions in LAMICS;

for example, group based task shared counselling for depressed HIV positive patients was found to be feasible and acceptable in South Africa [38] and CBT and IPT have been successfully delivered by CHWs in Pakistan and Uganda [43, 95].

As much as task sharing can be effective, qualitative process evaluations highlight factors that facilitate or hinder the effectiveness of such interventions [67]. The new United Kingdom (UK) Medical Research Council (MRC) framework for process evaluations looks at the relationship between three main factors of intervention delivery - *implementation* (training, resources, fidelity, dose and reach), *mechanisms* (participants responses to the intervention and how the intervention brings about changes in the participants) and *context* (external influences to the intervention) [54]. All three factors can be interrelated and could include both challenges and facilitators to the intervention, examining these three factors can therefore help to differentiate between an intervention that is faulty in its design and a well-designed intervention that is not implemented properly [135].

For task shared interventions to be sustainable, the following *implementation* factors should be taken into consideration: training, resources, fidelity, dose and reach of the intervention. Selecting respected and motivated lay counsellors and providing adequate resources such as training, a stipend, and transport together with consistent support and supervision, will encourage higher competence and reduce distress experienced by staff [98, 136].

The assessment of fidelity (the extent to which the counsellors follow the intervention protocol as intended) is necessary when counsellors use an intervention manual in order to ensure that intervention delivery is standardised with limited variation [50]. Higher fidelity to implementation can be achieved through adequate training, supervision which help sustain motivation to deliver the intervention [80]. A fidelity checklist can be used to assess whether core intervention components were included in the delivery of the intervention [86]. *Dose* (e.g. number of the intervention sessions delivered) and *reach* (actual number of participants who receive the intervention) are vital indicators of the success of an intervention as they reflect uptake of the intervention [50, 54]. Fidelity checking also assesses the quality of delivery of the intervention [81].

The MRC guidelines for conducting process evaluations refer to *mechanisms* as

participant responses to the intervention [54]. Examining the mechanisms of an intervention involves exploring how the delivered intervention is received and how that brings about change through identifying clear causal pathways [54]. In the case of a psycho-social intervention this involves looking at how the intervention leads to changes in cognitive style or problem solving skills which in turn influence mood and functioning [54]. These causal pathways cannot be examined in isolation since they are linked to the *implementation* and the *context* of the intervention [54]. Examining attendance patterns of an intervention, for example, can suggest how the participants receive the intervention [50]. The environmental *context* contains barriers and facilitators that affect the intervention [54]. Issues such as crime, violence, poverty and lack of private space are common barriers to interventions [98, 137] associated with poor attendance and drop out of care.

This study was necessary in order to explore lay counsellors' views of facilitators and barriers to their implementation of a task sharing counselling intervention for perinatal depression in a low resource context. This information is crucial for consideration when replicating task shared interventions and [54] and when scaling up interventions in developing countries [39].

## **4.2 Methods**

### **4.2.1 AFFIRM RCT**

This study is a sub-study of the AFrica Focus on Intervention Research for Mental health, South Africa (AFFIRM-SA) randomized controlled trial (RCT). Trial Registration: Clinical Trials (ClinicalTrials.gov): NCT01977326, registered on 24/10/2013; Pan African Clinical Trials Registry (www.pactr.org): PACTR201403000676264, registered on 11/10/2013. The AFFIRM study was an individual-level RCT with two arms. A sample of 419 depressed pregnant women was recruited from two clinics and randomly assigned to either the intervention group or the control group. The intervention group was given a series of six to eight sessions of manual based counselling sessions over a period of three to four months (approximately two sessions per month). The control arm received a monthly phone call for three months to check on well-being without providing any counselling. This paper will focus on the intervention delivered to the intervention group only.

#### **4.2.2 Intervention Development and Training of CHWS**

As part of the AFFIRM-SA RCT, we developed a task shared psycho-social counselling intervention, together with a basic counselling and training manual for perinatal depression in Khayelitsha, Cape Town. Detailed information on the AFFIRM-SA trial and the development of the intervention is available elsewhere [55, 56, 59]. We approached a local Non-Governmental Organisation (NGO) which provided twelve CHWs to participate in the training. These CHWs had previous experience doing health promotion visits to households in the community with mothers and their children under the age of 5 years [138]. They identified children who were underweight and at risk for malnutrition, and educated their mothers on how to improve their own wellbeing and their children's health [138]. The counsellors were trained during a five day workshop on how to implement the manual-based intervention. Six counsellors were selected after the training based on their understanding of the training material, their level of empathy and interpersonal style displayed during the role plays. These counsellors were employed to deliver the intervention in the main trial.

#### **4.2.3 The Intervention**

Intervention group participants received six to eight (participants had an option to finish their counselling sessions after the sixth session however they could have an additional two sessions if they felt the need for additional support). The sessions were structured manual based psycho-social individual face to face counseling sessions either at the participant's home or at the clinic. The intervention consisted of the following sessions; psycho-education on depression and psychoeducation on birth preparation; problem solving; behaviour activation; healthy thinking and lastly termination and evaluation. The intervention was based on CBT, IPT and problems solving therapy principles [55, 56]. Participants had sessions in the antenatal phase of their pregnancies and could continue sessions into the postnatal phase if sessions were not completed by the time of the baby's birth. Referrals were made to the Department of Health psychiatric services if participants showed any suicidal ideation. Referrals were also made to the social worker at the clinic and NGOs in the community if the assistance needed was beyond the scope of the CHWs' intervention. All counselling sessions were digitally audio recorded to facilitate fidelity monitoring.

#### **4.2.4 Supervision and ongoing training of the counsellors**

The CHWs were trained, supervised and supported by a mental health counselor (MHC) with a masters in Clinical Social Work (MM) and additional support was offered twice a month by CL (Senior Clinical psychologist and principal investigator of the AFFIRM-SA trial). Supervision consisted of two to three hours weekly group supervision and ongoing training in addition to 30 minutes of individual supervision every month by the MHC between May 2013 and August 2015. Supervision focused on updates on participant progress, discussion of difficult cases, follow up on previous referrals and feedback on session notes. The counsellors reflected on their feelings while they were conducting the sessions and discussed these. The MHC took field notes during supervision and counsellors were offered mental health support from external counsellors if needed. The MHC observed initial sessions, and assessed fidelity by listening to audio recordings of the sessions on a weekly basis depending on the issues raised by the counsellors. If counsellors felt uncertain about conducting a session or if the supervisor felt that most of the counsellors needed additional training based on fidelity checks, the supervisor provided *ad hoc* ongoing training to revise key aspects of the intervention.

#### **4.2.5 Fidelity Ratings of counsellors**

A fidelity checklist (see appendix L) was developed by the AFFIRM-SA team through linking the basic counselling skills and session guide from the AFFIRM-SA manual to a rating scale. The checklist has 10 items divided into three main sections which are: (i) the introduction to the session (ii) exploration of the topic, and lastly (iii) ending. Each item on the check list is scored by a three tiered scoring system which includes, “*not done*” = 0, “*needs improvement*” = 1, and “*well done*”=2.

For example, a counsellor gets a rating of 2 for introducing the topic of the session and clarifying if the participant understands the instructions before moving on to the next section compared to the counsellor who gets 1 for moving onto the next session without clarifying if the participant understands.

Scores for all three sections are added per session, and a percentage is calculated by dividing the total score by 20 (since there are 10 items with a maximum score of 2 per item) and multiplying the result by 100. Total fidelity ratings are classified into four

categories which are poor (0-40%), moderate (41-60%), good (61-80%) and excellent (81-100%).

#### **4.2.6 Data Collection**

##### **4.2.6.1. Sampling and procedure**

All six female CHWs from the AFFIRM-SA study were interviewed on their perceptions of delivering the intervention after the study concluded. Table 9 below highlights the main questions that were included in the interview schedule. The full interview schedule is included as an appendix K.

For the fidelity rating, stratified random sampling was used to select one participant from each counsellor who had received at least six intervention sessions. This resulted in a total of six participants who yielded thirty six transcripts which were analysed by MM, with four of the counsellor sessions (24 sessions) rated by a second researcher (MS).

**Table 8: Counsellor interview questions**  
(not the complete interview)

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<ul style="list-style-type: none"> <li>a. What is your reason for wanting to be a counsellor?</li> <li>b. What do you think about the week of training that you got before you started counselling?</li> <li>c. Can you describe your feelings and your story about how things changed from doing the training and when you actually started doing counselling sessions with participants?</li> <li>d. How did you manage to do counselling sessions in the clinics? For example, speaking to the nurses, getting space to have the sessions?</li> <li>e. How do you think other nurses and clinic staff accepted you at the clinic? If you could rate their acceptance of you there, between 0 and 10, what number would you give it? 0 (you weren't accepted) -10 (you were very accepted)?</li> <li>f. Before you started the sessions what were your fears?</li> <li>g. How did you rate yourself as a counsellor before you started working on AFFIRM? On a scale of 0 to 10. (Please explain)</li> <li>h. How would you rate yourself as a counsellor now? On a scale of 0 to 10. (Please explain)</li> <li>i. What did you find easy when delivering the intervention? Or what made it easy to deliver the intervention?</li> <li>j. What are the challenges that you faced in delivering the counselling sessions?</li> <li>k. What can be done to make these challenges easier?</li> <li>l. What would you say the difference is between working with younger or older clients?</li> <li>m. How many of your clients had all 6 sessions?</li> <li>n. What did you notice about the type of clients who were good at coming to sessions and the type of clients who didn't come?</li> <li>o. How many people stopped attending sessions?</li> <li>p. How would they show you that they were no longer interested in attending the sessions?</li> <li>q. How many clients did not attend any sessions? What were their reasons for non-attendance?</li> <li>r. How would you explain the different session topics:  <ul style="list-style-type: none"> <li>Psycho-education about depression</li> <li>Problem solving</li> <li>Behaviour Activation</li> <li>Healthy thinking</li> <li>Psycho-education for birth preparation</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>s. What do you think was the most effective part of the counselling (the part that helped the mothers most)?</li> <li>t. Were there particular sessions that you think were most helpful? Which <i>sessions were these</i>?</li> <li>u. Was there anything particular that you did that helped the mothers to feel more comfortable in the counselling? (If they need examples: e.g. listening, not judging, giving advice, providing a safe confidential place for the mothers to talk, etc.)?</li> <li>v. Were there any particular sessions, or any particular things that you did that you thought afterwards were not very helpful? If so, what were these?</li> <li>w. Which was your favourite session and why?</li> <li>x. Which was your worst session and why?</li> <li>y. Do you have any suggestions for ways of improving the way that the 6 sessions work?</li> </ul>
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Semi-structured interviews (SSI) were conducted with the six counsellors at the end of the intervention to explore their experience of counselling. The interview schedule used key process evaluation components based on the MRC and Steckler and colleagues frameworks as topic guides [50, 54]. The interviews were conducted in *isiXhosa* by a trained field worker. Additional information on the interviews is provided in appendix M. These six interviews were audio recorded then translated and transcribed into English. The session transcripts and fidelity checklist from the sample Memory Munodawafa Thesis 2018

participants were used to provide data on average preliminary fidelity ratings per counsellor. In addition to the SSIs, supervision notes were used to provide information on the development of counsellor skills and confidence, implementation challenges, strategies to overcome these challenges and the number of participants per counsellor who completed sessions.

#### **4.2.7 Data Analysis**

A thematic framework was developed *a priori* based on literature reviews with broad themes such as counselling motivation, implementation facilitators and challenges, and these were integrated into the framework approach listed below. Raw data were imported into NVivo v11 software for analysis and the framework approach was used to code the data [74, 139]. The framework approach to analysis includes five stages namely familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation. The first step was familiarisation [74, 139] (going over all the transcripts to get a better understanding of the themes). The next steps included identifying the thematic framework (integrating *a priori* framework and additional broad themes), indexing and charting (applying the thematic framework to data and identifying links between similar groups of broad themes), mapping (grouping more diverse themes into aggregated themes) and interpretation of what these themes mean in relation to the study that was conducted [74, 139]. The fidelity checklist was only used to code data from the thirty six session transcripts (six per counsellor) to provide an average fidelity rating for each counsellor. The supervision notes provided additional themes that were identified regarding implementation challenges and counsellor growth. Results from the fidelity checklist, supervision notes and the counsellor interviews were synthesised to provide broad assessment of the intervention implementation process.

##### **4.2.7.1. Reflexivity and methodological quality**

Reflexivity and methodological quality of the study was assessed using the Consolidated criteria for reporting qualitative studies COREQ, (a 32 item check list used to examine methodological rigour in qualitative studies) as set out in Appendix M [78]. Reflexivity refers to the examination of how the researcher's own context, perceptions and interests impact the qualitative process [140]. The researcher took

several steps to mitigate against bias: (i) an independent field worker conducted the interviews in order to avoid social desirability bias if talking to the MHC and to separate the role of the interviewer and analyst; (ii) in order to reduce fidelity bias, MM conducted the analysis of counsellor transcripts and fidelity checking of transcripts, MS also rated the transcripts for fidelity separately and any disagreements on coding were resolved through discussion until a consensus was reached; and (iii) all the researchers adhered to ethical standards required in studies of this nature as indicated in Appendix M.

### **4.3 Ethical Approval**

All counsellors and AFFIRM-SA study participants gave written informed consent to participate in the study and to have their interviews audio recorded and findings used for publication, please see appendix J. Ethical approval for the AFFIRM-SA study was granted through the University of Cape Town Health Sciences Human Research Ethics Committee (HREC Reference no: 226/2011 for the main trial and 842/2014 for this specific study), the Provincial Department of Health and the local Community Health Centre (CHC) head.

### **4.4 Results**

All six CHWs who were recruited were part of the study until the intervention concluded. The six CHWs had education levels ranging from grade 9 to grade 12 and had at least two and a half years of previous experience in the community doing health promotion. CHW ages ranged from 28 years to 46 years, with a mean age of 37.2 years (SD 7.2 years). The counsellors received transport money, a monthly stipend, and transport to inaccessible or dangerous areas. We provide information on the intervention reach, dose and fidelity ratings of the counsellors, before presenting the results from the post intervention interviews.

#### **4.4.1 Reach, dose and fidelity ratings**

Table 9 below presents a profile of the counsellors together with information on reach, dose and fidelity ratings.

Table 9: Profile of counsellors

Counsellor	Age	Marital Status	Education	**Experience before training	Fidelity rating Poor (0-40%) Moderate (41%- 60%) Good (61%-80%) Excellent (81 – 100%)	Participants with Miscarriages, still birth or baby death	Participants with no sessions	Participants who dropped out	Participants who completed	Proportion who completed (%)
<b>Counsellor 1</b>	46	Widow	Grade 9	2.5 years	70%	3	4	5	23/ 35	65.7
<b>Counsellor 2</b>	28	Married	Grade 12	4 years	60%	3	3	7	20/33	69.6
<b>Counsellor 3</b>	32	Single	Grade 11	2 years	62%	5	9	9	10/33	30.3
<b>Counsellor 4</b>	33	Single	Grade 12	2 years	55%	3	13	10	9/35	25.7
<b>Counsellor 5</b>	44	Single	Grade 12	5 years	65%	4	6	7	18/35	52.9
<b>Counsellor 6</b>	40	Widow	Grade 12	11 years	65%	4	3	9	18/34	52.9
<b>Total</b>						22	38	47	98	
<b>Mean Age of participants</b>						28.18	27.4	27.1	27.8	

\*\* Health promotion experience from working in the community for the NGO

The reach (the proportion of intended participants who actually attended the sessions) [50] of the AFFIRM intervention is 156 participants out of the 209 (74.6%) recruited in the intervention arm, including those women who dropped out of the intervention without completing six sessions. Session one (psycho-education for depression) was attended the most with 156 (74.6%) participants out of the total 209. Fifty three women (25.3%) did not engage in any sessions at all - twelve of these women (5.7% of n=209) due to miscarriage or stillbirth. Fifty-seven women (27.2%) dropped out of care before completing all six sessions, nine of these women due to miscarriage, or still birth and one due to participant death giving a total 22 miscarriages, still births or deaths (10.5%) out of the entire intervention sample. Only 100 participants (47.8%) completed six sessions. Out of 209 participants, 56 (26.7 %) women did not complete all 6 sessions. The average fidelity rating across the six counsellors was 62.8% which shows moderate to good adherence to the manual while implementing the AFFIRM intervention; however there was wide variation in the fidelity between counsellors.

#### Perception of counsellors

The results from the post intervention interviews will be presented in the form of facilitators and barriers to the implementation followed by mechanisms and context of the intervention. Quotes will be used to illustrate the themes where relevant.

#### **4.4.2 Implementation**

Facilitators to the *implementation* included counsellor factors such as motivation and competence to conduct the counselling. Intervention factors included content, supervision and using the local language as the medium of training and counselling.

All six of the counsellors were motivated to become counsellors because they were empathic and altruistic. All counsellors felt that positive feedback from participants further motivated them.

*The reason I wanted to be a counsellor is because I like to communicate with people, I like to help people. (Counsellor 6)*

Half the counsellors felt that they were confident enough to begin counselling after they received their initial training while the other half felt that they had grown as counsellors due to practice and supervision.

*I did not believe in myself that I would be able to do the job, but because of the support we received from our supervisor and the counselling I did previously I was built from that... I felt really small especially because I was not educated, but experienced... now I am very competent... (Counsellor 1)*

All the counsellors had good recall of the sessions and reported that since the content of the intervention was educational and beneficial to them and the participants, it made it easier to conduct the sessions. The counsellors enjoyed and thought the most helpful sessions were session two (problem solving) and session four (healthy thinking).

*I enjoyed session two because there were lots of twists and turns there. The mother would share her first problem and you stop her so we can talk about that problem. You ask her what she has to say about her problem. Sometimes she would leave without giving you a solution, but next time she returns with a solution...The fourth session also helped them a lot. They thought of how to move on with their lives. (Counsellor 1)*

All the counsellors felt that using the local language (*isiXhosa*) made conducting the sessions easier since participants could understand better. They also all felt that the manual based style of delivery made the sessions easier and they understood the importance of adhering to the manual.

*We could not change [the sessions]. We had to do them as they were outlined because if you changed it you would make mistakes. [The manual] provided guidance... (Counsellor 5)*

Counsellors indicated that having respect and professionalism made it easier to work with the nurses in the clinics.

*As they start witnessing the beauty of your work they become more receptive. We met with the nurses and introduced ourselves to them. Thereafter we worked together and respected each other. If they needed the room we would sacrifice and conduct the session outside. (Counsellor 1)*

Barriers to implementation of the intervention included counsellor anxiety based on fear of deviating from the manual and stress of providing emotional support. In some

cases counsellor fears were attributed to how the real life situation differed from the role plays used during training.

*I was worried if I would be able to follow the manual and not add my own stuff. I was worried if I would be able to help the client with the problem they had, but at the end I was able to do so much so that others would tell me which sessions they enjoyed. (Counsellor 2)*

Half the counsellors admitted to straying from the manual in order to help the participant understand some concepts outlined in the manual when needed.

*I followed the format of the sessions, but sometimes I would find that the mother does not understand. I would need to explain... (Counsellor 4)*

All counsellors reported feeling anxious at the beginning. However three counsellors (1, 2 and 4) felt they lacked confidence to begin counselling due to inadequate training while the other three counsellors (3, 5 and 6) felt confident to begin counselling due to an adequate training period.

The counsellors' anxiety could have been exacerbated by the supervisor's observation of sessions as indicated below;

*When I started doing counselling sessions I wished the supervisor would not be there in the room. It is your first time and the supervisor sitting there, writing down, you feel like you are making a mistake and not doing the right thing.... (Counsellor 3)*

Three counsellors mentioned how providing emotional support to mothers reminded them of their own problems and the other three mentioned how counselling participants was emotionally taxing for them.

*We forgot to take care of ourselves as counsellors. We put a lot of focus on the clients. We have our own problems and need to heal first before we help other people... (Counsellor 4)*

#### **4.4.3 Mechanisms**

Counsellors felt that teaching "healthy thinking" and "problem solving" skills changed participant's behaviour.

*A person would know that she has a problem, but not know the major problem. This session taught them to list their problems and know which problem is major. (Counsellor 2)*

Counsellors also felt that older people were easier to work with compared to younger ones.

*Older people know what they want. That makes it easy to work with older people than young people... A young person attends sessions once or twice and when she feels that she is fine she stops. (Counsellor 2)*

#### **4.4.4 Context**

Counselling and ongoing support allowed the counsellors to cope with their roles and prevent them from feeling overwhelmed. Two counsellors made use of external counselling services by attending one session each and the remaining four spoke to the supervisor about their personal problems during the course of the trial. Two workshops with an external organisation were conducted, the first one on trauma debriefing and the second one on managing personal finances as per the counsellors' request. The counsellors found the trauma workshop useful for coping with some of the difficult cases they encountered and the financial workshop helped them manage their personal finances.

The next section will highlight the barriers linked to the *implementation, mechanisms* and *context* of the intervention.

The counselors reported facing challenges negotiating the clinic environment. When asked in the interviews to retrospectively rate the clinics in terms of being welcome, (0 being not welcome and 10 welcome), the majority of the counsellors gave Clinic A ratings which ranged from 0 to 5, indicating that they did not feel welcome at the clinic when the project started, while clinic B was rated 10 by all the counsellors, showing that the counsellors felt welcome.

*Finding a venue at the clinics was hard. Sometimes we ended up doing sessions outside and that made other mothers not attend sessions because she viewed it as unimportant because you cannot talk about something serious outside. (Counsellor 2)*

All the counsellors indicated that working with participants who needed material assistance was emotionally challenging and made them feel helpless.

*A mother would give birth and there would be nothing at home...She would phone me, "Sister I am at the hospital and my baby does not have nappies or vests or anything." And I did not have anything myself and felt bad because I said I would be her counselor, but I am going to fail at supporting her in that way. (Counsellor 3)*

All the counsellors indicated that crime in the community made it dangerous to conduct home visits as they were worried about being robbed.

*I remember I was going to visit the mother after she gave birth...On the day that I was planning to visit her, we saw skollies (thugs) when we were on the station and had to turn back. (Counsellor 3)*

At times participants were experiencing difficult circumstances in their lives which made regular attendance and behaviour change difficult.

*Most of the problems they had were family feuds and with fathers of the children. A person would have problems because of the unexpected pregnancy. She would be confused and not know if she should keep the baby or not; she does not know if she will be a good mother or not... (Counsellor 5)*

The counsellors also felt that some participants dropped out because they felt ashamed for sharing sensitive information.

*...Some started, but dropped out after session 1. I think that maybe she thinks or feels that the information she shared with me is too much and cannot face me the following day. " (Counsellor 3)*

All the counsellors felt that reasons for non-engagement included: i) participants moving from the initial address given at recruitment and not leaving new contact details; ii) participants' phones getting stolen; and iii) participants living in dangerous or inaccessible areas which resulted in loss of contact. The counsellors indicated that they employed various strategies which were effective in following up participants, such as visiting the participant's last known address and speaking to neighbours, checking clinic records for updated details and being patient and persistent with following up their participants when they rescheduled appointments. These were in

addition to the trial initiated strategies such as giving participants vouchers to compensate them for participating in the study and providing transport to the counsellors for conducting home visits to inaccessible or dangerous areas.

#### **4.5 Discussion**

Our findings reflect a wide variation between the counsellors in the rate of dropouts, numbers of sessions attended and fidelity ratings. Together, the six counsellors managed to counsel a total of 156 women out of 209 (74.6%) in sessions which shows reasonable reach despite the challenges encountered. Only 100 (47.8%) of the total number of recruited intervention arm participants (n= 209) received at least 6 sessions. This compares reasonably well to the “Thinking Healthy Programme” in Pakistan which had 26% (n=463) receiving the full intervention [95]. The average fidelity rating for all six counsellors was 62.8% which reflects moderate to good fidelity to the manual. The findings however, reflect variation in fidelity measures, attendance and dropout rates. Further statistical analysis would be needed to conclude if there is a correlation between the fidelity scores and attendance rates. Counsellor 1 had the highest number of women who completed the sessions despite having the lowest education level. She had relevant work experience and maturity which is associated with respect in the community [98, 136]. This concurs with the AFFIRM-SA formative study which found that participants preferred counselling by an older woman with practical experience of ‘knowing what she was doing’ [59, 141].

Our findings also reflect positive feedback from all the counsellors who delivered the intervention despite the barriers to implementation. Counsellor facilitators included motivation, empathy and altruism which is consistent with findings from Greenspan and Colleagues [142]. Counsellors were further motivated and became more confident through positive feedback from participants. The counsellors’ health promotion background could have hindered their fidelity to the intervention since health promotion focused on advice giving whereas the intervention required them to be more collaborative by inviting the participants to develop their own solutions to problems. Although some counsellors reported deviating from the manual to explain concepts, they indicated that they enjoyed the sessions and maintained fidelity to the manual since they understood the importance of adhering to the manual. This concurs with

Hasson and colleagues who suggest that higher implementation fidelity is assumed when those delivering the intervention are enthusiastic [80].

The results indicate that some counsellors may not have been confident enough to begin counselling sessions and would have preferred a longer training period, however they eventually gained confidence through supervision. Having the supervisor sitting in on some of the early sessions was a way of mitigating the counsellor anxiety and seemed to be received well by some counsellors who attributed their growth to supervision. However, it could have exacerbated the counsellor's anxiety as indicated by the counsellor who wished the supervisor was not there. More self-reflection questions can be added to the training manual in future to assess counsellor readiness to begin counselling. While their confidence may have been low initially, counsellors also indicated that having a manual, conducting the counselling in their local language, ongoing supervision and training helped to make the counselling easier.

The findings show that the content of the intervention made it easier to deliver the intervention since it was beneficial to both the counsellors and their participants. The most popular sessions among the counsellors were healthy thinking and problem solving which offered practical steps on how the mother can prioritise and solve her problems, and identify unhealthy thoughts to replace them with healthy thoughts.

At times counsellors also experienced difficulties in their personal lives which affected how they coped with their work. Emotional support for counsellors assisted counsellors with maintaining their levels of motivation and preventing burnout [98]. Although the service was available only two counsellors made use of the external counselling while the others spoke to the supervisor. Some counsellors described feeling guilty for not being able to do more for participants who needed material assistance which made it harder to deliver the intervention. Supervision therefore focused on coping strategies and referrals of the participants to social workers and NGOs that could offer material assistance. Counsellors also reported growth by learning how to communicate about their own problems as a result of the intervention which concurs with findings from Jordans and colleagues [143].

Our study demonstrates that attendance rates could have been affected by the mechanisms (how the intervention was received by the participants) [54]. Session 1

was the most attended session, drop out occurred primarily after this session due to several reasons which will be explored in detail in a separate paper focusing on participants' perspectives of the intervention. It may be possible that women who were distressed due to a crisis, such as an unplanned pregnancy, can benefit from shorter term counselling which focuses only on problem solving and healthy thinking. On the other hand, women with long standing problems, such as recurrent partner infidelity and multiple trauma may benefit from long term counselling and referrals to other organisations. Revising the manual and reducing the number of total sessions from six to three based on the counsellor's perceptions of the two most helpful sessions would be the next step. This process would also need to be informed by views from the service users. Asking the participant if she feels that her issues have been resolved and would like to either terminate or continue with sessions also gives participants the responsibility to make their own decisions about the duration of the treatment. The use of telephonic counselling and social media could be investigated as other avenues for providing the intervention.

Lastly, counsellors thought older participants seemed more consistent in attendance compared to younger participants. This is similar to the finding by Baron and colleagues [144] on attendance rates for antenatal counselling by trained non-specialist workers. The counsellors experienced a lack of private space to conduct counselling which concurs with findings from Padmanathan and De Silva [98] and counsellors also reported not feeling welcome in clinic A. This is highlighted by the counsellors seeking alternative venues for their sessions and having introduced themselves repeatedly to the nurses. These barriers could have led to the erratic attendance as some participants had to have their sessions outside the clinic. Once the supervisors met with the clinic head this was resolved and a container with partitions was used for the counselling sessions. At times the counsellors wanted to do home visits but were concerned about their safety due to the crime in the community. The counsellors would have to wait for the participants to attend the clinic which affected their delivery of the intervention.

### **4.5.1 Implications**

This study reveals that process evaluation is necessary to pin point aspects of an intervention which need to be improved through looking at the implementation, mechanisms and context of the intervention for the replication an intervention [50, 54]. The findings also reveal that task sharing is a feasible way of delivering interventions in LAMICS provided there is adequate training and supervision for the lay counsellors. An individual can be trained to become a lay counsellor if they demonstrate the capacity and desire to be empathic and altruistic; however ongoing assessment of empathy and motivation is crucial when recruiting, training and supervising counsellors. Referral to other organisations is necessary when dealing with complex cases that are beyond the scope of the task shared intervention and counsellors should be given information on these additional resources. It is also important to ensure that supervisors of task shared interventions are supported in order to prevent burnout. With additional training and support CHWs can be absorbed as lay counsellors in resource-poor community health and social welfare services in order to Increase access to mental health care.

### **4.6 Limitations**

There are several limitations to this study, which need to be noted. While all six counsellors were interviewed, their perspectives would not necessarily be those of a larger group of counsellors. The fidelity rating identified in this study is based on six sessions of only one participant per counsellor. Although a good indication of fidelity, a larger sample size may provide a more consolidated assessment of fidelity. MM was the Mental Health counsellor who trained and supervised the counsellors including assessing for fidelity to the manual, although we do concede the possibility of bias, this was addressed as far as possible by the verification and moderation of the fidelity checks by MS who discussed any discrepancies with MM until consensus was reached. To control for fidelity bias the participants used for the rating were selected randomly. The addition of the perspective from the service users, the focus of a separate paper in preparation, will give a holistic picture of the intervention.

## **4.7 Conclusion**

Task shared interventions can be beneficial for treatment of perinatal depression. Exploring the counsellors' perspectives provided useful information on facilitators and barriers to the successful implementation of the intervention. Facilitating factors included the content of the intervention (especially problem solving and healthy thinking sessions), ongoing training and supervision, using a counselling manual, conducting counselling sessions in isiXhosa, maintaining fidelity to the manual, counsellors' motivation and confidence to conduct the sessions, and participant factors such as older age, commitment and a desire to be helped. Barriers included contextual factors such as poverty, crime and lack of space to conduct counselling sessions. Participant factors such as the nature of the participant's problem, young age, and avoidance behaviour were associated with erratic attendance and drop out of care. Careful attention needs to be paid to ongoing supervision and quality of care if community health workers are to deliver good quality task shared counselling interventions in under-resourced communities.

# CHAPTER 5

**Title: A process evaluation exploring participants' experience of receiving a task shared psycho-social intervention for perinatal depression in Khayelitsha, South Africa.**

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## **Description of candidate's contribution**

This study was designed with the guidance of the supervisors. Memory Munodawafa analysed the data and developed the first draft of the paper. All other co-authors were involved in critically revising the manuscript and all authors approved the final draft before publication.

Current status: To be submitted to Global Mental Health

## **Abstract**

*Background:* Perinatal depression is highly prevalent in Low and Middle Income Countries (LAMICS). Task sharing has been recommended as a way of narrowing the treatment gap for perinatal depression. It is important to understand the various components of an intervention including participants' views on the task shared intervention received.

*Methods:* We conducted a qualitative process evaluation nested within a randomized controlled trial of a task sharing psychological intervention for maternal depression in Khayelitsha, South Africa. Stratified purposeful sampling based on non-attendance, partial attendance and complete attendance of the intervention resulted in 34 participants being selected for the qualitative process evaluation from six counsellors' lists. Semi-structured interviews were conducted with the 34 women who had received a task shared intervention for perinatal depression from community health workers. The interviews were recorded, transcribed, translated and analysed using NVivo 11 to conduct a framework analysis.

*Results:* Several factors from the participants' context, mechanisms of the intervention and the implementation of the intervention acted as either barriers or facilitators to the intervention.

Contextual factors highlighted challenges within the participants' lives such as unplanned pregnancy, interpersonal difficulties and location of the counselling. Several implementation factors and mechanisms acted as facilitators and enabled participants to overcome their difficulties, these included counsellor motivation and empathy, and the content of the intervention. The majority of the participants found the following sessions to be valuable: "psycho-education for depression", "problem solving" and "healthy thinking" sessions, although a few participants did not have good recall of the sessions. A few participants encountered difficulties using the homework book and relaxation CD.

*Conclusion:* These findings highlight that several contextual, participant, counsellor and intervention factors need to be considered in the implementation of task sharing interventions. High prevalence of perinatal depression underscores the need to understand participants' perceptions of task shared interventions for perinatal depression.

*Keywords:* Process evaluation, task sharing, psycho-social intervention, perinatal depression.

## 5.1 Background

Low and middle income countries (LAMICS) have a large treatment gap for common mental disorders (CMD): approximately 75% of people with these disorders do not receive treatment [33, 34] due to inadequate resources and lack of adequately trained mental health staff [32], among other factors. The perinatal period can be defined as the period between conception until one year after birth [18, 40]. Perinatal depression is a highly prevalent CMD in LAMICS [19, 20, 90]. Untreated perinatal depression has been associated with adverse foetal and obstetric outcomes and poor maternal health outcomes [23, 30]. There is increasing evidence to show that trained community health workers (CHW) can deliver effective treatment for perinatal CMDs in LAMICs; for example, cognitive behavioural therapy (CBT) for perinatal depression in Pakistan [95].

The recent United Kingdom (UK) Medical Research Council (MRC) guidelines for conducting process evaluations highlight the importance of examining implementation, mechanisms and context of an intervention to understand how and why an intervention is or is not effective [54]. Examining the *context* helps us to understand the relationship between the components of an intervention, its outcomes and its external environment [50, 54]. Examining the *implementation* of the intervention includes examining the delivery of the intervention in terms of the content of the intervention and counsellor factors such as empathy and motivation. *Mechanisms* include participant factors such as willingness to learn and to change behaviour [145]. Participants' perceptions of the intervention can show their attitudes and beliefs and provide evidence to determine the extent to which the context, implementation and mechanisms manifested themselves [54]. The participants' experience of an intervention can also be revealed through examining attendance patterns. For example, a study by the Perinatal Mental Health Project (PMHP) exploring patterns of use of antenatal counselling by trained non-specialist workers found that women of a younger age with lower Edinburgh Postnatal Depression Scale (EPDS) scores tended to accept referral but did not attend counselling compared to older women [144].

Qualitative studies with service users are increasingly being conducted as a way of monitoring, evaluating and strengthening health systems as they provide insight into treatment barriers for postnatal depression such as acceptability, stigma and

communication difficulties [146-148]. The acceptability of psycho-social interventions for depression can be improved if the development of the intervention is informed by the views of service users [96, 115, 149, 150]. Qualitative studies of participants' experience are also important to help us understand diverse cultural experiences of perinatal CMD in LAMICs [151-153].

There is a paucity of information on the experience of participants who receive task shared psychosocial interventions for perinatal depression in LAMICs as revealed in a systematic review on qualitative evidence of process evaluations in LAMICs [154]. This paper presents a qualitative process evaluation of the participants' experience of a task shared intervention. It explores the perceptions of the participants who received a task shared psycho-social counselling intervention to understand the experience of non-attenders, partial attenders and complete attenders of the intervention. It complements a previous paper published on the perceptions and experiences of the counsellors in providing this intervention [62].

## **5.2 Methods**

### **5.2.1 AFFIRM-SA Randomized Controlled Trial**

Khayelitsha is a township on the outskirts of Cape Town with high rates of poverty, unemployment and crime [57, 119]. This study was part of a larger study - the AFrica Focus on Intervention Research for Mental health (AFFIRM) project which included a Randomized Controlled Trial (RCT) (AFFIRM-SA) examining the cost effectiveness of a task sharing maternal depression intervention [55, 56]. The RCT recruited 425 women, with 209 in the intervention group and 216 in the control group. The intervention group received six individual face to face counselling sessions in the antenatal and/ or postnatal phase of the pregnancy depending on participant availability while the control group participants received a monthly phone call over a period of three months. Participants had the options to end with six sessions or continue if they felt that they needed further support. This paper will focus on perceptions of women participating in the intervention group only. Detailed information on the AFFIRM-SA trial, the development of the intervention and training and supervision of the counsellors is available elsewhere [55, 56, 59, 62].

### 5.2.1.1 The AFFIRM-SA Intervention

The intervention was based on Cognitive Behavioural Therapy (CBT) [60] and Problem solving therapy (PST) principles [61]. The AFFIRM-SA counsellors used a structured manual to deliver all six sessions and fidelity to the manual was monitored regularly by a Mental Health counsellor who supervised the counsellors weekly during the delivery of the intervention [62]. The intervention content included six sessions presented in Table 10 below. Additional information on the trial and intervention development is presented elsewhere [55, 56, 59].

Table 10: Aim of the intervention

Description	Aims
Session One : psycho-education about depression	To provide basic information about depression symptoms and treatment options
Session Two: problem solving	To help participants to develop a problem solving framework by listing possible solutions to their problems based on the advantages and disadvantages
Session Three: behaviour activation	To teach participants to engage in a wider range of behaviours to improve their mood and to keep a log of activity and subsequent mood on a daily basis
Session Four: healthy thinking	To teach participants to identify unhealthy thoughts and replace them with realistic healthy thoughts
Session Five: psychoeducation for birth preparation and	To educate the participant on signs of labour, list of items to take to the hospital and how to get to the hospital
Session Six: termination and evaluation	To evaluate the sessions that they had attended and inform the counsellor if they needed more sessions or if they felt ready to terminate.
Additional Materials: Homework Activity book and Relaxation CD	The CD helped participant to practice progressive muscle relaxation and the booklet for practising activities that they had gone over in the counselling sessions

### 5.2.2 Sampling and recruitment

Pregnant women attending a Midwife Obstetric Unit (MOU) at a Community Health Centre (CHC) in Khayelitsha, Cape Town gave consent to be screened and recruited into the study. Participants were screened using the Edinburgh Postnatal Depression Scale (EPDS) which assesses for symptoms of Major Depressive Disorder (MDD) based on answers given by the respondent regarding their symptoms over the past seven days. The EPDS has an optimal cut-off score of 13 and has been translated and validated in isiXhosa [24]. Participants who scored 13 or higher on the EPDS were further assessed using the Major depression module of the Mini Neuropsychiatric Interview (MINI) v 6.0 [120]. In addition to their EPDS scores, women were recruited

into the study if they lived in Khayelitsha, were under 28 weeks gestation and 18 years or older. The recruited participants were randomly assigned to intervention and control arms.

Stratified purposeful sampling based on non-attendance, partial attendance and complete attendance of the intervention resulted in 42 participants being selected for the qualitative process evaluation from the 209 intervention arm participants who were allocated to the six counsellors. Eight participants from the total of 42 participants could not be reached which resulted in a sample of 34 participants including eight non-attenders (0 sessions completed), 14 partial attenders (1-5 sessions completed) and 12 complete attenders (6 sessions completed).

### **5.2.3 Data Collection**

Qualitative semi-structured post-intervention interviews were conducted with all participants. Twenty six interviews were conducted face to face and eight interviews were conducted telephonically for those participants who were not available for face to face interviews. Interviews were conducted in the local language *isiXhosa* by two field workers who were extensively trained in using semi-structured interview schedules, (see appendices O-Q). These fieldworkers had no prior contact with the participants. The schedule was developed by the research team to elicit participants' views on and experience of the counselling they had received. The interviews were recorded, translated into English and transcribed. Table 11 below presents some of the questions used for the semi-structured interviews.

Table 11: Participant interview questions

(Not the full questionnaire)

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**Non-Attenders (0 sessions)**

1. What did you understand about the study when you were asked to be part of it?
2. What changed between the time you agreed to take part in the study and when we tried to contact you?
3. Did you have any expectations that were not met by the study?
4. I just want to confirm, did you receive any phone calls from a counsellor asking you to come for sessions or to talk with you on the phone? How did you feel about it and what did you do?
5. Sometimes participants ignored the phone when they saw the counsellor's number, did that ever happen to you? Please tell me more about what you were feeling when you didn't want to talk to a counsellor?
6. What would help you to attend counselling sessions in the future?
7. When we last spoke to you, you described feelings of being sad, or down. Can you tell me a bit about what you were thinking, feeling or doing when you felt sad or down?
8. Please can you tell me more about how are you feeling now?
9. Are there any big changes in your life (positive or negative) that have happened since you were recruited?
10. How have these changes impacted your life?

**Partial Attenders (1-5 sessions)**

1. What did you understand about the study when you were asked to be part of it?
2. What changed between the time you agreed to take part in the study and when we tried to contact you?
3. Did you have any expectations that were not met by the study?
4. What would help you to attend counselling sessions in the future?
5. When we last spoke to you, you described feelings of being sad, or down. Can you tell me a bit about what you were thinking, feeling or doing when you felt sad or down?
6. Please can you tell me more about how are you feeling now?
7. Are there any big changes in your life (positive or negative) that have happened since you were recruited?
8. How have these changes impacted your life?
9. Describe for me how you feel about the counselling. Give me examples of what was good and bad, what you enjoyed or not, what was useful and what was not useful. How did you feel about the counselling from session 1-6?
10. Tell me about what you enjoyed and what you did not enjoy about the counselling.
11. At some point, you stopped coming for sessions. Tell me about that and what made you stop attending? Can you also tell me more about what you were feeling and thinking that made you stop?
12. Were there times that you did not feel like talking to a counsellor? If yes, explain....
13. How did you let the counsellor know that you did not feel like having more sessions?

**Complete attenders (6 sessions)**

1. What did you understand about the study when you were asked to be part of it?
2. What changed between the time you agreed to take part in the study and when we tried to contact you?
3. Did you have any expectations that were not met by the study?
4. What would help you to attend counselling sessions in the future?
5. When we last spoke to you, you described feelings of being sad, or down. Can you tell me a bit about what you were thinking, feeling or doing when you felt sad or down?
6. Please can you tell me more about how are you feeling now?
7. Are there any big changes in your life (positive or negative) that have happened since you were recruited?
8. How have these changes impacted your life?
9. Now think of all the sessions you attended and tell me which one you enjoyed the most and what did you learn from that session.
10. Which session do you think helped you the most?
11. How did that session help you?
12. The sessions tried to teach you skills and how to use these in your everyday life. Describe for me how you continue using them on an everyday basis. When you describe these, give me examples that will help me understand how you use these skills.
13. Can you please describe your relationship with your counsellor?
14. What do you think about the counselling being conducted in Xhosa?
15. Where did you have your sessions?
16. What do you feel about the counsellor using a manual?
17. What did you think about the home work activities and the relaxation CD?
18. What would you tell someone if you were telling them about your counselling experience?
19. Do you still need further assistance in terms of what you spoke to the counsellor about?

## **5.2.4 Data Analysis**

The transcribed interviews were imported into NVivo v11 software for analysis and using the framework approach to code the data [74, 139]. The framework approach was relevant for this study as it allowed us to use the MRC framework *a priori* to address the important key aspects of the participants' experiences as set out in the interview schedule. Themes addressed in the interview included context, implementation and mechanisms. The use of a semi-structured interview schedule allowed for more structured identification of themes as well as additional themes generated from the analysis and not identified in the *a priori* framework. The framework approach to analysis includes five stages: familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation. Familiarisation included going over all the transcripts to get an understanding of the themes [74, 139]. The *a priori* framework was integrated with the additional themes during indexing and charting which involved identifying links between similar groups of broad themes. Through mapping, more complex themes were grouped into aggregated themes and interpretation looked at the meaning attached to these themes in relation to the study purpose [74, 139].

### **5.2.4.1 Reflexivity and methodological quality**

Reflexivity is the examination of how the researcher's own experience, perceptions and interests impact on the qualitative process [140]. Reflexivity and methodological quality of this study was evaluated by using the Consolidated criteria for reporting qualitative studies (COREQ), a 32 item check list used in qualitative studies to examine methodological rigour [78] which is included as appendix R. The COREQ looks at three domains when conducting qualitative research. Domain one examines the research team and reflexivity (the credentials and training of the researchers), domain two examines the study design (sampling and data collections) and domain three examines the analysis and findings (coding and numbers of coders) [78]. The researcher took several steps to mitigate against bias: (i) two independent field workers (without prior contact with any of the participants) conducted the interviews in order to separate the role of the interviewer and analyst and (ii) all the researchers adhered to ethical standards required in studies of this nature as indicated in appendix

R. There was only one coder for the transcripts and the use of the semi structured schedule mitigates to some extent against potential bias.

### **5.3 Ethical Approval**

Ethical approval for the AFFIRM-SA study was granted through the University of Cape Town Health Sciences Human Research Ethics Committee (HREC Reference no: 226/2011 for the main trial and 842/2014 for this specific study), the Western Cape Department of Health and the local Community Health Centre (CHC) heads. All AFFIRM-SA study participants gave written informed consent to participate in the study and to have their interviews audio recorded and findings used for publication. Please see attached appendix N.

### **5.4 Results**

The sample for this study consisted of 34 participants who were divided into sub-groups of eight non-attenders 14 partial attenders and 12 complete attenders grouped into two groups of eight non-attenders and 26 session attenders (participants who attended more than one session). The age range was 18 – 45 with a mean age of 28.4 years and standard deviation of 6.3 years. The majority of the participants had completed school or obtained a post-school certificate or diploma. A profile of participants' demographic characteristics is presented in table 12.

Table 12: Profile of respondents

Participant	Age	Level of Education (Grade completed)	Number of sessions attended	Clinic
Participant 1	45	1	0	A
Participant 2	18	10	0	A
Participant 3	27	12	0	A
Participant 4	22	13	0	A
Participant 5	21	10	0	A
Participant 6	20	12	0	A
Participant 7	33	12	0	A
Participant 8	26	13	0	B
Participant 9	26	12	1	A
Participant 10	27	11	1	A
Participant 11	35	12	1	A
Participant 12	27	11	1	A
Participant 13	32	12	2	A
Participant 14	34	12	2	A
Participant 15	27	9	2	A
Participant 16	19	9	2	A
Participant 17	33	11	2	A
Participant 18	21	13	3	B
Participant 19	27	12	3	B
Participant 20	38	11	3	B
Participant 21	32	12	4	B
Participant 22	24	9	5	A
Participant 23	26	12	6	A
Participant 24	31	13	6	A
Participant 25	20	12	6	A
Participant 26	28	13	6	B
Participant 27	32	12	6	A
Participant 28	33	11	6	B
Participant 29	24	12	6	B
Participant 30	34	7	6	B
Participant 31	38	12	6	B
Participant 32	23	11	6	B
Participant 33	25	12	6	A
Participant 34	39	11	6	B

The main themes were identified in relation to the MRC framework and related to context (the nature of the problems faced and reason for inability to attend sessions), implementation (flexible location of sessions, use of intervention material and content of the sessions) and mechanisms (participants and counsellor mechanisms to the intervention). These will be presented in relation to the full sample and where applicable results for any one of the two or three sub-groups indicated above will be presented separately.

### **5.3.1 Context**

#### *Nature of problems faced*

Several themes emerged from all participants regarding their context which included the nature of the problem and reasons for inability to attend sessions. We will begin by highlighting the nature of the problems faced in order to highlight the personal context of the participants.

The most common problem highlighted by just under half of the participants (16), was that of interpersonal problems with their family or with the father of the baby resulting in lack of social support and partner rejection.

*What made me think and realize that I was unhappy is that after I found out that I was pregnant the father of the baby and I had problems and he did not want to support me, give me attention and talk to me. (Participant 10, partial attender)*

Eleven participants reported that their pregnancy was unplanned and this was associated with major life changes.

*At the beginning, I was thinking that I fell pregnant and it was not planned. I planned to work and go to school...Then I found out that I was pregnant. I blamed myself and I did not want the baby... (Participant 23, complete attender)*

In some cases, participants were unable to cope with their problems and resorted to alcohol use (6) or experienced suicidal ideation (7).

*I would think of committing suicide when I was drunk. I did not want anyone to talk to me... (Participant 30, complete attender)*

A few participants (3) experienced changes in circumstances such as acceptance of the pregnancy which led to increased social support, better mood and subsequent drop out of sessions.

*My family was upset at me when I was pregnant, but as time went by they accepted it and I was also happy (Participant 6, non-attender)*

#### *Reasons for Inability to attend sessions*

More than half of the total sample (18) reported the following *context* specific reasons for non-attendance or missed sessions: unavailability due to employment, running errands, or having moved from Khayelitsha. The only difference between non-attenders and attenders was that five non-attenders indicated that they still needed help with their problems and were referred to community organisations, whereas no session attenders expressed a need for additional referrals.

*To be honest, they were contacting me all the time asking if they can come to me.... I was the one who did not have time... (Participant 3, non-attender)*

A few participants (5) indicated personal issues such as irritability, laziness and forgetfulness which prevented them from attending the sessions.

*I was sometimes unavailable and other times I was lazy to go (Participant 9, partial attender)*

### **5.3.2 Implementation**

Three main themes were highlighted in relation to implementation flexible location of sessions, use of intervention materials and the content of the sessions.

#### *Flexible location of sessions*

The location of the counselling sessions was flexible depending on participant need, choosing between the clinic, home or a combination of both locations. More than half of the 26 participants who received sessions (14) reported having their sessions at the clinic. This was convenient as they had antenatal appointments already scheduled. The remaining twelve participants either had their sessions at home only (6), or both

the clinic and home (6). This shows that participants were able to accommodate having sessions both at home and clinic as set out in the trial protocol.

### *Use of intervention materials*

The majority of participants who attended sessions (22) indicated that they either liked the manual or did not have a problem with the counsellor using it while one participant explicitly indicated that she wished she spoke to the counsellor freely without her using the manual. Other participants did not comment on the use of the manual, including eight non-attenders (11).

Most of the participants indicated that it was good that the counselling was conducted in their local language and it was easier for them to fully express themselves.

*There are times when you can understand [English], but cannot express yourself fully. When you are speaking Xhosa, you can say everything.*  
(Participant 18, partial attender)

Of the 26 who attended sessions; 19 participants enjoyed the relaxation CD and 18 participants indicated that they made use of the homework book and liked it.

*I enjoyed listening to the CD....it made me relax and focus and not think of everything... When I wrote down [in the homework book] it was as if I was speaking to a person.* (Participant 29, complete attender)

A few participants highlighted negative perceptions of the intervention materials. Seven participants reported problems with the CD, five did not have any device to play the relaxation CD therefore did not use it, one participant did not receive the CD and one did not like the CD. Eight participants reported problems with the homework book- two did not receive the homework book, three did not like it and three found it difficult to use.

### *Content of the sessions*

Of all the 26 participants who attended sessions, eight did not have adequate recall of the content of the sessions to indicate the sessions they had enjoyed while the rest gave positive feedback about the sessions. Two participants in particular, one who

had attended four sessions and one who had attended six sessions, indicated that they liked all the sessions they had attended. Eighteen participants, seemed to have good recall of content of the sessions when reminded. Most participants who were able to remember the content enjoyed the following sessions the most: “psycho-education about depression” (8) followed by, “healthy thinking” (4), “problem solving” (4), “behaviour activation” (1) and “psycho-education for birth preparation” (1).

*I enjoyed the first session the most. I came here and I was in a bad space... and left here feeling alright. Everything was light.* (Participant 12, partial attender)

Participants who enjoyed “problem solving” the most indicated that it helped them to use new ways to solve their problems.

*Problem solving helped me the most.... I was able to solve the problems by writing them down and solving them one by one instead of being overwhelmed and confused.... I would write down the most important one and the least important one. Then I would choose which one I will solve and how I will solve it, in what time.* (Participant 25, complete attender)

Participants who enjoyed “healthy thinking” the most indicated that it helped them with unhealthy thoughts and in some cases with interpersonal problems that they were experiencing.

*I enjoyed the session about positive thinking the most because I thought of committing suicide when I thought of my problems at home and fights with my boyfriend. ...yes I will still have problems because I am human, but if I do the right thing everything will be fine...That session made me really happy because most of the time I had bad thoughts.* (Participant 32, complete attender)

### **5.3.3 Mechanisms**

Most participants (24) expected to get help with their problem through advice or counselling on how to deal with their problem. These needs highlight important mechanisms which are willingness to learn and willingness to change one’s thoughts or behaviour.

*The sessions were encouraging. They were interesting because I wanted to change how I was thinking. (Participant 29, complete attender)*

Ten participants out of the total sample of 34 indicated that initially they did not know what to expect from the study when they agreed to take part. However as time went on they understood the purpose of the study.

#### *Relationship with the counsellor*

All 22 participants who had more than one counselling session indicated that they either had a good relationship with the counsellor or that the counsellor had specific qualities, such as showing an interest in the participant when listening, which motivated the participant to talk.

*She [the counsellor] was interested in helping me and that motivated me to talk to her because she was interested in helping me. (Participant 25, complete attender)*

These same 22 participants also attributed their continued attendance to the way the counsellor spoke to them.

*The way she spoke to me made me think that the more I talk to her the [more] free I become. That is what made me come back to her. (Participant 10, partial attender)*

#### *Overall impact of intervention*

A total of 26 session attenders reported experiencing positive changes in their lives due to changes in circumstances and positive thinking.

Ten out of the 26 attenders specifically attributed their relief to counselling.

*.... I was very depressed and once I talked and got counselling I was able to breathe. Now I can talk. Before I could not talk (Participant 24, complete attender)*

More than half of the participants (20) indicated that they were no longer experiencing the problems they had after attending the sessions.

*I learnt that if you talk about what is causing you stress of depression you will feel better. If you don't talk... you remain stressed. (Participant 18, partial attender)*

Some participants attributed their continued attendance to the intervention and the help they received:

*I enjoyed the first one the most, the one about depression. It was the one I wanted help with and I did get help after that session. I was able to continue with other sessions because I did get help from the session I wanted to get help from. (Participant 25, complete attender)*

All the session attenders indicated that they learnt and continued using the following skills: problem solving, being able to communicate with others, and choosing not to be stressed by issues. Use of the skills led to improved mood, and enhanced problem solving skills and there were some indications of improved living conditions.

*Since I started ... [counselling] I don't have debts. It's not like before. I used to go to bed without food. Now I hardly sleep without food. (Participant 11, partial attender)*

## **5.4 Discussion**

Our study aimed to explore participants' views on the implementation of a task-shared psycho-social intervention and how this is affected by the context and mechanisms of the intervention.

### **5.4.1 Context**

In most cases the participant's problems were integrally linked to their experience of depression and their need for the intervention. Different aspects of *context* were reported: the participant's own state of being and living context highlighted by the nature of the problems that led participants to the intervention in the first place, the broader family context, and the physical context of where the intervention was provided in the community [50, 54]. The most common problems prior to counselling were unplanned pregnancy and interpersonal difficulties with partner or family, which

is consistent with findings from Omahen and colleagues in an underserved area of Michigan, USA [155]. In our study, some participants' depressive symptoms were exacerbated by financial difficulties, suicidal ideation and use of alcohol as participants attempted to deal with their problems. Our findings reflect that non-attendance was partly context-related, for example being unable to attend counselling sessions due to running errands, going back to work or moving out of town. This is consistent with other published findings that contextual barriers can lead to poor adherence to an intervention [98, 137].

When comparing the three groups of non-attenders, partial attenders and complete attenders, the main difference between these groups was that most of the non-attenders (5/8) were still experiencing problems at the time of the interview and were referred to other community organisations for additional help at the time of the final assessment as the AFFIRM-SA intervention had ended. On the other hand, some participants were distressed due to a crisis (e.g. an unplanned pregnancy) at the time of recruitment and agreed to take part in the study. However, once they informed their partners or families and accepted the situation, these participants were no longer distressed and could have decided not to attend any further sessions. As suggested in a related paper on counsellors' perceptions of intervention delivery, these women could benefit from short term counselling [62].

#### **5.4.2 Implementation**

Process evaluation helps us to understand the relationship between various components of an intervention, and which components contribute to the desired outcome [50]. Our results show that overall, participants had positive feedback on the AFFIRM-SA intervention and materials used. There are several factors that could have led to this: the intervention was appropriate to their needs; they had a congruent understanding of depression and its potential resolution; the intervention was delivered in an accessible place and format; the homework book was used by the majority who found it useful; and a generally good level of education of the majority (25 out of 34 having completed at least a high school certificate). These are only some of many possible factors that might have led them to find the intervention helpful. This positive feedback is further supported by the generally good recall participants had of the

session content and clear description of which sessions they found to be valuable with “psycho-education about depression” being the most popular followed by “healthy thinking” and “problem solving”. Those that found the “psycho-education for depression” session to be most valuable indicated that the session helped to give them knowledge and support for their depression which lays the foundation for subsequent sessions and highlights a strength of the intervention. Participants who found the “healthy thinking” and “problem solving” sessions to be valuable gained insight into what they were feeling, and also learnt practical steps to change the way they think, and ways to solve their problems. The intervention could therefore be condensed into fewer sessions focusing on the most popular sessions.

A minority of participants encountered negative experiences of the intervention material, which could be an implementation barrier. A few participants indicated that they either did not receive or did not use the material; for example, the lack of a device to play the CD was a barrier. Only a few participants either did not like or found the homework book difficult to use. It is possible that a low education level could have prevented some participants from using the material effectively. These findings will be useful for making further changes to the intervention through checking that every participant has received the intervention material is able to use it effectively.

### **5.4.3 Mechanisms**

Mechanisms include how the intervention was received by the participants and how the intervention leads to change within individuals. Through examining the reasons affecting attendance, we can start understanding some of these mechanism that may affect the effectiveness of the intervention [54, 145, 156]. We explored the participant’s expectations from the study together with reasons for non-attendance to gauge if attendance patterns were linked to the content of the intervention or the implementation of the intervention. We found that most participants, attenders and non-attenders, expected to get help or advice and felt that their expectations were met by the study. Only a few participants (10/34) non-attenders and partial attenders indicated that they did not know what to expect when they agreed to participate in the study and this could have led to drop out.

The impact of the sessions was gauged by the skills acquired and positive changes that had occurred in the participant's life which they attributed to the intervention. It is also important to note that some participants may have experienced positive changes such as finding employment prior to starting the intervention which could have affected the uptake of counselling sessions, while other participants may have avoided talking about their problems as it was too painful to go over them if they were not going to get practical assistance. For example, talking about being abandoned by the baby's father can be cathartic and release pent up anger but it does not bring the baby's father back. The content of the intervention is a facilitating mechanism since participants who attended sessions indicated they still use problem solving and healthy thinking skills which they acquired from the intervention. Common problems of an unexpected pregnancy associated with interpersonal conflict, combined with suicidal ideation could result in a cycle of conflict, depression and continued suicidal ideation. Teaching participants new ways of dealing with their challenges by using healthy thinking and problem solving techniques can help them to cope or break this cycle. This is congruent with findings of the Thinking Healthy programme (THP) in Pakistan [44] and the Friendship Bench intervention in Zimbabwe which helped participants to adopt healthy thinking and problems solving skills within the LAMIC context [47].

*Mechanisms* also included looking at both counsellor and participant characteristics. Most of the participants who returned for sessions attributed their continued attendance to a good relationship with the counsellor and empathic engagement by the counsellor. The combination of intervention factors such as useful content, counsellor characteristics (e.g. motivation and warmth) together with participant characteristics (e.g. willingness to learn and change behaviour) seemed to facilitate positive experiences of the intervention. Willingness to learn can be an important mechanism, as it facilitates an openness to receiving new information (the intervention) leading to changes in thinking, affect and behaviour. Teaching about empathic engagement and warmth can be incorporated into the development of future interventions and counsellor training and selection programmes [50]. The findings highlight that several contextual, participant, counsellor and intervention factors need to be considered in the implementation of task sharing interventions. This forms part of the growing field of implementation science theory and frameworks, which explores

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how implementation of intervention is variable due to multiple factors that are in constant motion[157, 158].

## **5.5 Limitations**

There are several limitations to this study: firstly, this was a relatively small sample and may not necessarily reflect the views of all study participants; secondly self-report of participants' experience of the intervention may not necessarily correspond with the effect of the intervention on their mood and functioning. We would have wanted to get more information from participants who had not attended as they can provide important feedback on intervention barriers. However, these participants were difficult to reach and resulted in only a few such interviews being completed.

## **5.6 Recommendations**

Key factors that came out of our process evaluation which are important for policy makers, service providers and researchers are that process evaluations help to identify barriers and facilitators to the successful implementation of task sharing psychological interventions. Service providers can ensure that counsellors are taught the relevant skills to deliver the intervention successfully in order to ensure that participants benefit from the intervention. Researchers can help determine what sufficient time and training is in order for an intervention to be effective and researchers can also invest sufficient time and funding in the training, selection, and supervision of counsellors to include lay counsellors who are empathic and motivated. There is also limited information on participants' experiences of task shared interventions in LAMICS as revealed in a systematic review [154] and this information would be helpful for the replication and development of interventions in LAMICS.

Applying the MRC framework in process evaluations could yield more effective information to aid the development of future interventions. Our process evaluation also revealed that a third of participants did not understand the purpose of the research initially (four non-attenders, five partial attenders and one complete attender) and this may be linked to their level of understanding of the intervention. Counsellors should assess the expectations and level of understanding of participants at different points of intervention to ensure that participants know what the counselling intervention aims

to do. More effort should be placed on ensuring that the participants who need help the most receive this help through, for example, home visits for encouraging families to assist in the participant's recovery.

## **5.7 Conclusion**

High prevalence of perinatal depression underscores the need to understand the mechanisms of psychological interventions for women during this time. Process evaluation is an important component of implementation research to complement the outcome evaluation, as it generates insight regarding how the intervention was implemented and the contextual factors and mechanisms influencing the implementation to yield the outcomes obtained. We looked at participants' perception of a task sharing psychosocial counselling intervention, and how this is affected by the context and mechanisms of the intervention. We found that most of the participants who attended or completed sessions had expected to get help from the intervention. We also found that most of the participants reported having a good relationship with their counsellor and valued the way that the counsellors spoke to them which is important for future counsellor training.

# CHAPTER 6

## Discussion

This chapter collates and discusses findings presented in previous chapters such as the research objectives and the implications of findings in relation to policy, research, training and practice. A large part of this study focused on process evaluation and the use of qualitative methods to inform the evaluation through a number of different components – feasibility study (Chapter 3), counsellor perspectives (Chapter 4) and participant perspectives (Chapter 5). The PhD also generated new knowledge on the experience of delivering a task shared counselling intervention for perinatal depression in LAMICS.

As shown in preceding chapters (1-5), there are several risk factors that leave women vulnerable to depression in particular, being of child bearing age, being in the perinatal period and certain contextual factors (for example, lack of social support, unplanned pregnancy and poverty) which in turn can lead to a cycle of poverty and mental ill health [19, 132]. Screening and treatment for perinatal depression in poor resource settings should be prioritised in order to prevent or reduce the disability and adverse consequences associated with depression [17]. The thesis also highlighted a large treatment gap for depression [33, 34] and a need to develop interventions to fill this treatment gap. It also documents how lay health workers can be used to deliver psycho-social interventions. Finally, the effectiveness of the MRC framework for developing and evaluating task-sharing psycho-social interventions has been demonstrated [46]. This final chapter will reflect on the key contributions that have been made by this study.

The PhD has provided knowledge and experience on the development and implementation of a task-shared intervention for perinatal depression in a low resource setting. This includes a systematic review which provides qualitative evidence of process evaluations of task shared interventions for perinatal depression in LAMICs. The study also documents the assessment of feasibility prior to the development of the intervention. Lastly, the PhD provides evidence of qualitative process evaluations with the first component documenting the counsellor's experience of delivering the

interventions, and the last component documenting the participant's experience of receiving the task-shared counselling.

### **6.1 Task sharing interventions in LAMICS**

Our systematic review was useful for understanding previous research in the field, and how our study can fill key gaps in our knowledge. This study is the first publication synthesising evidence of qualitative process evaluations of task shared interventions for perinatal depression in LAMICs. The review highlights the need for more qualitative process evaluations [154]. The small number of studies that met inclusion criteria (3) in the review limits the generalisability of studies but shows common contextual, implementation factors and mechanisms that affect task shared interventions. The context of the studies highlights the importance of cultural appropriateness when designing psychological interventions [41, 44]. The theme of cultural appropriateness was illustrated by how the personnel delivering the intervention observed “chilla” in Pakistan (40 day confinement period post-partum) [44] and also “doing the month” in China (a 30 day confinement period which includes rest, seclusion and avoiding bathing or washing hair) [106, 112].

The studies included in the review highlighted the importance of conducting qualitative studies with intervention participants and those involved in the delivery of the intervention as part of the process evaluation. The studies identified in the review however, lacked detailed information on the assessment of fidelity. Assuming that these studies did include fidelity assessments of one kind or another, a key output of this thesis is the recommendation that including such detail would facilitate their replication. This should include detailed information as discussed further below. The systematic review paved the way for our own qualitative process evaluation which is also discussed in the sections below.

### **6.2 The development of a task shared intervention for perinatal depression in LAMICS**

This component of the study fits into stages one and two of the MRC framework which look at the development of the intervention and feasibility and piloting of complex interventions [46]. The study highlights the importance of assessing feasibility and

acceptability of a proposed intervention, as recommended by the MRC framework. This is similar to the THP which also conducted a feasibility and pilot study in Pakistan [44] and a study on peer-led psychosocial intervention in South Asia which also found that participants preferred local, middle-aged women to deliver their counselling [159]. Our formative work also concurs with a study by Balaji and colleagues which used the MRC framework to develop and evaluate their intervention for the treatment of schizophrenia [79] and followed similar steps in order to develop a task shared intervention. Conducting a feasibility study helped to facilitate the smooth development of the intervention and helped us prepare for the recruitment and training of CHWs in the community.

The MRC guidelines propose the use of evidence based approaches together with the appropriate theoretical understanding, followed by pilot testing and then evaluating the intervention [46]. Our study generated qualitative evidence on the acceptability and feasibility of a task sharing psycho-social counselling intervention for perinatal depression among Xhosa-speaking depressed pregnant women or mothers of young babies in Khayelitsha [59]. By conducting this formative research we were able to improve the acceptability of the intervention and gauge the feasibility of the intervention in terms of location, possible providers and possible content of the intervention. As indicated in Chapter 3, we found that perinatal women were willing to attend counselling sessions provided the sessions were by someone who speaks their language and has practical experience with counselling in terms of knowing what they are doing and not necessarily with a formal qualification. These findings can be linked to the above mentioned cultural appropriateness of an intervention since language is an important part of culture and participants prefer to be able to express themselves in their local language [41]. These findings show that in the context of task sharing (using non-specialists), having local experience and understanding of culture is essential in order to allow participants to express themselves freely.

Our formative study also documents the importance of a consultative process with potential service providers. We found that nurses, who we initially thought were in the best position to deliver the intervention, felt overloaded and would find additional training overwhelming. This notion has been well documented by several researchers examining the job satisfaction of nurses in relation to the HIV/AIDS epidemic. This has

resulted in an increased workload due to task sharing of antiretroviral treatment (ART) in the clinics by nurses which in turn is leading to increased stress and pressure on the nurses at local clinics [160-163]. There are also findings to support how increased burden at clinics presented by the HIV/AIDS epidemic has also led to HIV stigma and avoidance of local clinics as some people living with HIV (PLWH) choose to receive their ART at a different clinic to protect anonymity. Since nurses had indicated their disgruntlement, in our formative interviews we interviewed community health workers (CHW) and found that they were willing to conduct the counselling since they had flexible work schedules and also seemed motivated to receive training and provide the counselling. These formative interviews also gave us insight into the level of training that would be required to ensure that CHWs were adequately trained and given the necessary support through supervision. The post-intervention findings show that CHWs felt satisfied with their level of training, supervision and confidence to begin counselling sessions which highlights how important motivation to deliver counselling is in an intervention.

Our study also demonstrated the importance of collaborating with existing community resources when we worked together with a local NGO to recruit and train potential counsellors. By collaborating we were able to obtain counsellors who already knew how to build a relationship with pregnant women and mothers of young babies, which was crucial for our study. Such collaboration is in line with the WHO recommendations for task sharing [17]. Collaboration was also important as the counsellors became a resource for the community thus further building the capacity of the community. This facilitates ongoing collaboration and capacity building within the community as the trained CHWs become a useful resource to the community. Including potential service users and providers in formative research ensured cultural relevance of the intervention. This improves the acceptability and feasibility of the proposed intervention as supported by several researchers, who advocate for consultation with the people who will benefit from the intervention [41, 98, 115].

### **6.3 Qualitative evidence of process evaluations**

The PhD study adds to the literature on qualitative evidence of process evaluations by conducting two components of post-intervention process evaluations; one from the

perspective of the providers and one from the perspective of the recipients of the intervention. The first post-intervention component with the six AFFIRM-SA counsellors contributes to the body of evidence of delivery of the intervention and fidelity assessment of a task shared psycho-social intervention, linked to an RCT. Similar to the qualitative research on the THP in Pakistan [44] and the Friendship Bench in Zimbabwe [47, 48], this study also reflects on counsellor motivation and intervention components that the counsellors found difficult or easier to deliver. These findings contribute to literature on how to conduct a qualitative process evaluation and provide valuable qualitative evidence on the feasibility, acceptability, usefulness and application of the intervention from a counsellor's perspective. The study also shows how including assessment of fidelity and quality of implementation in the process evaluation as part of an RCT can complement the quantitative outcome evaluation of the trial [101], although this was not done for the AFFIRM-SA trial within this thesis. We found that counsellors were motivated to conduct the counselling and felt supported adequately through supervision although some did not feel comfortable with having the supervisor in the room [62]. These findings are useful for the development of training tools for training and supervision of lay counsellors. Recommendations were made from this analysis for improving the implementation of the intervention in terms of the content and structure as well as factors outside of the manual content. For example, on completion of the RCT, revisions were proposed to make the intervention manual shorter by reducing the number of sessions. The recommendation was to exclude behaviour activation and the psychoeducation on birth preparation. The proposed revised intervention would have three sessions: psycho education for depression, problem solving and healthy thinking [62].

The final component of the qualitative process evaluation with a sample of 34 participants of the task shared intervention contributes knowledge on the experience of receiving a task shared counselling intervention for perinatal depression in LAMICS [164]. Interviewing non-attenders and partial attenders helped us to explore what factors either prevented them from attending or led to their drop out. We also explored factors which enabled the complete attenders to come back for sessions. We found contextual factors such as having moved away from the area, having gone back to work and personal factors such as laziness or lack of interest reported by a few participants as reasons for not attending. It is also possible that some of the

participants experienced decreased depressive symptoms as a result of natural transient trajectories of depressive symptoms in the post-natal phase [165-167]. This natural improvement in mood could be attributed to a decreased need for support. These findings highlight the role of contextual factors in non-attendance. We are aware that this was a qualitative study based on a small sample and we cannot show a causal link due to the small sample size and qualitative nature of the study. Nevertheless, it is important for future researchers to note potential contextual factors that could affect the delivery of their intervention. Both post-intervention process evaluation components provided evidence on qualitative process evaluations that play an important role in complementing the quantitative components of the RCT. The process evaluation forms part of the growing field of implementation science research which explores how multiple variables that are constantly changing can influence each other, [157, 158] and although for this PhD study we did not explore the outcomes of the larger AFFIRM-SA trial, we obtained valuable insights into counsellor and participant points of view.

This PhD study is the first to present information from a South African trial with depressed pregnant women and mothers of young children. The friendship Bench and Thinking Healthy programmes [44, 47, 48] are therefore the closest examples of task shared interventions in similar contexts. These two programmes document how task shared interventions can be implemented in LAMICs and make use of similar approaches to the AFFIRM-SA intervention such as problem solving therapy and cognitive behavioural therapy techniques. It is important to note that although a comparison has been drawn between all three programmes, their limitations should also be acknowledged. For example, the Friendship Bench is not specifically for perinatal women, and the Thinking Healthy programme was conducted in an Asian setting.

### **6.3.1 Provision of evidence on supervision**

This study also provides information on the fidelity assessment and supervision of a task shared intervention. A fidelity checklist was developed to ensure that counsellors were following the intervention manual as intended. Our findings reveal wide variation

between counsellor's fidelity scores and a moderate to good average fidelity rating of 62.8% across the counsellors. This finding indicates moderate to good adherence to the intervention manual while delivering the AFFIRM-SA intervention.

Supervision was provided in both individual and group format in order to follow up on cases, provide debriefing after a difficult case, and to provide ongoing training and support to the counsellors. More information is provided in the paper on counsellor perspectives [62] see in Chapter 4. This information is useful for the replication of the model of supervision in future studies.

### **6.3.2 Refinement of the intervention**

Findings from this research are relevant to inform ongoing development in the field of implementation science [157, 158]. Our studies led to the refinement of the intervention and intervention materials. As indicated above, the findings indicate the need for flexibility in the number of sessions, and adapting the length of the counselling to women's specific needs. As a result, we reduced the number of sessions by removing three sessions leaving the three on psycho-education for depression, problems solving and healthy thinking. Additional training was conducted with the NGO where the counsellors went back to in order to equip more CHWs with counselling skills when dealing with perinatal depression in the community. However, this revision was not evaluated and this would be necessary in future.

### **6.3.3 Reflexivity**

Reflexivity is important in the context of a study of this nature as it takes into account the researcher's background and point of view and how that impacts the study [66, 140]. In this study a reflexive approach enriched my understanding of the data, for example, I was aware of how my role as a trainer and supervisor assisted and compromised my engagement with the research. On the one hand it assisted me in gaining a detailed in-depth understanding of the challenges the counsellors faced, and the details of the interactions between clients and counsellors. On the other hand, my proximity to the research may have compromised me in that I may have been invested in the clients benefitting from the intervention, which means a less objective approach

to the data. I therefore mitigated these potential sources of bias by the following ways; making use of independent field workers to conduct the interviews with the counsellors and the participants of the intervention and use of an additional coder (MS) who was the project manager to analyse the transcripts to assess for counsellor fidelity when conducting the intervention. It is important to note that (MS) was blinded and therefore unaware of the identity of the intervention recipients.

#### **6.4 The way forward: implications for policy makers, mental health researchers, service providers and lay counsellors**

Findings from this PhD have shown feasibility and acceptability of a task-shared intervention for perinatal depression which can be used by local NGOs in communities that work with women in the perinatal phase. The PhD also highlights implementation facilitators such as counsellor and participant motivation, counsellor warmth, fidelity to the intervention and potential contextual barriers such as concerns around safety when conducting home visits and fluctuation in attendance rates of intervention participants. It is therefore important for service providers to come up with innovative ways of retaining participants.

Based on our findings, we would like to recommend that existing policies that address mental health services should support the scaling up and implementation of task shared interventions, in line with the WHO mental neurological and substance abuse service package guidelines [17]. In South Africa, the Mental Health Care Act of 2002 promotes access to care and emphasises the rights of patients with mental illness. Task sharing would help many perinatal women gain access to care in their local communities. Current research on task sharing should be integrated into any future mental health policies. Both components of the post-intervention process evaluation with the counsellors and with the participants contributed further evidence and recommendations on points for consideration when looking at the development of interventions to ensure local relevance and cultural sensitivity.

Findings also suggest that there should be more counselling services provided as part of current perinatal mental health services in the primary care clinics in order to improve the reach for perinatal women. This can be done by ensuring that there are

CHWs at antenatal services to screen and counsel depressed women and to refer them to other service providers when necessary. However governments need to allocate a bigger budget to support mental health services [17]. There should also be provision made for perinatal women to seek counselling services at different time points including at their antenatal and postnatal appointments, and when they return to work. These appointments could be through government led perinatal wellness programmes which ensure that perinatal women are supported during these phases.

Such initiatives would be particularly useful for those women who find the perinatal phase to be extremely stressful or who lack social support. Our findings in Chapter 4 also indicate that miscarriages, stillbirths and baby deaths are common and concerning. It is important for women who experience this trauma to be offered counselling services and support at their local clinics. More financial resources should be allocated for the treatment of perinatal depression as a priority due to the high rates in LAMICS and its impact on households and child development. By investing in the treatment of perinatal depression governments will either prevent or help treat perinatal depression thus reducing DALYS [2, 17] and other adverse consequences of perinatal depression, such as deaths from suicide and self-inflicted injuries [17].

These recommendations are in line with the Department of Health's Mental Health Policy Framework and strategic plan of 2013 – 2020 (MHPF) for South Africa. The MHPF has eight objectives: advocacy, mental health promotion and prevention of mental illness; human resources for mental health; intersectoral collaboration; research and innovation; institutional capacity building; surveillance; infrastructure and capacity building in facilities; mental health equipment, medicines and technology; district-based mental health facilities and primary health care revamping [168, 169]. As part of the implementation surveillance we would recommend a detailed assessment of fidelity to the intervention which looks at the four main ingredients of fidelity intervention protocol and design, quality intervention training, monitoring quality of delivery of the intervention and monitoring of the intervention receipt [81-83].

The studies included in this PhD provide suggestions on important issues to consider such as the recruitment, training and supervision of lay counsellors (set out in Chapters 2 and 3). The AFFIRM-SA counsellors who returned to the local NGO are now able to use a manual to counsel depressed women in the perinatal period as part

of their home visiting programme. We also trained a further 38 counsellors and supervisors at this NGO in order to build capacity in the organisation for CHWs to continue with the intervention in the community, which is one of the key objectives of the MHPF. The counsellors used in the study were a crucial resource during the training of additional CHWs as they could provide practical examples of scenarios they had encountered, and demonstrated how to conduct the sessions during the role plays. Our intervention recipients indicated that they kept attending sessions because of the way the counsellors spoke to them, particularly their warmth and empathy which is a crucial component of the therapeutic relationship. More efforts should go into training and supervision of CHW in order to strengthen human resources in the communities [17, 32, 116]. As indicated in Chapters 3, 4 and 5 potential qualities of counsellors include empathy, warmth and active listening [164] which are useful attributes to target when screening and recruiting lay counsellors. An individual who is empathic and motivated to learn more about counselling can therefore be recruited as a CHW as part of pre-service and in-service training of CHWs.

This PhD has shown that task shared interventions can be effectively developed and evaluated. Based on our findings, we recommend that there be a standard reporting format on qualitative process evaluations for trials of task shared interventions which can be influenced by the MRC and Steckler et al. frameworks [50]. This framework can focus on training and supervision of CHWs, fidelity assessment and dose received in order to provide more information for the replication of intervention delivery. Recommendations for reporting of process evaluations in this context are set out in table 13. In addition, qualitative data on the provider and recipient will prove to be beneficial to the South African National Department of Health's campaign on the first 1000 days if it includes intervention for maternal mental health [170].

Table 13: Standard reporting format for process evaluations

<b>Component</b>	<b>Description</b>
<b>Context</b>	What aspects of the larger social, political and economic environment affected the intervention such as taxi strikes, poverty
<b>Implementation</b>	How was delivery of the intervention achieved? Resources.
Capacity Building	To what extent was previous training and experience relevant to CHW role? What additional knowledge, skills and attitudes did CHWs and participants learn?
Current training and supervision	What key competencies did CHW need to deliver the intervention? How long was training and how often was supervision conducted?
Fidelity	Was the intervention delivered as intended according to manual? Were there any adaptations to the intervention? Was there a fidelity checklist to indicate how fidelity was assessed?
Dose delivered and received	How many sessions did they manage to have on average? How many clients completed all sessions?
Reach	Overall attendance? Did some participants attend more sessions than others?
<b>Mechanisms</b>	What were participant responses and interactions with the intervention? Were participants motivated to attend sessions and what made them motivated?

## 6.5 Strengths and Limitations

This thesis has highlighted several strengths and limitations.

### Strengths

1. It provides original data on the process of developing and implementing a task sharing intervention for perinatal psycho-social intervention for depression.
2. It uses in-depth qualitative methods that allow for a detailed investigation of the experiences of women in delivering and receiving the intervention.
3. It draws attention to the importance of qualitative process evaluations, alongside the quantitative outcomes in RCTs.
4. It uses the MRC framework as a coherent theme in all the papers presented in this thesis. Firstly, in the systematic review to provide qualitative evidence of

process evaluations, secondly in the formative research and intervention development, and lastly to explore two components of qualitative process evaluations of interventions for perinatal depression.

5. The methods used to deliver the intervention are consistent with other studies on task sharing that have been conducted in LAMICS such as the Thinking Healthy Programme in Pakistan and The friendship Bench intervention in Zimbabwe [44, 47, 48]. It highlights the importance of cultural relevance when examining the location and context of an intervention [44, 105, 106]. The study forms part of implementation research which is an important growing field for filling the mental health treatment gap [171] as it provides evidence of useful techniques together with qualitative evidence of participant experiences.

#### Limitations:

1. This study makes use of a relatively small sample in a specific context – therefore findings need to be engaged with critically before generalizing to other settings.
2. Qualitative methods need to be supplemented with quantitative findings when looking at effectiveness of the interventions.
3. As with any qualitative findings, the perspectives of the investigators need to be critically engaged with.
4. The fidelity rating of 62% is good, which indicates that there is substantial room for improvement, in addition to normal fidelity assessment, Singla and colleagues suggested that counsellor competence can be assessed at specific intervals during a trial in order to track any changes in counsellor skills [172]. Although our study made use of ongoing supervision and training with role plays, a formal counsellor assessment by an external individual could have helped us to improve implementation fidelity. It might also be helpful to develop and evaluate strategies to identify barriers to training and supervision of counsellors [171].

General strengths and limitations of this research are embedded in the qualitative paradigm. However efforts have been made to ensure rigour through use of the

COREQ and discussions with all co-authors of the papers. Detailed limitations are included in all the papers that are included in this thesis.

## **6.6 Future research**

Based on our findings from this research, it is helpful to propose the following future directions of research;

1. It will be helpful to integrate findings from AFFIRM-SA's mixed methods by comparing the qualitative process evaluations with the quantitative outcomes of the trial. It will also be helpful to conduct a larger fidelity assessment study with a larger sample in order to have a detailed account of fidelity to the intervention.
2. We need more psycho-social interventions of a task shared nature in LAMICS to cater for women in the perinatal phase. We need to conduct more qualitative process evaluations of these interventions in order to get culturally relevant information on participants' experiences of the interventions that have been delivered. We also recommend that researchers use the proposed table above which highlights standard reporting format for process evaluations
3. The AFFIRM-SA intervention can be improved and adapted for delivery in local CHCs. We would recommend that the effectiveness, feasibility and acceptability of the adapted brief intervention be assessed prior to the roll out.
4. Qualitative process evaluation methods can be standardised as suggested by the MRC framework and we further recommend that the reporting of process evaluations be standardised as recommended above in order to narrow the treatment gap. If reporting on process evaluations includes assessment of fidelity and checklists it can help with the replication of further studies and facilitate the sharing of information and capacity building in LAMICS.
5. We recommend more collaboration between researchers developing interventions in LAMICS in the form of networks in order to facilitate best practice sharing when evaluating interventions for scale up in larger populations. Qualitative process evaluations can be useful when considering scale up as they will obtain valuable information on participant perceptions of

the proposed interventions prior to scale up. Potential populations should be consulted in terms of the possible location, content, structure and frequency of any new interventions which will be delivered in their communities.

6. Lastly, we would recommend partnerships with the Department of Health and other potential service providers in order to ensure that women in the perinatal phase are supported efficiently. This support can include telephone contact or face to face sessions by a community worker who is available if the women need additional support. These CHWs would need ongoing training and supervision in order to assess the quality of their intervention and to continue supporting and building their capacity to counsel the women on an ongoing basis.

### **6.7 Concluding remarks**

This thesis has explored the development and process evaluation of a psycho-social task sharing intervention for maternal depression in Khayelitsha, Cape Town. The thesis has also highlighted the context of the emerging field of global mental health, prevalence of mental disorders from LAMICS and the human resource constraints and treatment gaps for mental disorders. Findings from this research highlight the importance of filling the treatment gap through task shared interventions for perinatal depression which have been shown to be feasible and acceptable in resource limited settings, such as Khayelitsha. The thesis has highlighted a paucity of qualitative process evaluations, and highlighted the importance of conducting a detailed qualitative evaluation of interventions to complement more quantitative evaluations in RCTs, and thus consolidate the evidence base. Furthermore, the study has shown how process evaluations assist in understanding how interventions should be conducted and what aspects are effective. The thesis has shown how CHWs are able to deliver task shared interventions in order to reduce the treatment gap, provided that there is adequate training, supervision and support to sustain their efforts. The study forms part of implementation research which is an important field for filling the mental health treatment gap in LAMICS.

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# Appendices

## Appendix A

### Edinburgh Postnatal Depression Scale (EPDS)

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

IN THE PAST 7 DAYS:

1. I have been able to laugh and see the funny side of things
  - As much as I always could [0]
  - Not quite so much now [1]
  - Definitely not so much now [2]
  - Not at all [3]
  
2. I have looked forward with enjoyment to things
  - As much as I always did [0]
  - Rather less than I used to [1]
  - Definitely less than I used to [2]
  - Hardly at all [3]
  
3. I have blamed myself unnecessarily when things went wrong
  - Yes, most of the time [3]
  - Yes, some of the time [2]
  - Not very often [1]
  - No, never [0]
  
4. I have been anxious or worried for no good reason
  - No, not at all [0]
  - Hardly ever [1]
  - Yes, sometimes [2]
  - Yes, very often [3]
  
5. I have felt scared or panicky for no good reason
  - Yes, quite a lot [3]
  - Yes, sometimes [2]
  - No, not much [1]
  - No, not at all [0]
  
6. Things have been getting on top of me
  - Yes, most of the time I haven't been able to cope at all [3]
  - Yes, sometimes I haven't been coping as well as usual [2]
  - No, most of the time I have coped quite well [1]
  - No, I have been coping as well as ever [0]
  
7. I have been so unhappy that I have had difficulty sleeping
  - Yes, most of the time [3]
  - Yes, sometimes [2]
  - Not very often [1]
  - No, not at all [0]
  
8. I have felt sad and miserable
  - Yes, most of the time [3]
  - Yes, quite often [2]

- Not very often [1]
  - No, not at all [0]
9. I have been so unhappy that I have been crying
- Yes, most of the time [3]
  - Yes, quite often [2]
  - Only occasionally [1]
  - No, never [0]
10. The thought of harming myself has occurred to me
- Yes, quite often [3]
  - Sometimes [2]
  - Hardly ever [1]
  - Never [0]

SCORE:

## **Appendix B**

### **HAMILTON DEPRESSION RATING SCALE (AFFIRM 2013)**

Adapted from POTS et al. 1990, Structured Interview Version of Hamilton Depression Rating Scale (SI--HDRS): Items and Range of Response Categories.

#### **1. WORK AND ACTIVITIES**

**During the past month, have you been less able than usual to work or do your usual activities? Do your activities make you feel tired, or have you lost interest in your activities?**

- 0 *No decrease in productivity or time spent at work and/or doing usual activities*
- 1 *Activities make you feel tired*
- 2 *Lost interest in work or activities*
- 3 *Decrease in productivity of work or activities*
- 4 *Spending less time at work or doing activities*

#### **2. LOSS OF WEIGHT**

**Have you gained or lost any weight during the past month?**

- 0 *No*
- 1 *Possibly*
- 2 *Yes, definite change in weight (not on diet)*

#### **3. SOMATIC SYMPTOMS: GASTROINTESTINAL**

**During the past month, have you experienced a loss of appetite?**

- 0 *No loss of appetite*
- 1 *Some loss of appetite but still eating*
- 2 *At least some loss of interest in food and requires encouragement to eat*

#### **4. GENITAL SYMPTOMS**

**During the past month, have you had an interest in sex?**

- 0 *Yes, normal interest in sex (or is not sexually active)*
- 1 *Somewhat less interest*
- 2 *A lot less interest than usual or no interest at all*

## 5. INSOMNIA EARLY

During the past month, have you had troubles or difficulties falling asleep?

- 0 No
- 1 Sometimes
- 2 Yes, almost every night has difficulty

## 6. INSMONIA MIDDLE

During the past month, have you been waking up during the night?

- 0 No
- 1 Sometimes
- 2 Yes, almost every night has difficulty and gets out of bed, other than for urinating/ peeing.

## 7. INSOMNIA LATE

During the past month, have you either been waking up earlier in the morning than you wanted to or sleeping too much?

- 0 No
- 1 Sometimes
- 2 Yes, wakes early and cannot go back to sleep, or sleeps too much most of the time

## 8. SOMATIC SYMPTOMS: GENERAL

During the past month, have you experienced fatigue or had less energy than usual? Or have you had headaches, backaches, or aches in specific parts of your body?

- 0 No loss of energy, fatigue, or body aches
- 1 Some loss of energy and body aches
- 2 Yes, marked loss of energy, and/or has a clear symptom of pain, e.g., headaches or local muscle aches

## 9. GUILT

During the past month, have you been feeling guilty or bad about something you have done? Do you feel you have let people down or that you are evil? Do you think your illness is punishment for something?

- 0 No feelings of guilt
- 1 Feels she has let people down
- 2 Feels she has let people down AND feels evil or bad
- 3 Thinks that her illness is a punishment
- 4 Hears voices or feels that her badness will hurt others or will lead to her own death

## 10. ANXIETY, PSYCHIC

During the past month, have you been feeling nervous, anxious, worried or frightened?

- 0 Never
- 1 Sometimes
- 2 Quite often
- 3 Most of the time
- 4 Yes, severe symptoms all the time which are incapacitating or disabling

## 11. ANXIETY, SOMATIC

Now I am going to read you a list of physical symptoms. Tell me if you experience any of these and how severe they are.

- A. Stomach or digestive problems or pains
- B. Heart palpitations
- C. Breathing very fast or trouble breathing
- D. Urinating often
- E. Muscle aches, body aches
- F. Unusual sensations like trembling or ringing in your ears
- G. Flushing, feeling faint, or sweating

Code for the most severe symptom:

- 0 Absent
- 1 A little bit
- 2 Some
- 3 A lot
- 4 Severe and incapacitating problem

## 12. HYPOCHONDRIASIS

During the past month, have you been worrying more than usual about your health and how your body is working? (Apart from normal fears about your pregnancy)

- 0 Not worried at all
- 1 Some unnecessary worry about her health
- 2 A lot of unnecessary worries about her health
- 3 Strong beliefs she has a physical problem and doctors won't believe her
- 4 Delusional, i.e., has false beliefs, eg. Thinks her body is rotting

## 13. SUICIDE

During the past month, have you had thoughts that life is not worth living, or that you would rather be dead? Have you had thoughts of hurting or killing yourself?

- 0 No
- 1 Sometimes
- 2 Most of the time
- 3 Often
- 4 Suicide attempt

## 14. INSIGHT

Do you think that you have a psychological problem, such as depression?

- 0 Acknowledges being depressed or having a psychological problem (OR is not currently depressed)
- 1 Acknowledges illness but blames it on something else
- 2 Denies any illness but is currently depressed in interviewer's opinion

## 15. DEPRESSED MOOD

During the past month, have you been feeling sad, depressed, helpless, hopeless, or worthless? If yes, how often do you feel this way?

- 1 *No, not at all*
- 2 *Occasionally*
- 3 *Quite often*
- 4 *Very often*
- 5 *Yes, almost all the time*

## **16. RETARDATION**

**Observe and rate slowness of thought, speech, concentration, and physical movement (Observation only)**

- 0 *Normal speech and thought*
- 1 *Slight retardation (a bit of slowness in thinking or speaking)*
- 2 *Obvious retardation (a lot of slowness in thinking or speaking)*
- 3 *Interview difficult (a lot of very long pauses)*
- 4 *Interview impossible*

## **17. AGITATION**

**Observe and rate restlessness, fidgetiness and physical activity (Observation only)**

- 0 *None*
- 1 *Fidgetiness*
- 2 *Playing with hands, hair, obvious restlessness (restless, unfocused, playing with hands or clothes)*
- 3 *Moving about; can't sit still*
- 4 *Hand wringing, nail biting, hair pulling, biting of lips, patient is moving about a lot*

**Total score: |**

**APPENDIX C: Preferred Reporting Standards for Systematic Reviews and Meta-analysis (PRISMA) Statement**

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional	6

		studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	8

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7

Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	7
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	7
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	8-14
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	7
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	15-17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	18

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	20

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement.

PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).

## Appendix D: Data Extraction Table

Study Site	Sample size	Inclusion criteria	Study Design	Intervention type	Process Evaluation	Main Findings	Implementation	Mechanisms	Context
Rawalpindi, Pakistan	30 Perinatally depressed women, 24 LHWs, 6 primary care staff	Depressed women, LHWs and Primary healthcare staff	Multi-method formative study	CBT for depression	Post intervention interviews with community health workers and participants of the Thinking healthy programme.	Exploring socio-cultural aspects of depression from participant's point of view. Exploring aspects of delivering the intervention from LHW point of view, most health workers felt that intervention was useful and they were able to understand the concepts and explain them to participants. Most did not feel that the programme was a burden to their work.	Making intervention easy to follow to include illiterate participants same 3 steps to every session. Not calling the intervention "therapy" but "training", could prevent stigma of labelling. Difficulty accessing women if agenda was to treat depression. Discussing infant outcomes, window for access to intervention- health promotion and shared goals, more culturally appropriate, intervention involving the whole family, making mothers active	Problem perception- depression not a problem needing intervention. Stigma, from being labelled as depressed, talk therapy not material assistance/ or gain. Willingness to learn new childcare practices for optimum child development	LHW were already visiting mothers in homes, additional training required to facilitate the THP. Making the intervention culturally appropriate, e.g. observing cultural practices such as observing chilla (when a woman rests after giving birth). Culturally appropriate illustrations important

							<p>participants as opposed to passive recipients in order for changed in thinking to change behaviour .E.g. passiveness is I was told I should take it, versus I should take it because it is important. Heavy workload for LHWs, therefore need to integrate into existing schedules. Patchy services in existing LHW programme due to poor selection of workers, unmotivated health workers, and poor governance- which needed changing for intervention to be effective.</p>		
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Jharkhan and Orissa, India	244 women's groups, population of 114 141, 18 Group facilitators in intervention areas	Pregnant women	Mixed methods process evaluation	Participatory learning and action cycle	Context, content, and implementation of intervention, potential mechanisms for impact and indication of challenges experienced in the field.	6 broad interrelated factors influenced the intervention's impact. 1) acceptability, 2) participatory approach to the development of knowledge skills and 'critical consciousness' 3) community involvement beyond the groups 4) a focus on marginalised communities 5) the active recruitment of newly pregnancy women into groups 6) high population coverage. If key characteristics of participatory interventions with community groups are maintained and adapted to fit the local context then they can influence maternal and child outcomes. In order to scale up these interventions, a detailed understanding of the way in which context affects the acceptability and delivery of the intervention, planned but flexible adaptation and replication of key intervention features and strong support for participatory methods from implementing agencies. Lay health workers as facilitators	Acceptability affects the implementation of the intervention, participatory approach leads to critical consciousness, active recruitment of newly pregnant women into the groups, high population coverage,	Community involvement beyond the groups, willingness to learn and to change child care practices	Focus on marginalised communities, rural communities, limited access to health services,
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China	20 participants	women who received the intervention	mixed methods process evaluation	Psycho-education , IPT techniques	one on one in-depth interviews with service users	IPT conducted by midwives	Knowledge, information and skills, interaction with midwife and other women	Motivation to attend the programme, positive feedback, better interpersonal relationships, willingness to learn	China, chines culture, family oriented,
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**Appendix E: Critical Appraisal Skills Programme Qualitative data checklist**

Article(s)	Clear statement of aims	Appropriate methodology	Appropriate research design	Detailed, justified, recruitment strategy	Appropriate data collection methods	Researcher-participant relationship considered	Ethical issues considered	Rigorous data analysis	Clear findings	Value of research discussed
2007 Rahman, A.	Y	Y	Y	I	I	Y	Y	Y	Y	Y
2010 Rath et al.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2012 Gao, Luo, Chan	Y	Y	Y	I	Y	y	Y	Y	Y	Y

**(Y=Yes, N=No, I=Insufficient information)**

## Appendix F

### AFFIRM FORMATIVE RESEARCH STUDY

#### FORMATIVE RESEARCH INFORMED CONSENT FORM FOR SERVICE USERS

#### INFORMATION SHEET FOR PARTICIPANTS: (Mothers)/ (Pregnant Women)/ (Circle Appropriate Group)

##### The Research Study

We are asking you to take part in this research study. You should only take part if you want to. Choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

The study will be conducted by researchers from the **AFrica Focus on Intervention Research for Mental health (AFFIRM)**, South Africa. AFFIRM is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health, and funded by the National Institute of Mental Health.

##### Aims of the research

The aim of the study is to find out what should be involved in a programme that suggests ways for depressed mothers to solve problems, using community health workers as the assistants, in Khayelitsha, Cape Town.

##### What are we trying to learn?

In this research we want to understand how mothers suffering from mental distress and depression get help with their problems, how they view their problems, and what stops them getting the care they need.

We want to know:

1. What kind of visits and help depressed mothers require, and how many visits are acceptable to them.
2. How acceptable it is for Community Health Workers to help depressed mothers.
3. What problems the research may come across.

##### Why is it important?

This study is important so that we can develop better quality and cheaper services for depressed mothers.

##### Who will be involved and how long will it last?

1. Pregnant mothers in the third trimester and mothers with babies up to one year old, screened to have a mental health problem, who are attending the Michael Mapongwana Community Health Centre.
2. Community Health workers based at the Michael Mapongwana Community Health Centre, who work with pregnant mothers and/or mental health in Khayelitsha.

3. Registered Nurse Midwives based at the Michael Mapongwana Community Health Centre, who work with pregnant mothers and/or mental health in Khayelitsha.
4. Service managers at the Michael Mapongwana Community Health Centre.

The interviews will run over a period of four months from July 2012 to November 2012.

**What will it mean if you participate in the study?**

If you agree to participate in this study you will be asked to answer a number of questions about your mental health in an interview. A research assistant will ask you questions about your own experience and knowledge of how people with mental illnesses get help, how they view their illness and the factors that get in the way of them getting the care they need. The interview will take about one hour. If you are happy to do so, we will tape-record this interview.

This information will be used to help us put together a low cost counselling programme to help mothers who are suffering from depression.

**Would there be any harm to me if I participate in this study?**

There is the possibility that you may have a mental health problem yourself or that answering the questions may remind you of a time that you had such a problem. If you get upset by this, we will refer you for help with a counsellor.

**Is there any good reason for the study?**

We hope that the information we get will help to improve mental health services and treatment in South Africa and other countries in Africa.

**What if I change my mind later?**

You are free to stop participating in the study at any stage and your decision will not affect you in any way.

**Who will see the information that we collected?**

All interviews will be recorded and transcribed. The records will be kept completely confidential and private. Your name will not be used, and the recordings and interviews will be destroyed after we have worked with them. The information will only be seen by the researchers and not by anyone in the community.

**Who to contact if you want to know more, or if you have a problem at any time?**

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

The project manager for Affirm.

Centre for Public Mental Health, University of Cape Town

Tel: 021 685 9625

Memory Munodawafa Thesis 2018

Or: Prof C. Lund, Centre for Public Mental Health, University of Cape Town

Tel: 021 685 0120

If you have any questions about your rights and welfare in the research, please contact:

The Human Research Ethics Committee, Groote Schuur Hospital.

Tel: 021 406 6626

### **Consent to Enroll**

I, \_\_\_\_\_ agree to participate in the research study on mental health in Khayelitsha, to help to develop relevant and low-cost ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Witness 1

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Witness 2

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

You may keep the information sheet. The signed consent form will remain in our study files.

### **Appendix G**

#### **AFFIRM UCT RANDOMIZED CONTROL TRIAL**

#### **INFORMED CONSENT FORM FOR SERVICE PROVIDERS: Community Health Workers/ Midwives/ Nurses (*Circle Appropriate Group*)**

##### **The Research Study**

We are asking you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

The University of Cape Town is doing this project to research maternal mental health in mothers in Memory Munodawafa Thesis 2018

Khayelitsha. The project is called AFFIRM, (**A**frica **F**ocus on **I**ntervention **R**esearch for **M**ental health), which is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health. It is funded by the National Institutes of Health, USA.

### **Why is it important?**

The study is important because one out of every three women in Khayelitsha experience depression or anxiety when they are pregnant or after having a baby.

### **What is it for?**

This study is looking at ways to provide counselling services and mental health assistance to depressed pregnant women and mothers, so that they can learn to manage and cope with maternal distress.

We want to find out how best to use a “task-shifting” approach, which means using community health workers instead of psychologists and psychiatrists, to provide counselling services for depression. We want to develop appropriate and cost effective mental health services for these women, and we hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

### **Who will be involved?**

1. 420 pregnant women at their first antenatal booking at Michael Mapongwana Community Health Centre, who show symptoms of depression when assessed on the EPDS
2. Community Health workers who work in the catchment area of Michael Mapongwana Community Health Centre.
3. Registered Nurse Midwives based at Michael Mapongwana Community Health Centre, who work with perinatal mothers and/or mental health in Khayelitsha.
4. Service managers at the Michael Mapongwana Community Health Centre.

**How long will it last?** The study will run from July 2012 to July 2015.

### **What will it mean if you participate in the study?**

If you agree to participate in this study you will be asked a few screening questions about depression with the EPDS. If you are distressed according to the EPDS, we will continue with an interview which will take approximately one hour. The interviews will ask some sensitive questions and all information you give us will be kept strictly confidential. You can refuse to answer any questions that you feel uncomfortable answering. The information you give us will be used to help us design a cost effective counselling intervention to help mothers who are suffering from depression.

After this, you will EITHER receive 6 counselling sessions when you come for your pregnancy check-ups, OR monthly telephone calls from a community health worker to discuss your depression and ways to help to improve it. The sessions will be audio recorded to ensure the quality of the counselling. You will then be asked to participate in three more interviews at: one month before birth, three months after birth, and twelve months after birth. We intend to conduct the interviews and counselling sessions on the same days you come for your pregnancy and baby check-ups at the clinic so that you will not incur any additional costs.

We will inform you if any new findings arise during the duration of the study that may affect your participation.

### **Is there any disadvantage from participating in this study?**

There is the possibility that you may have a mental health problem or that participation in the study may remind you of a time that you had such a problem. The risks associated with worsening of your depression are present whether or not you participate in this study. If you get distressed by a mental health problem or feel suicidal, we will refer you for psychological help. If you have a serious substance abuse problem or psychiatric illness that was not initially picked up at the interview, we will refer you for external assistance and you will no longer be able to participate in the study.

If you receive counselling from us, there a small risk that counsellors may breach confidentiality and/or disclose personal information to you or others. We will minimize this risk by careful evaluation of the counsellors and through weekly group supervision and monthly individual supervision for them.

**Is there any advantage to the study?**

We hope that the counselling will improve your mental health and help you to build better ways of coping with depression in the future. We also hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

**What if I change my mind later?**

You are free to withdraw at any stage from participating in the study and your decision will not disadvantage you in any way. You will need to inform a member of the project if you wish to withdraw, and if you require, we can refer you to relevant local mental and social health services.

**Who will see the information that we collected?**

All interviews will be recorded and transcribed. The records will be kept completely confidential and private. Your name will not be used, and the recordings and interviews will be destroyed after we have worked with them. The information will only be seen by the researchers and not by anyone in the community.

**Who to contact if you want to know more, or if you have a problem at any time?**

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

Prof C. Lund, Department of Psychiatry and Mental Health, University of Cape Town,

Tel: 021 685 0120

If you have any questions about your rights and welfare in the research, please contact: The Human Research Ethics Committee, Groote Schuur Hospital.

Tel: 021 406 6626

**Consent to Enrol**

**Research ID #**

I, \_\_\_\_\_ agree to participate in the research study on maternal mental health in Khayelitsha, to help to develop relevant and cost effective ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness 1**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness 2**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

You may keep the information sheet. The signed consent form will remain in our study files.

## Appendix H

### AFFIRM UCT FORMATIVE RESEARCH

#### Service User Interview Schedule

Statement – At the moment in South Africa, many people who suffer from problems like depression can't get treatment because there are not enough professionals to deliver the care, in this study we are working with South Africa's DEPARTMENT of health to try to help make the situation better

We are interested to hear about your opinion on how people with depression can be helped So that we can make sure that services in the future are relevant to you and people in your community.

Thank you for agreeing to participate and giving your time .please remember we do not share any of your information except the researchers

This is not a test there are no right or wrong answers. We want to find out from you about your Experiences. Everything you tell us will be kept confidential

1. Are you married? Add sections to the questionnaire, look at protocol version.
2. Does your partner /husband live with you?
3. Does your partner/husband give you financial support?
4. What were you happy about when you found out you were pregnant?
5. What were you most worried about when you realized you that [were pregnant]
6. What were you really worried about?
7. Have you told your family and/or your husband that you are pregnant?
8. What did they say?
9. What made them so happy?
10. Is this your first pregnancy?
11. Have ever heard of the word depression?
12. What word/words would you use to describe depression?
13. How would you know if someone is hurt?
14. Do you think you have depression?
15. Why?
16. Has anyone told you they have depression?
17. How does being hurt or these feelings that you have change your daily life?
18. Can further tell me what are the things that change?
19. When did you first start having these feelings being hurt?
20. What do you think caused these feelings or depression?
21. Do you mind sharing one of these things?
22. Do you think these feelings or the depression will go away or do you think they will always be there?
23. Can you explain why you say that/
24. Think about a days when these feelings are really bad. Tell me what such a day is like.
25. Can you tell me what makes it really bad?
26. Can you describe a day you feel better and not so depressed?
27. What makes it better?
28. Was there anything you did yourself?

29. Do you think there is something you can do yourself?
30. Ok how does feeling like this change or affects the way you look at yourself?
31. Do you feel that you have lost confidence in yourself since you have had these feelings?
32. How have you lost hope?
33. How can you feel more hopeful and confident?
34. Do you miss out on socializing because of these feelings or depression?
35. When did you start feeling depressed?
36. For how long with these thoughts?
37. How does feeling like this affect how you feel about having a baby?
38. What makes the situation difficult?
39. Are there times you didn't or don't feel so good about having a baby?
40. How do you think people with depression are treated by health workers?
41. Have you ever have such an experience like this because of depression?
42. What about your family and community, what do they think about people with depression?
43. Have you or someone you know who is depressed looked for help for this depression?
44. How can we find people with depression in the community, so that they can be helped?
45. If mental health services are closer to where people live, will it help them to use the services?
46. Do you know of any services offered by the clinics or hospital or any other organization to help people with depression?
47. Can someone use those services freely/easily?
48. What makes it easy or difficult to use these services?
49. Is distance or transport that make it easy or difficult or money or maybe cost of services or getting someone to go with you?
50. The word/name counselling involves somebody helping you, listening to you talking about your problems, and helping you to find some solution to those problems. It does not mean the counsellor will fix your problems for you, but they can help you find ways to solve some of your own problems by giving you new skills that you can use. This counselling is not the same as HIV counselling. Do you understand what I have just told you?
51. Do you think that counselling could help you with your feelings of depression?
52. In what way could it help you?
53. Do you know what a community health worker is and what they do?
54. Can you explain?
55. Do you know who the community health workers are in Khayelitsha?
56. What do they do?
57. If you could choose, would you want to see a nurse a community health worker or an HIV counsellor?
58. Why?
59. If you could see a counsellor to help you with depression, would you rather see that person at the clinic or at home?
60. Why?
61. If you could choose, what type of person would you choose like to give you counselling?
62. What age?

63. What culture should they have?
64. What language should they speak?
65. What race should they be?
66. Where should they come from?
67. What status should they have?
68. How many times in a month would you like to see the person?
69. If someone came to your house what will your family think?
70. What will the community think?
71. Do you think it is safe for that person to come and visit you?
72. Why?
73. If someone came to home, do you have any private space where you can talk?
74. What makes it easy to manage having a baby?
75. Is there anyone in the house who helps you look after the baby?
76. Can you tell me who and where they are from?
77. Is there anyone who helps to clean the house?
78. If you could imagine the best to help people like yourself who are troubled by depression in this community, what would it be?
79. Would it be best done alone or in a group with other people who are depressed?
80. Can you explain to me why you would choose a group?
81. Where should it take place?
82. Who should provide this help?
83. What can be done by nurses?
84. What could be done by community health workers?
85. What do you think some of the problems to getting this help might be?
86. The question is asking what some of the problems to getting this help might be.
87. What do you do to make things better for yourself?

We have come to the end of our interview, is there anything else you would like to say about depression and pregnancy or the help you would like to get for depression?

I thank you for taking the time to go and look for help like u said you go to counselling continue with it and be strong

## **Appendix I**

### **AFFIRM FORMATIVE RESEARCH**

#### Service Provider Interview Schedule

7. Can you explain to me what your understanding of depression is and how you would know if a person has depression?
8. What are the different words that you and other people use to describe depression?
9. What typical symptoms do people have who are depressed and how do these symptoms affect their lives? How long do these symptoms usually last?
10. What do you think causes these feelings?

11. How common is depression in Khayelitsha? Are pregnant women and mothers more likely to be depressed than other people? If so, why?
  12. What do you think would be the best way to help pregnant women and mothers with depression in Khayelitsha?
  13. What kind of support do you think depressed pregnant women and mothers need?
  14. When do they need help the most – during or after pregnancy, or both? If they need both, would the help they need be different at each time? If so, in what way?
  15. Would you say it would be better to have a CHW or HIV counsellor to do the counselling to the mothers?
  16. Do you know what **mental health counsellors** are? What do mental health counsellors do?
  17. How often should a counsellor come and visit, before and after the birth, if the mother is depressed? How long do you think the visit should be and what should the mental health counsellor do during that visit?
  18. What kind of counsellor is acceptable to depressed mothers or pregnant women? (Gender, age, qualification, culture, race, locality, relationship/ community relations).
  19. Tell me about your work - Which organisation you work for?
  20. Who is your supervisor? How often do you see your supervisor and how do you report to your supervisor?
  21. Do you visit patients at their homes? And if yes, how often do you do this? What kind of work do you normally do with patients?
  22. How comfortable do you/would you feel visiting patients at home – how acceptable is it? (Probe for issues of confidentiality, safety, etc.)
  23. If you were working with pregnant women and mothers who are depressed, how many home visits do you think you could manage, over a period of 6 months? [*If the person struggles to think about 6 months ask about 1 month or even 1 week and then multiply this by 6 for months and by 26 for weeks*].
  24. When in the day and week do you think such home visits would be possible for you?
  25. What training did you do to become an HIV counsellor?
- Q – Would a CHW or HIV counsellor be better for this position?
26. What experience do you have in working with mental health problems, including depression?
  27. Have you completed any training for working with people with mental health problems? What is this qualification called?
  28. Do you have any counselling experience? If so, describe this experience.
  29. What do you do when you counsel somebody?
  30. What skills would you like to learn if you were to provide counselling to depressed pregnant women or mothers of young infants in Khayelitsha?
  31. What kind of support and supervision would you need in order to do counselling for depressed mothers in their homes? How often would you like to meet with a supervisor/manager?
  32. When working with depressed pregnant women and mothers, would it also be helpful to provide information and help mothers with caring for and bonding with their infant?
  33. What limitations/obstacles do you see in delivering a counselling programme to depressed patients at their homes? What are the potential benefits of counselling women in their homes that you wouldn't get if you counselled them at the clinic?
  34. What limitations/obstacles do you see in delivering a counselling programme to depressed patients at the clinic? What are the potential benefits of counselling women at the clinic that you wouldn't get if you counselled them at their homes?

35. How different would it be to do mental health counselling compared to the work you are doing in HIV counselling?
36. Is there anything more you would like to say, or feel we have left out? Do you have any questions you would like to ask me?

## **Appendix J**

### **AFFIRM UCT RANDOMIZED CONTROL TRIAL**

#### **POST INTERVENTION INFORMED CONSENT FORM FOR COUNSELLORS**

##### **The Research Study**

We are asking you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

The University of Cape Town is doing this project to research maternal mental health in mothers in Khayelitsha. The project is called AFFIRM, (**A**frica **F**ocus on **I**ntervention **R**esearch for **M**ental health), which is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health. It is funded by the National Institutes of Health, USA.

##### **Why is it important?**

The study is important because one out of every three women in Khayelitsha experience depression or anxiety when they are pregnant or after having a baby.

##### **What is it for?**

This study is looking at ways to improve the counselling services and mental health assistance to depressed pregnant women and mothers, so that we can improve the quality of our intervention.

##### **Who will be involved?**

Community Health workers who delivering the counselling for the AFFIRM study.

##### **How long will it last?**

The study will run from April 2015 to July 2015.

##### **What will it mean if you participate in the study?**

If you agree to participate in this study you will be asked questions about delivering the AFFIRM intervention and what made it easier or harder to deliver the intervention. The interviews will ask some sensitive questions and all information you give us will be kept strictly confidential. You can refuse to answer any questions that you feel uncomfortable answering. The information you give us will be used to help us design a cost effective counselling intervention to help mothers who are suffering from depression. The interviews will be audio recorded to help us to take a closer look at the issues that you may bring up.

##### **Is there any disadvantage from participating in this study?**

If you participant in our study, there a small risk that you might be reminded of sessions which you found distressing. We will minimize this risk by carefully exploring the sessions that you discuss and giving you the option to refuse to talk about things which you may find too distressing. You will also be referred to a counsellor outside of the project if you would like to speak to them.

##### **Is there any advantage to the study?**

We hope that the counselling will help improve the participants' mental health and help them to build better ways of coping with depression in the future. We also hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

##### **What if I change my mind later?**

Memory Munodawafa Thesis 2018

You are free to withdraw at any stage from participating in the study and your decision will not disadvantage you in any way. You will need to inform a member of the project if you wish to withdraw, and if you require, we can refer you to relevant local mental and social health services.

**Who will see the information that we collected?**

All interviews will be recorded and transcribed. The records will be kept completely confidential and private. Your name will not be used, and the recordings and interviews will be destroyed after we have worked with them. The information will only be seen by the researchers and not by anyone in the community.

**Who to contact if you want to know more, or if you have a problem at any time?**

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

Prof C. Lund, Department of Psychiatry and Mental Health, University of Cape Town,

Tel: 021 685 0120

If you have any questions about your rights and welfare in the research, please contact: The Human Research Ethics Committee, Groote Schuur Hospital.

Tel: 021 406 6626

**Consent to Enrol**

**Research ID #**

I, \_\_\_\_\_ agree to participate in the research study on maternal mental health in Khayelitsha, to help to develop relevant and cost effective ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness 1**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness 2**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

You may keep the information sheet. The signed consent form will remain in our study files.

## **Appendix K**

### **Post Intervention Semi-Structured Interview schedule for counsellors**

#### **1. Capacity building**

- z. What is your motivation for counselling?
- aa. Do you feel that you received enough training to start the sessions?
- bb. Can you describe the shift from receiving the training to delivering the intervention?
- cc. What improvements can you recommend for the training?

#### **2. Environment Issues**

- a. How did you negotiate your way into the clinic environment?
- b. How would you rate the level of acceptance by other nurses and other workers in the clinic on scale of 0(least acceptance) -10 (most acceptance)?
- c. How did you obtain the clients for intervention?
- d. How many clients did you have in total during the course of the trial?

#### **3. Self-Assessment**

- a. Before you started the sessions what were your fears?
- b. How would you rate yourself as a counsellor? On a scale of 0 to 10.
- c. How was your first session? Were any of these fears confirmed or removed after this session?
- d. What did you find easy when delivering the intervention? Or what made it easy to deliver the intervention?
- e. What are your thoughts on the counselling being conducted in Xhosa?

#### **4. Challenges Faced**

- a. What are the challenges that you faced in delivering the intervention?
- b. What can be done to counter these challenges?
- c. What was helpful and what hindered you from implementing what they have been taught?
- d. What aspects of the larger social, political and economic environment that could have affected the intervention e.g. taxi strikes, poverty

#### **5. Attendance**

- a. Describe your experience of working with younger or older clients in terms of overall attendance. How many clients had all 6 sessions?
- b. How many sessions did you manage to have on average with each client? OR What was the highest session number attended?
- c. What was the overall attendance like? E.g. older or younger clients who attend the counselling?
- d. How many people stopped attending sessions?
- e. What reasons did they give for no longer attending the sessions?
- f. How would they show you that they were no longer interested in attending the sessions?
- g. How many clients did not attend any sessions? What were their reasons for non-attendance?
- h. Describe the progress of the clients in terms of being better or worse after receiving the intervention, were there any clients who you feel got worse after the counselling?
- i. Describe your relationship with your clients, in terms of counselling methods or style.

#### **6. Fidelity**

- a. Were you able to use the manual as intended?

- b. Were you always able to conduct sessions in prescribed manner? If not what was the reason for changing the session?
- c. How did you make referrals and collaborate with other service providers
- d. What did you understand by the session topics?
  - Psycho-education about depression
  - Problem solving
  - Behaviour Activation
  - Healthy thinking
  - Psycho-education for birth preparation
  - Termination and evaluation

**7. Motivation for sessions**

- a. Which was your favourite session and why?
- b. Which was your worst session and why?
- c. What could you have done differently in the sessions?
- d. Do you have any suggestions for ways of improving the intervention?
- e. Do you feel that you have changed as a counsellor?
- f. If yes, are the changes positive or negative?
- g. Would you recommend that others do this work?

**Appendix L Fidelity Checklist**

Name of counsellor: ----- PID of participant: -----

Session Number: -----

Topic for the session: -----

Description	Not done [0]	Needs Improvement [1]	Well done [2]	Not applicable [99]	Comments
<b>Step 1: Introduction</b>					
1. Build rapport (small talk)					
2. Clarifies issues for discussion					
<b>Step 2: Exploration</b>					
	Not done [0]	Needs Improvement [1]	Well done [2]	Not applicable [99]	Comments
1. Explores use of relaxation CD and activity book					
2. Introduces topic to be explored and explains exercise clearly					
3. Active listening and probing					

4. Clarifies the participant's concerns					
5. Empathy and non-judgemental attitude					
6. Practices exercise with participant and encourages healthy behaviour					
<b>Step 3: Ending</b>					
	Not done [0]	Needs Improvement [1]	Well done [2]	Not applicable [99]	Comments
1. Summarises and clarifies the main issues					
2. Gives clear instructions for homework and checks if participant understands					
<b>TOTAL</b>					

**Additional Notes:**

## Appendix M

### Consolidated criteria for Reporting Qualitative Research (COREQ 32. Item checklist)

#### Number Item

#### Guide Questions/ Description

#### Domain 1: Research Team and Reflexivity

##### Personal Characteristics

1. Interviewer Which author conducted the interview?  
None of the authors conducted the interviews. A trained field worker, Pahlwe Memani conducted the interviews.
2. Credentials What were the researcher's credentials?  
The field worker has a grade 12 certificate (High school qualification) and a Diploma in public administration. The field worker has undergone extensive training on qualitative research methods as part of the study.
3. Occupation What was their occupation at the time of the study?  
Pahlwe Memani was a field worker who was trained to conduct interviews for the control group during the randomized control trial and then trained to conduct qualitative interviews after the conclusion of the intervention.
4. Gender Was the researcher male or female?  
The researcher was female.
5. Experience and training What experience and training did the researcher have?  
The researcher was trained on qualitative research, and how to conduct the telephonic follow-up questions for the AFFIRM RCT control group between May 2013 and May 2016.
6. Relationship established? Was a relationship established prior to study commencement?  
No, a relationship was not established prior to study commencement. This was to avoid familiarity that could affect the participant's freedom to talk during the interview.
7. Participant knowledge of the interviewer What did participant know about the researcher?  
Participants knew that the interviewers was a field worker for AFFIRM who conducted telephone calls with the control participants prior to the interviews.
8. Interviewer characteristics What characteristics were reported about the interviewer?  
The interviewer was interested in the interviews as she was already part of the AFFIRM team, bias was controlled for by providing her with training.

#### Domain 2: Study Design

9. Methodological orientation and theory What methodological orientation was stated to underpin the study?  
Content analysis was used to underpin the study.

##### Participant selection

10. Sampling How were participants selected?  
There was no sampling as all the lay counsellors from the AFFIRM study were included.
11. Method of approach How were participants approached?  
Participants were approached face-to-face.
12. Sample size How many participant were in the study?  
6 counsellors were selected and 6 participants (1 per counsellor were selected for fidelity checking of 6 counselling sessions).
13. Non-participation How many people refused to participant or dropped out? Reasons?  
No participants refused to participate or dropped out.

##### Setting

14. Setting of data collection Where was the data collected?  
The data was collected at the clinic

15. Presence of non-participants participants and researchers? Was anyone else present besides the participants and researchers?  
No one else was present besides participants and researchers.
16. Description of sample What are the important characteristics of the sample?  
All the participants were female counsellors who had delivered a task shared intervention for perinatal depression. They all had at least 2 and a half years of health promotion experience amongst themselves. Their ages were 28, 32, 33, 40, 44 and 46. Please refer to table 2 for a profile of respondents.
- Data Collection
17. Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?  
Questions, prompts and guides which were developed by the AFFIRM team were provided and piloted in order to test and correct any errors.
18. Repeat interviews Were repeat interviews carried out? If so how many?  
One repeat interview was carried for a counsellor due to the battery going flat in the middle of the interview.
19. Audio/Visual recording Did the research use audio visual recording to collect the data?  
Yes, the research used digital audio recorders to collect the data.
20. Field notes Were field notes made during and or after the interview or focus group?  
No field notes were not made during the interviews.
21. Duration What was the duration of the interviews or focus groups?  
The interviews last between 40 to 60 minutes per counsellor.
22. Data Saturation Was data saturation discussed?  
No, data saturation was not discussed as the full population of 6 counsellors participated.
23. Transcripts returned Were transcripts returned to participants for comment and or correction?  
No transcripts were not returned to participants for comment and or correction as they had already been invited to provide additional comments during the interview stage. There are various methodological and ethical questions that arise due to the member-check strategy, although it can increase credibility, it is quite complex and it is difficult to predict how the participants will experience the gesture. Member-check therefore presents a topic which needs further research

### Domain 3: Analysis and findings

#### Data Analysis

24. Number of data coders How many data coders coded the data?  
MM coded the interview transcripts and MS reviewed the themes and discussed with MM if there was any query. MM and MS coded the counselling session transcripts for fidelity coding independently and discussed if there were any queries.
25. Description of coding tree Did authors provide a description of the coding tree?  
No, the authors did not provide a description of the coding tree.
26. Deviation of themes Were themes identified in advance or derived from data?  
Some broad themes were identified in advance after conducting the literature search and some were derived from the data all themes were integrated once coding had been completed.
27. Software What software if applicable, was used to manage data?  
NVivo v11 was used to manage the data.
28. Participant checking Did participant provide feedback on the findings?  
No, participants did not provide feedback on the findings.

29. Quotations presented Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified?  
Yes, participant quotations were presented to illustrate the themes/ findings and each quote was identified.
30. Data and findings consistent Was there consistency between the data presented and the findings?  
Yes, there was consistency between the data presented and the findings.
31. Clarify the major themes Were major themes clearly presented in the findings?  
Yes, major themes were clearly presented in the findings.
32. Clarity of minor themes Is there a descriptions of diverse cases or discussion of minor themes?  
Yes, there is a discussion of minor themes.

## **Appendix N**

### **AFFIRM UCT RANDOMIZED CONTROL TRIAL**

### **POST INTERVENTION INFORMED CONSENT FORM FOR PARTICIPANTS**

#### **The Research Study**

We are asking you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

The University of Cape Town is doing this project to research maternal mental health in mothers in Khayelitsha. The project is called AFFIRM, (**A**frica **F**ocus on **I**ntervention **R**esearch for **M**ental health), which is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health. It is funded by the National Institutes of Health, USA.

#### **Why is it important?**

The study is important because one out of every three women in Khayelitsha experience depression or anxiety when they are pregnant or after having a baby.

#### **What is it for?**

This study is looking at ways to improve the counselling services and mental health assistance to depressed pregnant women and mothers, so that we can improve the quality of our intervention.

#### **Who will be involved?**

1. 36 participants who were recruited for the AFFIRM TRIAL who either did not attend any counselling sessions, those who dropped out of the intervention, and those who completed the intervention.
2. Community Health workers who work in the catchment area of Michael Mapongwana Community Health Centre.

**How long will it last?** The interviews will run from April 2015 to July 2015.

#### **What will it mean if you participate in the study?**

If you agree to participate in this study you will be asked a few questions about participant in the study. The interviews will ask some sensitive questions and all information you give us will be kept strictly confidential. You can refuse to answer any questions that you feel uncomfortable answering. The information you give us will be used to help us to improve our intervention to help mothers who are suffering from depression.

The interviews will be audio recorded to ensure the quality of the questioning. We will inform you if any

new findings arise during the duration of the study that may affect your participation.

**Is there any disadvantage from participating in this study?**

There is the possibility that you may have a mental health problem or that participation in the study may remind you of a time that you had such a problem. The risks associated with worsening of your depression are present whether or not you participate in this study. If you get distressed by a mental health problem or feel suicidal, we will refer you for psychological help. If you have a serious substance abuse problem or psychiatric illness that was not initially picked up at the interview, we will refer you for external assistance.

**Is there any advantage to the study?**

We hope that the counselling will improve your mental health and help you to build better ways of coping with depression in the future. We also hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

**What if I change my mind later?**

You are free to withdraw at any stage from participating in the study and your decision will not disadvantage you in any way. You will need to inform a member of the project if you wish to withdraw, and if you require, we can refer you to relevant local mental and social health services.

**Who will see the information that we collected?**

All interviews will be recorded and transcribed. The records will be kept completely confidential and private. Your name will not be used, and the recordings and interviews will be destroyed after we have worked with them. The information will only be seen by the researchers and not by anyone in the community.

**Who to contact if you want to know more, or if you have a problem at any time?**

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

Prof C. Lund, Department of Psychiatry and Mental Health, University of Cape Town,

Tel: 021 685 0120

If you have any questions about your rights and welfare in the research, please contact: The Human Research Ethics Committee, Groote Schuur Hospital.

Tel: 021 406 6626

**Consent to Enrol**

**Research ID #**

I, \_\_\_\_\_ agree to participate in the research study on maternal mental health in Khayelitsha, to help to develop relevant and cost effective ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness 1 Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness 2 Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

You may keep the information sheet. The signed consent form will remain in our study files.

## **Appendix O**

### **Post intervention Semi-Structured Interview schedule for participants who have not attended any sessions**

#### **Instructions**

Use this questionnaire **ONLY** for participants who were recruited and never attended counselling sessions.

Remember to probe if participant is not answering the questions fully, examples are below:

- ask for examples to explain what she says
- 'Tell me more'.
- That's really useful to know. Please tell me more and explain further.

Thank you for making the time to talk to us today. The purpose of talking to you is to find out how things have been for you since you agreed to take part in the study. Please remember that you will not be judged for anything you say in this interview therefore I would like you to be as honest as possible.

#### **Questions**

I would like us to firstly talk about taking part in the study .....

1. What did you understand about the study when you were asked to be part of it? What did you want from participating in the study?
2. I just want to confirm. Did you receive any phone calls from a counsellor asking you to come for sessions or to talk with you on the phone?
  - a. If yes, how did you feel about it and what did you do?
3. Sometime participants ignored the phone when they saw the counsellor's number, did that ever happen to you? Probe e.g. please tell me more about that....
4. What changed between the time you agreed to take part in the study and when we tried to contact you (probe E.g. emotionally, behaviourally and in terms of your relationships with others)?
5. Did you have any expectations that were not met by the study? If yes, what were they?
6. What would help you to attend counselling sessions in the future?

I am now going to talk to you about feeling down or sad....

7. When we last spoke to you, you described feelings of being sad, or down. Can you tell me a bit about what you were thinking, feeling or doing when you felt sad or down?
8. Please can you tell me more about how are you feeling now?
9. Are there any big changes in your life (positive or negative) that have happened since you were recruited?
10. How have these changes impacted your life?

***Thank you for participating in our study!***

## Appendix P

### Post intervention Semi-Structured Interview schedule for participants who have attended some sessions, but then stopped attending sessions

#### Instructions

Use this questionnaire ONLY for participants who were recruited, started some counselling sessions, but then stopped attending counselling sessions.

Thank you for making the time to talk to us today. The purpose of talking to you today is to find out how things have been for you since you agreed to take part in the study. Please remember that you will not be judged for anything you say in this interview therefore I would like you to be as honest as possible.

#### Questions

Let's firstly talk about taking part in the study.....

1. You agreed to take part in the study when you signed the consent form. Do you remember that? Tell me what you thought about the study and what you expected from it when you agreed. Did you have any expectations that were not met by the study? If yes, what were those?
2. If you were to tell a friend of yours about the counselling, how would you explain it?
3. Tell me about what you enjoyed and what you did not enjoy about the counselling.
4. Describe for me how you feel about the counselling. Give me examples of what was good and bad, what you enjoyed or not, what was useful and what was not useful. How did you feel about the counselling?
5. At some point you stopped coming for sessions. Tell me about that and what made you stop attending? Can you also tell me more about what you were feeling and thinking that made you stop?
6. Were there times that you did not feel like talking to a counsellor? If yes, explain.....
7. How did you let the counsellor know that you did not feel like having more sessions?

I am now going to talk to you about feeling sad or down....

8. When we last spoke to you, you described feelings of being sad, or down. Can you describe what you were thinking feeling or doing when you felt sad or down?
9. Can you tell me more about how are you feeling now?

Have there been any changes in your life (good or bad) since you joined the AFFIRM study? For example, with your family, your job, your partner, or your home situation? How do you think these changes have affected you?

Has the counselling helped you in any way with things like money problems, employment, worries about food, or clothing etc? How has the counselling helped/not helped with these things?

I am now going to talk to you about missed sessions.....

10. What made you come back for the sessions that you attended?
11. What made you miss sessions when you had agreed to an appointment?
12. What made you stop attending the counselling sessions? What could help you to attend the sessions again?

I am now going to talk to you about skills taught in the sessions

13. What skills or knowledge do you feel that you have learnt from the sessions?
14. Let's go through all the sessions you attended. [Interviewer will need to know which ones were completed.] I can remind you of these.
15. Let's start with session 1. This was about psycho-education for depression. Tell me how you felt about this session and what you learnt in this session.
16. Let's now talk about session 2. This was about problem solving. Tell me how you felt about this session and what you learnt in this session.
17. Let's now talk about session 3. This was about behaviour activation. Tell me how you felt about this session and what you learnt in this session.
18. Let's now talk about session 4. This was about healthy thinking. Tell me how you felt about this session and what you learnt in this session.
19. Let's now talk about session 5. This was about birth preparation. Tell me how you felt about this session and what you learnt in this session.
20. Let's now talk about session 6. This was about terminating and evaluating the sessions. Tell me how you felt about this session and what you learnt in this session.
21. Now think of all the sessions you attended and tell me which one you enjoyed the most and what did you learn from that session.
22. Which session do you think helped you the most?
23. How did that session help you?
24. Which session did you not enjoy and not learn anything from.
25. The sessions tried to teach you skills and how to use these in your everyday life. Describe for me how you continue using them on an everyday basis. When you describe these, give me examples that will help me really understand how you use these skills.
26. Maybe some of the skills are difficult to use. Is this the case for you? [If yes, ask for examples and what makes it difficult.]
27. What makes you continue to use those skills? Or if you don't use the skills, what are the reasons you do not use them anymore?

Now we are getting to the end of our discussion, but before we finish let's look at a few points about the counselling.

28. Can you please describe your relationship with your counsellor?
29. What do you think about the counselling being conducted in Xhosa?
30. What do you think about the counsellor being from Khayelitsha?
31. How did you feel about being counselled by a community health worker?
32. Would you prefer being counselled by a psychologist or a community health worker? Why?
33. Do you think the counselling should be conducted at the clinic or at home? Where did you have your sessions?
34. What do you feel about the counsellor using a manual?
35. What did you think about the home work activities and the relaxation CD?  
I am now going to talk to you about recommendations for changes to the sessions
36. What would you tell someone if you were telling them about your counselling experience?
37. Do you still need further assistance in terms of what you spoke to the counsellor about?
38. What changes can be made to the counselling for it to work better for you?

**Thank you for participating in our study!**  
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## Appendix Q

### Post intervention Semi-Structured Interview schedule for participants who have completed all counselling sessions

#### Instructions

Use this questionnaire ONLY for participants who were recruited and have completed all counselling sessions.

Thank you for making the time to talk to us today. The purpose of talking to you today is to find out how things have been for you since you agreed to take part in the study. Please remember that you will not be judged for anything you say in this interview therefore I would like you to be as honest as possible.

#### Questions

Let's talk about taking part in the study....

39. You agreed to take part in the study when you signed the consent form. Do you remember that? Tell me what you thought about the study and what you expected from it when you agreed. Did you have any expectations that were not met by the study? If yes, what were those...?
40. If you were to tell a friend of yours about the counselling, how would you explain it?
41. Tell me about what you enjoyed and what you did not enjoy about the counselling.
42. Describe for me how you feel about the counselling. Give me examples of what was good and bad, what you enjoyed or not, what was useful and what was not useful. . How did you feel about the counselling?
43. At some point you stopped coming for sessions. Tell me about that and what made you stop attending? Can you also tell me more about what you were feeling and thinking that made you stop?
44. Were there times that you did not feel like talking to a counsellor? If yes, explain.....
45. How did you let the counsellor know that you did not feel like having more sessions?

I am now going to talk to you about feeling sad or down....

46. When we last spoke to you, you described feelings of being sad, or down. Can you describe what you were thinking feeling or doing when you felt sad or down?
47. Can you tell me more about how are you feeling now?  
Have there been any changes in your life (good or bad) since you joined the AFFIRM study? For example, with your family, your job, your partner, or your home situation? How do you think these changes have affected you?  
Has the counselling helped you in any way with things like money problems, employment, worries about food, or clothing etc? How has the counselling helped/not helped with these things?

I am now going to talk to you about missed sessions.....

48. What made you come back for the sessions that you attended?
49. What made you miss sessions when you had agreed to an appointment?
50. What made you come back for all the sessions that you attended? What made you complete all 6 sessions?

I am now going to talk to you about skills taught in the sessions

51. What skills or knowledge do you feel that you have learnt from the sessions?
52. Let's go through all the sessions you attended. [Interviewer will need to know which ones were completed.] I can remind you of these.
53. Let's start with session 1. This was about psycho-education for depression. Tell me how you felt about this session and what you learnt in this session.
54. Let's now talk about session 2. This was about problem solving. Tell me how you felt about this session and what you learnt in this session.
55. Let's now talk about session 3. This was about behaviour activation. Tell me how you felt about this session and what you learnt in this session.
56. Let's now talk about session 4. This was about healthy thinking. Tell me how you felt about this session and what you learnt in this session.
57. Let's now talk about session 5. This was about birth preparation. Tell me how you felt about this session and what you learnt in this session.
58. Let's now talk about session 6. This was about terminating and evaluating the sessions. Tell me how you felt about this session and what you learnt in this session.
59. Now think of all the sessions you attended and tell me which one you enjoyed the most and what did you learn from that session.
60. Which session do you think helped you the most?
61. How did that session help you?
62. Which session did you not enjoy and not learn anything from.
63. The sessions tried to teach you skills and how to use these in your everyday life. Describe for me how you continue using them on an everyday basis. When you describe these, give me examples that will help me really understand how you use these skills.
64. Maybe some of the skills are difficult to use. Is this the case for you? [If yes, ask for examples and what makes it difficult.]
65. What makes you continue to use those skills? Or if you don't use the skills, what are the reasons you do not use them anymore?

Now before we end of our discussion, let's look at a few points about the counselling.

66. Can you describe your relationship with your counsellor?
67. What do you think about the counselling being conducted in Xhosa?
68. What do you think about the counsellor being from Khayelitsha?
69. How did you feel about being counselled by a community health worker?
70. Would you prefer being counselled by a psychologist or a community health worker? Why?
71. Do you think the counselling should be conducted at the clinic or at home? Where did you have your sessions?
72. What do you feel about the counsellor using a manual?
73. What did you think about the home work activities and the relaxation CD?

I am now going to talk to you about recommendations for changes to the sessions

74. What would you tell someone if you were telling them about your counselling experience?
75. Do you still need further assistance in terms of what you spoke to the counsellor about?
76. What changes can be made to the counselling for it to work better for you?

**Thank you for participating in our study!**

## Appendix R

### Consolidated criteria for Reporting Qualitative Research (COREQ 32. Item checklist)

#### Number Item

#### Guide Questions/ Description

#### Domain 1: Research Team and Reflexivity

##### Personal Characteristics

1. Interviewer Which author conducted the interview?  
None of the authors conducted the interviews. 2 trained field workers, Pahlwe Memani and Nomakhaya Mdala conducted the interviews.
2. Credentials What were the researcher's credentials?  
The field worker PM has a grade 12 certificate (High school qualification) and a Diploma in public administration. The other field worker NM has a grade 12 certificate (High school qualification). Both field worker has undergone extensive training on qualitative research methods as part of the study.
3. Occupation What was their occupation at the time of the study?  
Both interviewers were field workers who were trained to conduct interviews for the control group during the randomized control trial and then trained to conduct qualitative interviews after the conclusion of the intervention.
4. Gender Was the researcher male or female?  
Both researchers were female.
5. Experience and training What experience and training did the researcher have?  
The researchers were trained on qualitative research, and how to conduct the telephonic follow-up questions for the AFFIRM RCT control group between May 2013 and May 2016.
6. Relationship established? Was a relationship established prior to study commencement?  
No, a relationship was not established prior to study commencement. This was to avoid familiarity that could affect the participant's freedom to talk during the interview.
7. Participant knowledge of the interviewer What did the participant know about the researcher?  
Participants knew that the interviewers were field workers for AFFIRM who conducted telephone calls with the control participants prior to the interviews.
8. Interviewer characteristics What characteristics were reported about the interviewer?  
The interviewers were interested in the interviews as they were already part of the AFFIRM team, bias was controlled for by providing her with training.

##### Domain 2: Study Design

9. Methodological orientation and theory What methodological orientation was stated to underpin the study?  
Content analysis was used to underpin the study.

##### Participant selection

10. Sampling How were participants selected?  
There was no sampling as all participants from the AFFIRM study were included.
11. Method of approach How were participants approached?  
Participants were approached face-to-face.
12. Sample size How many participants were in the study?  
6 counsellors were selected and 6 participants (1 per counsellor were selected for fidelity checking of 6 counselling sessions).
13. Non-participation How many people refused to participant or dropped out? Reasons?  
No participants refused to participate or dropped out.

##### Setting

14. Setting of data collection Where was the data collected?  
The data was collected at the clinic

15. Presence of non-participants participants and researchers? Was anyone else present besides the participants and researchers?  
No one else was present besides participants and researchers.
16. Description of sample What are the important characteristics of the sample?  
All the participants were female counsellors who had delivered a task shared intervention for perinatal depression. They all had at least 2 and a half years of health promotion experience amongst themselves. Their ages were 28, 32, 33, 40, 44 and 46. Please refer to table 2 for a profile of respondents.
- Data Collection
17. Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?  
Questions, prompts and guides which were developed by the AFFIRM team were provided and piloted in order to test and correct any errors.
18. Repeat interviews Were repeat interviews carried out? If so how many?  
One repeat interview was carried for a counsellor due to the battery going flat in the middle of the interview.
19. Audio/Visual recording Did the research use audio visual recording to collect the data?  
Yes, the research used digital audio recorders to collect the data.
20. Field notes Were field notes made during and or after the interview or focus group?  
No field notes were not made during the interviews.
21. Duration What was the duration of the interviews or focus groups?  
The interviews last between 40 to 60 minutes per counsellor.
22. Data Saturation Was data saturation discussed?  
No, data saturation was not discussed as the full population of 6 counsellors participated.
23. Transcripts returned Were transcripts returned to participants for comment and or correction?  
No transcripts were not returned to participants for comment and or correction as they had already been invited to provide additional comments during the interview stage. There are various methodological and ethical questions that arise due to the member-check strategy, although it can increase credibility, it is quite complex and it is difficult to predict how the participants will experience the gesture. Member-check therefore presents a topic which needs further research

### Domain 3: Analysis and findings

#### Data Analysis

24. Number of data coders How many data coders coded the data?  
MM coded the interview transcripts and MS reviewed the themes and discussed with MM if there was any query. MM and MS coded the counselling session transcripts for fidelity coding independently and discussed if there were any queries.
25. Description of coding tree Did authors provide a description of the coding tree?  
No, the authors did not provide a description of the coding tree.
26. Deviation of themes Were themes identified in advance or derived from data?  
Some broad themes were identified in advance after conducting the literature search and some were derived from the data all themes were integrated once coding had been completed.
27. Software What software if applicable, was used to manage data?  
NVivo v11 was used to manage the data.
28. Participant checking Did participants provide feedback on the findings?  
No, participants did not provide feedback on the findings.

29. Quotations presented  
Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified?  
Yes, participant quotations were presented to illustrate the themes/ findings and each quote was identified.
30. Data and findings consistent  
Was there consistency between the data presented and the findings?  
Yes, there was consistency between the data presented and the findings.
31. Clarify the major themes  
Were major themes clearly presented in the findings?  
Yes, major themes were clearly presented in the findings.
32. Clarity of minor themes  
Is there a description of diverse cases or discussion of minor themes?  
Yes, there is a discussion of minor themes.